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 of Master of Medicine in Obstetrics and Gynecology, University of Nairobi

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H58/69089/2013

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I declare that this dissertation does not incorporate without acknowledgement, any

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ACKNOWLEDGEMENTS

I convey much gratitude and appreciation to my supervisors Dr F. X Odawa and Dr J. Ong'ech for their availability and invaluable input in the conception, implementation and analysis of this research project.

I acknowledge Kenyatta National Hospital Research and Programs Department for the support received in funding of this study.

Special mention to Mr Josephat Kiongo, Mrs Beatrice Kimani and the team at the Kenyatta National Hospital records department, whose ardent work ensured the timely completion of this study.

I acknowledge Francis Njiiri, Brian Odhiambo, Angela Chebet, Wangui Maina and Kevin Njoroge for their technical expertise in the writing of this dissertation.

I am also grateful to the University of Nairobi for providing an enabling learning environment, and the Ministry of Health for facilitating and supporting my training.

My sincere gratitude goes out to all the consultants and lecturers at the University of Nairobi and Kenyatta National Hospital, to the nurses and other KNH staff as well as my fellow registrars whose continuous input has molded my thinking and practice as a future Obstetrician and Gynecologist.

Finally, I acknowledge God, whose grace and favour has strengthened me through every step of this research project.

DEDICATION

This work is dedicated to the most significant people in my life:

To my dear husband Moses, for your love, strength, encouragement and unwavering belief in me.

To my parents Isaiah and Jane, for your sacrifices and love throughout the course of my studies.

DEFINITION OF TERMS

Early Neonatal Death: The death of a live newborn in the first 7 days of life

Live Birth: The complete expulsion or extraction from its mother of a product of conception, irrespective of the duration of the pregnancy, which, after such separation, breathes or shows any other evidence of life

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

Maternal Mortality Index: The number of maternal deaths divided by the number of women with life-threatening conditions expressed as a percentage

Maternal Mortality Ratio: The number of maternal deaths per one hundred thousand live births

Maternal Near-Miss: A woman who nearly died but survived a complication that occurred during pregnancy, child birth or within 42 days of termination of pregnancy

Maternal Near Miss ratio: The number of maternal near-miss cases per 1000 live births

Maternal near-miss mortality ratio: The ratio between maternal near-miss cases and maternal deaths

Neonatal Mortality rate: The number of a neonates dying within the first 28 days of life, per 1000 live births in the same time period

Perinatal Mortality: The number of stillbirths and early neonatal deaths

Perinatal mortality rate: The number of perinatal deaths per 1000 total births

Stillbirth: A baby born with no signs of life at or after 28 weeks' gestation*

Universal Health Coverage: Ensuring that all people can use the promotive, preventive, curative, rehabilitative and palliative health services they need, of sufficient quality to be effective, while also ensuring that the use of these services does not expose the user to financial hardship.*

^{*} WHO definition

ABBREVIATIONS

ANC Ante Natal Care

CCU Critical care unit

CS Cesarean Section

FSB Fresh Still Birth

GA Gestational Age

GoK Government of Kenya

HIV Human Immunodeficiency Virus

ICU Intensive Care Unit

IUFD Intra Uterine Fetal Death

KDHS Kenya Demographic Health Survey

KHSP Kenya Health Strategic Plan

KNH Kenyatta National Hospital

MDG Millennium Development Goals

MI Mortality Index

MMR Maternal Mortality Ratio

MNCH Maternal Neonatal and Child Health

MNM Maternal Near Miss

MNMR Maternal Near Miss Ratio

MNMMR Maternal Near Miss Mortality Ratio

MSB Macerated Still Birth

NBU New Born Unit

PM Perinatal Mortality

PNC Post Natal Care

PPH Post Partum Hemorrhage

RMNCH Reproductive Maternal Neonatal and Child Health

SVD Spontaneous Vertex Delivery

SB Still Birth

SMO Severe Maternal Outcome

UHC Universal Health Coverage

WHO World Health Organization

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ABSTRACT

BACKGROUND:

Universal health access is currently a target for the global health movement, particularly in maternal and child health. One of the strategies used to pursue this is 'user fee exemption policies'. In line with this, the Government of Kenya (GoK) implemented free maternity services, for all women in government facilities, on 1st June 2013. The GoK has, and continues to invest a significant amount of funds in running this program. It is therefore imperative that the performance of the health system be evaluated, to determine whether this intervention has indeed resulted in improved maternal outcomes.

The World Health Organization suggests that the maternal near miss concept be routinely used in national programs, as a tool for evaluating quality of maternal health care as well as the performance of health systems (10). Utilization of this concept enables us to assess the effect of introduction of free maternity services on maternal outcomes.

OBJECTIVE: To compare the difference in the pattern of severe maternal and neonatal outcomes among women managed in Kenyatta National Hospital, after and before introduction of free maternity services (FMS), on 1st June 2013.

METHODOLOGY

Study Design: A quasi experimental study of the pre and post type was carried out between February and October 2016. A comparison was done between 1,264 women admitted in the time period 1st June 2009 to May 31st 2010, and 1,277 women admitted from 1st June 2014 to May 31st 2015.

Setting: Kenyatta National Hospital, Nairobi, Kenya.

Study Population: Women admitted to Kenyatta National Hospital due to pregnancy and or its complications from 28 weeks gestation regardless of delivery status during the data collection period, up to 6 weeks postpartum.

Data Analysis: Data was collected using a pre-tested, structured data abstraction form. The difference in incidence of severe maternal and neonatal outcomes before and after FMS was determined using difference of proportions.

The association between socio-demographic and clinical factors, as well as severe maternal and neonatal outcomes was determined using the relative risk. A p value of < 0.05 was used to denote statistically significant differences. Analysis was carried out using SPSS version 21.

Results:

A total of 2,541 women were included in this study (1,264 before the introduction of FMS, and 1,277 after its introduction). Prior to FMS, 1,202 births were observed and 1,204 births were observed after. Maternal mortalities decreased from 22 (1.7 %) to 11 (0.9%) (p=0.05). The maternal mortality ratio decreased from 1982 to 962 per 100,000 live births. Maternal near misses decreased from 57 (4.5 %) to 48 (3.8%) p=0.342. The maternal near miss mortality ratio increased from 2.3 to 4.4 after introduction of free maternity services.

A reduction in the number of still births born to mothers who died was observed after the introduction of FMS from 6 (27.3%) to 2 (20%). In both eras, a strong association was observed between poor birth outcomes and maternal deaths, p=<0.001 and p=0.031 respectively. Amongst mothers who experienced a near miss, still births reduced from 23 (41.1%) to 15 (32.6%). In spite of this reduction, maternal near miss continued to be associated with poor neonatal outcomes p=<0.001, both before and after FMS.

Following a maternal death, the proportion of neonates admitted to the NBU increased from 36% before FMS, to 63.6% (p= <0.0001). In both time periods, a strong association was observed between maternal death and admission to NBU, p=0.033 and p=<0.001 respectively. For neonates born to mothers who experienced a near miss, admissions to NBU increased from 12 (21.1%) to 19 (39.6%), (p=<0.0001). Before FMS, maternal near miss was not significantly associated with NBU admission (p=0.155), however after FMS, it is (p=<0.001).

Before FMS, pre-eclampsia (p=0.01, p<0.0001), post partum haemorrhage (p<0.0001 for both), eclampsia (p=0.019, p<0.0001) and septicemia (p<0.0001, p=0.001) were associated with both death and near-miss respectively. This changed after introduction of free maternity services as PPH (p<0.0001), eclampsia (p<0.0001) and sepsis (p<0.0001) are the only complications which remained associated with near-miss. Complications that were associated with near miss during both periods were APH (p=0.013, p=0.019), and ruptured uterus (both p<0.0001). Prolonged labour was not associated with severe maternal outcomes in any of the periods.

Conclusion

Introduction of free maternity services has resulted in a significant reduction in severe maternal outcomes, and still births. Neonatal morbidity has increased. Eclampsia, PPH, and sepsis which were previously associated with death, are now only associated with maternal near miss. Therefore, the management of these maternal complications should continue to be prioritized to prevent associated morbidity and mortality. Studies should also be done to establish the long term sequelae experienced by the neonates born to mothers who experience a severe outcome.

INTRODUCTION

Universal Health Access is a noble and lofty goal. In pursuit of this, the global health movement has gradually shifted focus to Universal Health Coverage (UHC), defined as ensuring that all people can use the promotive, preventive, curative, rehabilitative and palliative health services they need, of sufficient quality to be effective, while also ensuring that the use of these services does not expose the user to financial hardship.(1) This, in a bid to address inequitable access to health. This is particularly pronounced in the middle to lower income countries. Driven from a global platform, governments have been encouraged to develop policies that promote prepaid and pooled financing, reach the poor with demand side incentives, ensure an integrated national strategy and support accountability.(2) Various partners have come on board, availing funding to support these initiatives. One such initiative that has been employed successfully in various countries is the removal of cash payments at the point of accessing health services. These payments have been demonstrated to be a deterrent to accessing health care as they may constitute a significant part of the family budget. Inevitably, opportunity cost would result in forfeiture of health interventions in favor of other basic needs such as housing and food. (3)

Several methods have been utilized to do this, such as state funded health insurance systems, use of vouchers as well as abolition of user fees. All of these require efficient administrative capacity as compensatory mechanisms to the health care provider have a direct effect on sustainability. These have been largely used in accessing maternal and child health interventions, as these are areas of major concern for the global community. This was clearly illustrated in the Millennium Development Goals (MDGs). MDG 4 targeted reduction by two thirds, the under-five mortality rate between 1990 and 2015. MDG 5a focused on reducing by three quarters, between 1990 and 2015, the maternal mortality ratio, and 5b targeted universal coverage in reproductive health by 2015. (4) As is evidenced in the 2014 MDG status report, Sub-Saharan Africa was one of the poorest performing regions in achieving these MDGs. (5) The fact that other regions and nations achieved them, some even on a fast track basis, demonstrated that with effective, contextual policy making and implementation, strides can be made in reducing maternal and under five mortality rates. These targets were reinforced in the sustainable development goal number 3, wherein by 2030 maternal mortality should have reduced globally to less than 70 maternal deaths per 100,000 live births and under-five mortality reduced to less than 12 deaths per 1000 live births. This goal also emphasizes universal health coverage by 2030 (39).

As highlighted by the Africa Union in their policy brief on 'Improving domestic financing for Reproductive, Maternal Newborn and Child Health in 2013, Africa presents some very unique challenges. Twenty six years after signing the Abuja Declaration, very few countries have allocated 15% of their national budget or more to health expenditure.

This forces the countries to depend heavily on out of pocket payments as well as donor funding. This creates issues for long term sustainable financing of RMNCH initiatives. The management of available resources is also often poorly aligned to national health strategies.

As a result, the focus has shifted to what African countries can do not just to raise money for health, but also to improve the value for money of existing resources (i.e. more health for money.) It also begs for evidence based decision making, not just on the safety and effectiveness of interventions, but also their cost effectiveness.(6)

One such intervention by the Kenya Government is the provision of free maternity services. In his Madaraka day speech on June 1, 2013, His Excellency the President of the republic of Kenya, Uhuru Kenyatta, gave an unprecedented directive: "With respect to health, my Government has made adequate budgetary arrangements to enable all pregnant mothers to access free maternity services in all public health facilities, with effect from 1st June, 2013. Consequently, I direct that no charges of whatever nature shall be imposed by government health institutions to access maternity services." (7) To this end, the Government of Kenya (GoK) committed Kenya Shillings (Kes) 3.8 billion in the 2013/2014 fiscal year and Kes 4.0 billion in the 2014/2015 fiscal year. This was increased to Kes 4.3 billion in 2015/2016 (8). This represents a massive investment from the government, and in effect from tax payers. This initiative addresses one of the barriers to accessing maternal healthcare, which is cost. It also addresses equity as those in the lower wealth quintile now can access health facilities, thereby mitigating poor maternal and neonatal outcomes.

It is therefore imperative given the scale of investment that a critical analysis is done for both maternal and neonatal outcomes. By comparing them in the era before and after the introduction of the free maternity services, it can determined whether the desired goals are being achieved.

LITERATURE REVIEW

"No mother should die while giving life." This is a quote from the first lady's 'Beyond Zero' campaign that aims to reduce both maternal and child mortality.(9) The truth of this statement cannot be over stated. It holds true across the world, for the death of a mother in pregnancy and/or childbirth has a definite negative impact on the baby she is to deliver, any other children that she has and her family as a whole. It is no surprise then that maternal morbidity and mortality continue to be major global health concerns.

Maternal mortality is defined as the death of a woman while pregnant or within 42 days of termination of pregnancy, irrespective of the duration and site of the pregnancy, from any cause related to or aggravated by the pregnancy or its management but not from accidental or incidental causes. On the other hand, a maternal near miss is defined as a woman who nearly died but survived a complication that occurred during pregnancy, child birth or within 42 days of termination of pregnancy. Severe Maternal Outcomes (SMO) is a measure of both maternal deaths and near misses combined. Closely associated with these is neonatal mortality, which is the number of a neonates dying within the first 28 days of life. (10)

I. Epidemiology

The global picture on maternal and neonatal mortality

The WHO has made maternal and child health a priority by setting targets in MDG 4 and 5, as outlined previously. As per the MDG status report of 2014, globally, the maternal mortality ratio dropped by 45 per cent between 1990 and 2013, from 380 to 210 deaths per 100,000 live births. Worldwide, it is estimated that 289,000 women died in 2013 alone, from causes related to pregnancy and childbirth. It is also reported that the global rate of under-five mortality in 2012 was almost half of its 1990 rate, dropping from 90 to 48 deaths per thousand live births. The estimated number of under-five deaths fell from about 12.6 million to 6.6 million in that period, which works out to 17,000 fewer children dying each day in 2012 in comparison with 1990. Neonatal mortality is also on the decline. Between 1990 and 2012, the world neonatal mortality rate fell by almost one third, from 33 to 21 deaths for every thousand live births. The significant gains on a global scale are commendable and confirm that with focused interventions, these MDG's are achievable. (4)(11)

In spite of these global gains, there are massive disparities between the developed and developing world. In 2013, the maternal mortality ratio in the developed world was at 16 deaths per 100,000 live births. This is in sharp contrast to the the developing world at 230 deaths per 100,000 live births. Sub-Saharan Africa notably had a rate of 510 deaths per 100,000 live births, which accounts for 62% of the global deaths.

This indicates that as a region, we are lagging behind both the developed world, and the developing world in reduction of maternal deaths. (4)(11)

In 2014, Say et al did a systematic review to identify the causes of maternal mortality globally. Amongst direct causes, hemorrhage, sepsis and hypertensive disorders accounted for more than 50 % of all deaths.(12)

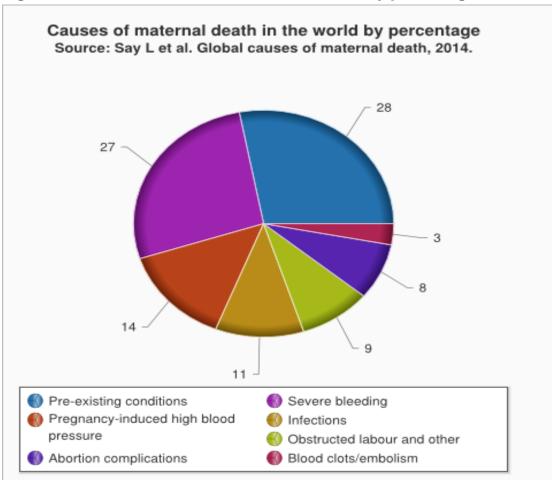


Figure 1: Causes of maternal death in the world by percentage

As of 2012, the under five mortality in the developed world was at 6 deaths per 1,000 live births. The developing world was at 53 deaths per 1,000 live births, with sub-Saharan Africa being the largest contributor at 99 deaths per 1,000 live births. (4)(11) Of the 6.6 million deaths in children under age five in 2012, 3.2 million occurred in sub-Saharan Africa. This is almost half of the total number. It is also of concern that of the total number, 2.9 million deaths occurred during the first 28 days of life-the neonatal period. While this paints a grim picture, it is encouraging to note that the rate of decline has rapidly increased from 0.8 per cent per year to 4.1 per cent per year, in the period 2005–2012 as compared to 1990–1995.(4)

The Kenyan picture on maternal and neonatal mortality

Kenya is one of several countries that are making insufficient progress in the pursuit of MDG 5.(6,12,14) Initially having an MMR of 590 in 1990, a target of 147 is the standard we should have achieved by now. The trend as recorded in the Kenya Demographic Health Surveys (KDHS) is an MMR of 414 in 2003, with an increase to 488 in 2008-2009. (15) This is a far cry from our neighbors, Ethiopia and Rwanda who are on track with reductions of 69% and 77% in MMR respectively. (4,5,11)

Indicators for MDG 4 in Kenya tell a better story, with reduction in the under 5 mortality rate from 91, to 74 and then to 52 in 1990, 2011 and 2014 respectively. The Neonatal Mortality Rate has also progressively reduced from 33 to 31 and finally to 22, in 2003, 2008/2009, and 2014 respectively.(13,15)

II. The WHO Near-Miss approach

In a bid to curb the high maternal mortality rate, maternal near miss surveillance has emerged as a focal area in obstetric practice. (10) Audits involving maternal mortality only, do not offer sufficient insight into the scope of obstetric complications. Near misses result in significant morbidity and as such cannot be disregarded. Hence reviewing cases of near miss has the potential to highlight both deficiencies and positive elements in the provision of obstetric services and to provide information about the nature of obstetric complications.(16) The ultimate purpose of the near-miss approach is to improve clinical practice and reduce preventable morbidity and mortality through the use of best evidence-based practices

In 2004, the WHO did a systematic review to determine prevalence of severe acute maternal mortality. At the time it was difficult to pool together all cases due to the disparity in the criteria used to identify cases. Their results showed that prevalence varied between 0.80%–8.23% in studies that use disease-specific criteria, while the range was 0.38%–1.09% in the group that use organ-system based criteria. Rates were within the range of 0.01% and 2.99% in studies using management-based criteria. (16)

In 2008, the WHO adopted the current maternal near-miss definition and established standard criteria for identifying women presenting with life threatening, pregnancy related complications. This definition allows common ground for the implementation of near-miss assessments across the globe, allowing international comparisons. These criteria are as follows:(10)

Table 1: The WHO maternal near miss criteria: a woman presenting with any of the following criteria life-threatening conditions and surviving a complication that occurred during pregnancy, childbirth or within 42 days of termination of pregnancy should be considered as a maternal near miss case (10)

Dysfunctional system Clinical criteria		Laboratory markers	Management based proxies	
Cardiovascular	Shock Cardiac arrest	Severe hypoperfusion (lactate>5 mmol/L or >45mg/dL) Severe acidosis (pH<7·1)	Use of continuous vasoactive drugs Cardio-pulmonary resuscitation	
Respiratory	Acute cyanosis Gasping Severe tachypnea (respiratory rate >40 bpm) Severe bradypnea (respiratory rate <6 bpm)	Severe hypoxemia (Oxygen saturation < 90% for ≥ 60 minutes or PaO2/FiO2<200)	Intubation and ventilation not related to anaesthesia	
Renal	Oliguria non responsive to fluids or diuretics	Severe acute azotemia (creatinine ≥300µmol/l or ≥3.5 mg/dL)	Dialysis for acute renal failure	
Haematologic/ Coagulation	Failure to form clots	Severe acute thrombocytopenia (<50,000 platelets/ml)	Massive transfusion of blood / red cells (≥ 5 units)	
Hepatic	Jaundice in the presence of preeclampsia	Severe acute hyperbilirubinemia (bilirubin>100 µmol/l or >6.0mg/dL)		
Neurologic	Prolonged unconsciousness (lasting >12h) Stroke Uncontrollable fit / status epilepticus Global paralysis			
Alternative severity proxy			Hysterectomy following infection or haemorrhage	

a) Shock is a persistent severe hypotension, defined as a systolic blood pressure <90 mmHg for ≥60 minutes with a pulse rate at least 120 despite aggressive fluid replacement (>2L)

b) Cardiac arrest refers to the Loss of consciousness AND absence of pulse/heart beat

- c) Gasping is a terminal respiratory pattern and the breath is convulsively and audibly caught.
- d) Oliguria is defined as an urinary output <30ml/hr for 4 hours or <400ml/24hr
- e) Clotting failure can be assessed by the bedside clotting test or absence of clotting from the IV site after 7-10 minutes
- f) Loss of consciousness is a profound alteration of mental state that involves complete or near-complete lack of responsiveness to external stimuli. It is defined as a Coma Glasgow Scale <10 (moderate or severe coma).
- g) Stroke is a neurological deficit of cerebrovascular cause that persists beyond 24 hours or is interrupted by death within 24 hours
- h) Pre-eclampsia is defined as the presence of hypertension associated with proteinuria. Hypertension is defined as a blood pressure of at least 140 mm Hg (systolic) or at least 90 mm Hg (diastolic) on at least two occasions and at least 4–6 h apart after the 20th week of gestation in women known to be normotensive beforehand. Proteinuria is defined as excretion of 300 mg or more of protein every 24 h. If 24-h urine samples are not available, proteinuria is defined as a protein concentration of 300 mg/L or more (≥1 + on dipstick) in at least two random urine samples taken at least 4–6 h apart
- i) For instance, continuous use of any dose of dopamine, epinephrine or norepinephrine

Souza et al went to great lengths to validate these eligibility criteria in a multicentre cross-sectional survey. They confirmed that the identification of maternal near-miss cases using the WHO list of pregnancy-related life-threatening conditions is valid, as these conditions are accurately associated with maternal deaths. (16)

In addition to these, the maternal mortality index and the maternal near-miss mortality ratio are used as measures of the overall quality of care. The maternal mortality index is the number of maternal deaths divided by the number of women with life-threatening conditions expressed as a percentage. The higher the index the more women with life-threatening conditions die (low quality of care), whereas the lower the index the fewer women with life-threatening conditions die (better quality of care).(10)

The maternal near-miss mortality ratio refers to the ratio between maternal near-miss cases and maternal deaths. Higher ratios indicate better care. (10)

WHO did a multi country survey on maternal and newborn health in 2014. (17) This examined severe maternal outcomes in 29 countries and the contributing causes. Twenty facilities in both the public and private sectors in Kenya participated in this survey, with records of over 20,354 women being reviewed. The number of women with severe maternal outcomes was 133. Maternal near misses were 78, and mortalities were 55. Hemorrhage was the largest contributing factor towards near misses at 52.5%, while the largest contributing factor towards mortalities was pre-eclampsia/eclampsia at 35%. (18) The contributing factors were as follows:

80
70
60
50
40
30
20
10
Maternal Near Miss
Maernal Mortality

Figure 2: WHO Multi-country survey on maternal and newborn health, Kenya 2014.

III. The effect of user fees on health care

a. The global context

User fees for health services were popularised in many low income countries in the 1980s as part of policies championed by the World Bank. This also was taken up in African countries following the 1987 joint World Health Organization/ United Nations Children's Fund Bamako Initiative. This was expected to address the difficulties in financing basic health services, especially maternal and neonatal services. Charging clients for essential drugs was seen as an income generating activity. The monies raised would then be used to improve the quality of care offered, and equitable access to the same.19) Opinions differed as to whether these fees actually achieved these objectives or were a deterrent to accessing healthcare and therefore self defeating. With the current focus on MDG's, many countries have opted to abolish these fees, in order to increase the number of deliveries done at a health facility and attended by a skilled provider, as well as increase access of children to healthcare.

A systematic review by Dzakpasu et al (19) looked at "The effect of user fees on maternal health service utilization and related outcomes" in 2013. The focus was mainly on lower to middle income countries and twenty studies met the necessary criteria for inclusion into this analysis. This was a modification of the Cochrane systematic review by Lagarde and Palmer in 2011,that looked at "The impact of user fees on health service utilization in low- and middle- income countries". (20) They highlighted the challenges presented by the cost of delivery care. Firstly, these costs my take up a large part of a family's income. Payment may therefore impoverish the family. Secondly, both the cost of delivery as well as the final outcome of the birth cannot be ascertained prior to delivery. This means that families cannot save beforehand. This is compounded by the fact that failure to get proper care can have negative effects on both the other and the baby. (19,20)

The effect of user fees on Ante natal clinic visits was assessed in nine of these studies. The visits were observed to increase where the fees were introduced and decrease when the charges were removed. In Cambodia, the contrary was observed, where visits increased with fees being introduced. This was credited to an improvement in the quality of care offered. Clients also expressed relief at being able to predict the charges for delivery, thus facilitating saving and planning for delivery. (19)

Facility delivery was one of the other factors assessed. This was documented in seventeen of the studies. Fewer facility deliveries were observed where fees were introduced, and the converse was also true. Cambodia was the one exception. Increased facility deliveries after introduction of user fees was deemed to be due to improved quality of care. (19)

In Nigeria, the proportion of women admitted for delivery who had complications increased after user fees were introduced. (19,21) These findings were based on two urban facility studies. This increase was attributed to a delay in seeking care, as the new charges were prohibitive. In Ghana (19,22,23) Senegal (24) and Nepal, (25) women with complications such as hypertensive disease, hemorrhage and those needing a cesarean section increased when the fees were reduced or done away with altogether.(19,22–24)

In their study at a South African Tertiary Hospital, Daponte et al found that the MMR increased after the removal of user fees. Authors hypothesized that this was due to the negative impact on quality of care. In their assessment, this was occasioned by greater number of patients, which was not matched by an increment of staff or other facility infrastructure. (26)

Conversely, following delivery fee exemptions, reductions in institutional MMRs were reported in Ghana's Central and Volta regions. The central region had a reduction in MMR from 953 to 856, and in the Volta region, it reduced from 1439 to 911 (a decrease of 37.1%).(19,23) Bosu et al hypothesized that the apparent lack of negative effect on institutional MMR may be related to operational or methodological reasons. Operationally, it is possible that some health facilities were operating below capacity and so could accommodate the resulting increased workload following the exemption, particularly where the increase in workload was small. On the other hand, health workers may have worked above their capacity to contain the increased workload. Methodologically, the design of their study was unable to isolate the effects of the exemption policy on institutional MMR. This is because there was already a downward trend in institutional MMR in the Central and Volta Regions prior to the introduction of the exemption. They also acknowledged that their results could have been affected by under-reporting.(23) They recommended that further evaluation of the effect of the fee exemption policy on maternal morbidity and mortality be done. In keeping with the other studies on facility delivery, the magnitude of the effect attributable to fee changes was not estimated.

Maternal and perinatal deaths were observed after introduction of fees, in the two Nigerian hospital studies. (19,21)

In Ghana, the impact of fee changes among different socioeconomic groups was investigated. Following the abolition of delivery fees, the proportion of deliveries at the different facilities increased in all wealth quintiles. (27)

In Mali, a study by El-Khoury et al demonstrated that after a fee exemption policy on caesarean sections, women in the 2 richest quintiles accounted for 58% of caesarean sections, and the poorest 2 quintiles accounted for 27%. They postulated that transportation costs and difficult road conditions were seen as significant barriers to reaching facilities and accessing caesarean services. Transport costs were typically most prohibitive among the poorer wealth groups who were more likely to live in remote areas. Also user fees were still charged for normal deliveries, thus wealthier women who could afford to go to a health facility in expectation of a normal delivery were more likely to have access to a caesarean delivery should complications arise during labor (28) It was also noted that the proportion of caesarean deliveries that resulted in maternal deaths reduced from 2% to 1.3%, and those that resulted in neonatal deaths reduced from 14% to 12% (29)

In their assessment, Dzakpasu et al concluded that even with the increased momentum in policies that focus on elimination of user fees, their effect on use of MNCH services is unclear. There was a paucity of evidence on how this affects health outcomes and inequalities. Consistency in the direction of effects provided some evidence that user fees have an effect on utilization of maternity health services, particularly on facility delivery. It follows then that in places where it is possible to provide good quality care, increasing the number of deliveries happening at facilities by eliminating user fees is a useful and practical strategy.(19) Nonetheless, there is room for research on how user fees affect health outcomes and access across different socioeconomic strata.

Nepal started safe delivery incentive program 2005 nationwide with the aim of increasing utilization of professional care at childbirth and institutional deliveries. It provided cash incentives to women who gave birth in health facilities and incentives to the health provider for each delivery attended, either at home or in the facility. It was expected that the cash incentive would reduce transportation barriers and delays in maternal care seeking. In 2009, the government then introduced a free delivery service which covered delivery at the facility, as well as transport to the facility. Consequently, Nepal is now on track in achieving MDG 5a. Their maternal mortality ratio has declined from 850/100,000 live births in 1990 to 415 in 2000 and further to 229 in 2011.(30) This was achieved by also including a national safe abortion plan. This demonstrates that targeted nationwide interventions that target both the provider and the patient are more likely to yield the desired results. Addressing indirect costs such as travel to the facility is also essential in removing barriers to accessing care.

b. The Kenyan context

Kenya implemented the new policy on abolition of user fees for maternity care on 1st June 2013. As it stands, no study has documented comparative maternal and neonatal outcomes, before and after its implementation.

However, in 1995, Mbugua et al studied the effect of user fees for primary health care in Kibwezi, a rural area. This was based on the introduction of user fees for inpatient and curative outpatient care at facilities in December 1989. Children under five years old were among the groups exempted from fees. In September 1990, outpatient registration fees were removed, but other fees were retained.

Attendance at government fee-charging health facilities for both outpatient and inpatient care was lower during the period when full fees were charged than during the same months of the previous year. Outpatient attendances rose again when the registration fees were lifted. This implied that the fees were significant enough to deter health seeking behavior, and thus their reduction/removal improved utilization. They also noted that the poorest households made much less use of the fee-charging government facilities than the better-off households.(31) The study did not assess health outcomes for the population.

A study done in Kenya by Collins et al that looked at the effects of the above fee introduction in 1989, and the phased fee re-introduction in 1992 confirmed the above trends. Furthermore, they suggested that implementing user fees in phases by level of health facility is important to gain patient acceptance, to develop the requisite management systems, and to orient ministry staff to the new systems. (32)

III. Free Maternity Services in the context of Kenyatta National Hospital

The free maternity services (FMS) directive abolished fees for ante-natal care (ANC), intra-partum care and post-natal care (PNC) up to six weeks postpartum. The government undertook to reimburse hospitals for these fees, using a claim system. The reimbursement is pegged on two things. Firstly, the level of the facility, e.g. health center, referral hospital. Secondly, the mode of delivery: I.e. spontaneous vertex delivery (SVD) or delivery by caesarian section (C/S), occurring after 28 weeks. The government contends that 10-20% of all the deliveries will complicate, thereby requiring specialized care e.g. care in the critical care unit (CCU). Thus a flat reimbursement rate of would provide a buffer, with the excess in those that do not complicate, catering for those that do.

The fee schedule is as follows for Kenyatta National Hospital, which is the national referral hospital.

Table 2: Cost and reimbursement schedule at KNH Source: Department of Reproductive Health, Kenyatta National Hospital

	Pre-Policy fees		Reimbursement	
	Kes*	USD**	Kes*	USD**
ANC	6,450	61.61	Nil	Nil
SVD (After 28 weeks)	11,900	113.67	17,500	167.16
C/S (After 28 weeks)	29,550	287.26	17,500	167.16
PNC	1,100	10.51	Nil	Nil

Kes* - Kenya Shillings **USD**** - US Dollars

Exchange Rate 1USD:104.69 Kes as at 3rd September, 2015. (33)

It is evident that a deficit in funding was inevitable, given these rates. Costs for critical care, early pregnancy complications, other co-morbidities and new born care are fairly high, and were not catered for in this flat rate. This created challenges in the implementation of the program, with reimbursements coming late, as well as being insufficient. This led to the hospital charging for ANC and PNC services, as well as post delivery complications from February to April of 2014, in a bid to overcome this challenge. However on further government directive issued in April 2014, it was clarified that all these services should be offered free, and this was immediately put into effect.

The reproductive health department at Kenyatta National Hospital aims to be a world class reproductive health department. The hospital has undertaken to conduct audits as well as set targets so as to improve patients' experiences and outcomes. It also aims to be a hub for research and evidence based practice. As per the departmental objectives in the period 2014/2015, the target was to reduce the MMR from 50.7 to 8 for KNH ANC attendees and 895.6 to 800 for non KNH ANC attendees.

Prior to the introduction of FMS, a study done by Owiti et al in 2009 at the hospital demonstrated a prevalence of 4.7% of women either near miss or maternal mortality, with the prevalence of near miss morbidity alone being 3.9%. The maternal mortality ratio was 829.7 per 100,000 live births. The near miss to mortality ratio was 4.7:1 with a mortality index of 0.176. This study also revealed that hypertension and HIV/AIDS were the leading causes of mortality at 32%. Hemorrhage on the other hand was the leading cause of near miss morbidity at 36.8%. Of these, 2.8% had attended KNH clinic and none of them died. She also noted that babies born to these women had poor outcomes: still births 30%, admission to NBU 30% and neonatal deaths 15%. (34)

Murage et al in 2001 reported the near miss prevalence at KNH to be 5.8%. They also demonstrated a much higher near miss to mortality ratio of 7:1. The leading cause of near miss mortality then was hemorrhage at 67.5%, followed by hypertension at 22.5%.(35)

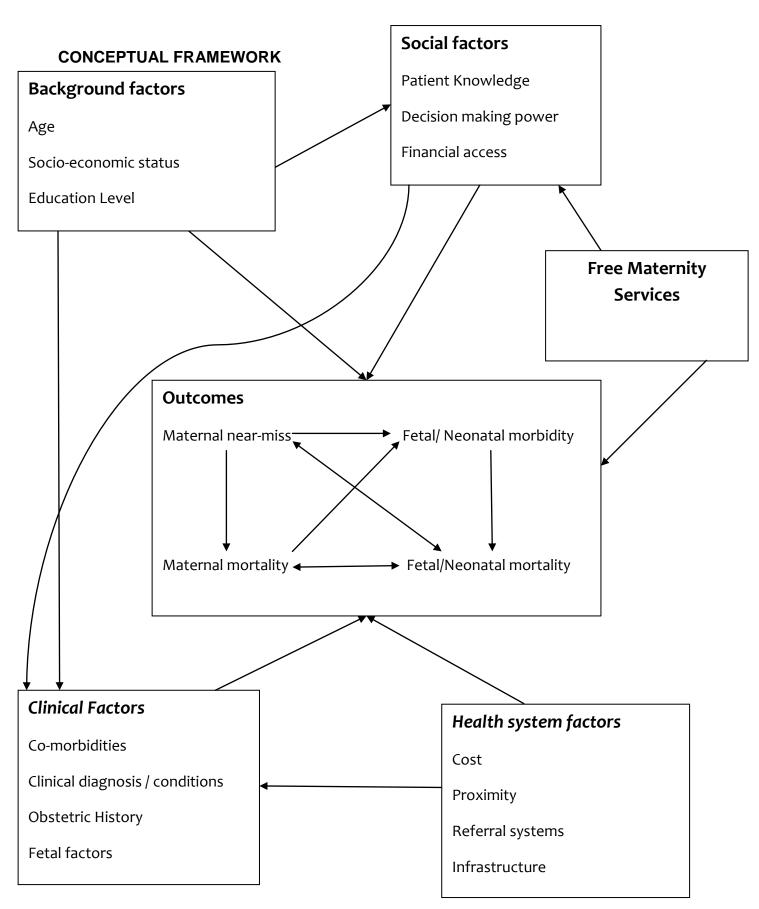
The published studies assessing the impact of fee exemption policies in other countries support the hypothesis that utilization of health services increases with fee exemptions, and decreases with fee introductions. While most studies focused on uptake of services, few studies documented comparative maternal outcomes, and even then statistical significance was not indicated. The maternal conditions associated with severe maternal outcomes have not been compared in the context of a fee exemption policy. There is also a paucity of data on the impact of free maternity services on neonatal outcomes which is a vital indicator of the quality of obstetric care.

RATIONALE

Kenya has set an ambitious goal to transform into a globally competitive and prosperous country with high quality of life by the year 2030, as stipulated in 'vision 2030.' This vision is firmly grounded in the new Kenyan constitution promulgated in 2010, which guarantees the rights of her citizens. One of these is that every Kenyan has the right to health of the highest attainable standard, including reproductive health. In view of this, the Kenya health strategic plan 2013-2017, now in its second phase of implementation has prioritized investments and interventions relating to improvement in maternal and child outcomes, areas in which progress was not attained in phase one. Recommendations have also been made to improve evidence based decision making. To do this, concrete research of the outcomes on the ground must be done. (36)

Furthermore, according to KDHS 2008-2009, 17% of the women who delivered outside of a health facility indicated that cost was the main obstacle to accessing a health facility. In the provincial survey, cost ranked as a factor above 30% only for women in Nairobi, with rural women citing distance and transport as the main barriers. (14) The free maternity program is thus most likely to have the deepest effect in Nairobi, amongst the middle to lower income class who cannot access private care. In this regard, the

No study had been done as yet, comparing maternal mortality and near misses, as well as neonatal outcomes, before and after the introduction of free maternity care at KNH. This needed to be done so as to determine whether the free maternity service program has resulted in better outcomes. Thus the data garnered here will be highly valuable to those in policy and planning at KNH as well as on a national level.



CONCEPTUAL FRAMEWORK NARRATIVE

It is well known that a maternal near miss is the pre-terminal event, before a maternal mortality occurs. These severe maternal outcomes have a direct negative impact on the fetus, often resulting in still births, or neonates that need specialized care and support. The factors contributing to these outcomes are varied.

Background factors such as age, education level and socio economic status have a direct effect on how much the patient understands regarding pregnancy, their ability to make decisions in terms of health seeking behavior as well as their access to finances. Their education level allows them to source for information, as well as understand provisions such as the user fee exemption policies. Those with higher education levels are therefore more likely to utilize these policies. Age and socio-economic status have been demonstrated to be associated with various clinical conditions such as hypertensive disease in pregnancy. Extremes of age are also significant. Fetal abnormalities are more prevalent in women above 35 years of age, while complications such as cephalo-pelvic disproportion, leading to obstructed labor will be more pronounced in the younger mothers. This is one of the conditions associated with high morbidity and mortality.

The fact that free maternity services directly target 'cost' as a barrier to accessing health is telling. This is because both direct and indirect costs determine whether a patient will access health interventions adequately and in a timely manner. These may deter or delay access to focused ante natal care or a skilled birth attendant, thereby resulting in poorly managed pregnancy and its complications, and finally in severe maternal and neonatal outcomes.

The clinical factors may be the most obvious co-relate with the feto-maternal outcomes. A poor obstetric history, any co-morbidities, order of pregnancy and others will influence the course of the pregnancy. However these are also directly affected by system factors. Diagnosis and evidence based management are a function of the system, its efficiency, the cost involved and adequate infrastructure.

Free maternity services therefore should have a direct impact in the reduction of severe maternal and neonatal outcomes. It directly influences a mother's decision making power and financial access, by removing the direct cost of ante natal care and delivery. It means that mothers can now access the facility nearest them, or one that may be further away but having enhanced facilities for maternal or neonatal care, as per their needs. It should also result in more efficient referral systems, as cost related delays are no longer pertinent.

RESEARCH QUESTION

Is there a difference in the pattern of severe maternal and neonatal outcomes among women admitted in KNH, after and before introduction of free maternity services in June 2013?

NULL HYPOTHESIS

There is no difference in the pattern of severe maternal and neonatal outcomes among women admitted in KNH, after and before introduction of free maternity services in June 2013.

OBJECTIVES

Broad objective

To compare the pattern of severe maternal and neonatal outcomes among women admitted in KNH after 28 weeks gestation, after and before introduction of free maternity services in June 2013.

Specific objectives

- Compare the maternal mortality ratio, and incidence of maternal near-miss and mortality after and before introduction of free maternity services
- II. Compare the incidence of neonatal morbidity and mortality after and before introduction of free maternity services
- III. Compare the pattern of clinical conditions constituting severe maternal outcomes after and before introduction of free maternity services
- IV. Compare factors associated with severe maternal and neonatal outcomes after and before introduction of free maternity services

METHODOLOGY

Study Design

This was a quasi-experimental study of the pre and post type, carried out between February and October 2016. A comparison was done between 1,264 women admitted in the time period 1st June 2009 to May 31st 2010, and 1,277 women admitted from 1st June 2014 to May 31st 2015. The intervention of interest was the introduction of free maternity services.

Study Site and Setting

The study was done at Kenyatta National Hospital, which is situated in Upperhill, Nairobi Kenya. It has a bed capacity of 2063, with the obstetric unit as a whole offering 115 beds. This is complemented by an acute gynecological ward with a capacity of 45 beds where patients with early pregnancy complications are managed. It is the largest referral hospital in the region, but also serves a large population of walk-in patients. The catchment area is the surrounding peri-urban Nairobi County, reaching as far as the surrounding counties of Kiambu, Thika, and Machakos. The population served is mainly the lower to middle economic strata in these areas, as well as those referred from afar.

Care at KNH is offered by highly qualified staff inclusive of consultants, midwives, residents, medical officers and interns in different cadres. This team combined offers ANC and PNC on weekdays between 8am and 5pm, as well as 24 hour care in the ante natal, post natal, labour, and acute gynecological wards besides the casualty department. The labor ward is fairly busy with at least 1000 deliveries being conducted every month. Two theatres are dedicated to the maternity unit with a full staff complement, and a third theater available on need basis. Other specialists in the hospital are consulted on a need basis, with admission in the CCU as well as the renal unit possible on indication. The unit is also supported by a functional laboratory service and a blood transfusion service.

Study Population

➤ All women admitted to Kenyatta National Hospital due to pregnancy and or its complications from 28 weeks gestation regardless of delivery status

Inclusion Criteria:

- Gravid women from 28 weeks gestation regardless of delivery status
- Maternal near misses or deaths occurring from 28 weeks gestation up to 42 days postpartum

Exclusion Criteria

Over 50 % of required data missing from the patient's file

Sample Size

The sample size was calculated as follows: (37*)

$$n = (\frac{r+1}{r}) \frac{(\bar{p})(1-\bar{p})(Z_{\beta} + Z_{\alpha/2})^{2}}{(p_{1} - p_{2})^{2}}$$

Ratio of cases:controls ®	1	
		Based on Maternal mortality meetings
Estimated maternal mortality before FMS p ₁	2.0%	at KNH
Estimated reduction in mortality	50%	
Estimated maternal mortality after FMS p ₂	1.0%	
Average of proportions $(p_1 + p_2)/2$	0.015	
Level of confidence $(1-\alpha/2)$	95%	
Power (1-β)	80%	
Sample size per group	1160	
Adjusting for incomplete data	1276	(10%)
Total sample size	2552	

^{*} Fleiss, Statistical Methods for Rates and Proportions, formulas 3.18 &3.19

Sampling Procedure

Women admitted to KNH due to pregnancy and or its complications after 28 weeks gestation in the designated periods, were randomly sampled until the desired sample size was achieved.

Data Variables

The dependent variables were severe maternal and neonatal outcomes. The independent variable was free maternity services. Exposure variables were the socio demographic characteristics, the clinical factors and background factors.

DATA COLLECTION, MANAGEMENT AND ANALYSIS

Data was collected using standardized data abstraction forms, by the research assistants. The research assistants were medical students. The principal investigator inducted them by taking them through the purpose of the study, the issues pertaining confidentiality as well as the data abstraction tool.

A test run of filling the tool was done with each of them to ensure understanding of the same, as well as completeness and accuracy in filling out the tool.

Patient file records were accessed from the KNH records department. These records were not removed from the department at any point. The tool was then used to abstract data, and once filled, kept in a filing cabinet under lock and key, accessible only to the Principal Investigator, the Statistician and the Data Entry Clerks.

The data was subsequently entered into a password protected Microsoft Access database accessible only to the Principal Investigator, the Statistician and the Data Entry Clerks. Once data entry was complete, the entered data was compared with the hard copy forms to ensure completeness and accuracy.

Exploratory data analysis was carried out to determine extreme values and identify inconsistencies. Once these were resolved, categorical variables were summarized using frequency tables while continuous variables were summarized using measures of central tendency and dispersion (mean, median, standard deviation, Inter-quartile range).

During bivariate analysis, Chi-squared tests and Fisher's exact tests were utilized to characterize associations between categorical neonatal and severe maternal outcomes and categorical predictors. Analysis of variance (ANOVA) tests were used to demonstrate associations between categorical neonatal and maternal outcomes and continuous predictors. Pearson correlation coefficients were used to show associations between continuous outcomes and continuous predictors. A p value of less than < 0.05 will be considered significant, with a 95 % confidence interval.

Multivariate analysis to determine independent factors that demonstrate the impact of free maternity services in KNH was carried out using logistic regression methods.

RESEARCH ETHICS

In the data collection tool, no personal identifiers were employed for patients. A code was assigned to each, for purposes of identification. The key, linking the patient to the identifying code was stored separately from the research data, in a password protected database. This was only accessible to the principal investigator and the research assistants.

No patients were interviewed as data was collected from the files, which negated against the need for informed consent, from the patients.

The study proposal was submitted to the KNH/UoN Ethics and Research Committee for approval. The results of the study will be shared with the obstetrics and gynecology department at KNH as well as UoN, with a view to informing and improving obstetric practice and patient care.

STUDY LIMITATIONS

This was an intra-hospital study. The results may not be generalisable to the entire population. The resources available to KNH are not necessarily the same as those available to lower level facilities. The patient profile may also affect this, as patients referred to this institution may have more complex illnesses or complications. However, it is expected that the impact of free maternity services would be of maximal effect in a facility like KNH, hence it is still an ideal site to carry out the study.

The quality of care in terms of human resource, inventory, patient and staff satisfaction were not directly compared in this study, as they were beyond the scope. However, based on the WHO near miss concept, assessing maternal near misses is a measure of quality of care, and utilizing the maternal near miss to mortality ratio is a suitable measure to assess the improvement or decline of quality of care.

The neonatal outcomes assessed were those immediately after delivery. Outcomes in the entire neonatal period were not assessed, and thus the study findings may underestimate the morbidity and mortality. This is mitigated by the fact the majority of poor neonatal outcomes occur in the immediate term, extending to the first 24 hours after birth. Thus the majority of poor outcomes would be reflected in the study.

RESULTS Study Flow

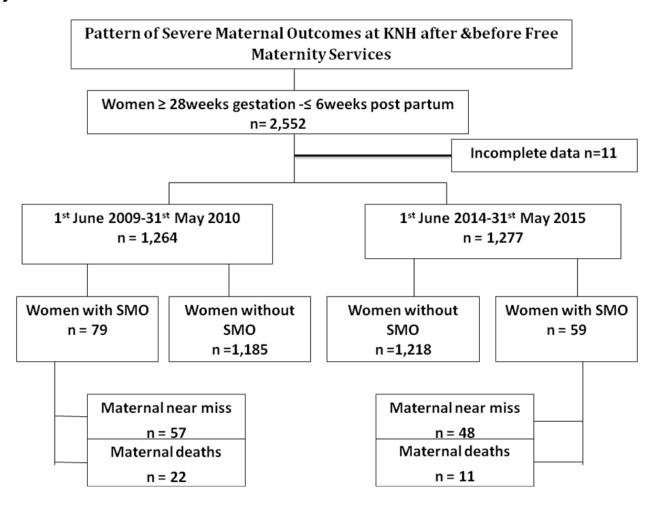


Figure 3: Study flow. Source: Author

This study was carried out between February and August 2016. Free Maternity Services (FMS) were introduced in Kenya and specifically at Kenyatta National Hospital (KNH), in the month of 1st June 2013. Maternal and neonatal outcomes before and after the introduction of FMS at KNH were compared. As illustrated above, a total of 2541 births were observed in both study periods, with 1264 (50%) of the admissions being observed prior to the introduction of FMS.

Table 3: Comparison of Gravid status before and after introduction of free maternity services

			Maternity rices	Before Maternity		
		n	%	n	%	p-value
	Gravid >/= 28 weeks	1173	93.2	1151	92.4	0.486
Gravidity	Within 42 days postpartum	86	6.8	94	7.6	
	Total	1259	100.0	1245	100.0	

Women admitted in the ante-partum and post-partum period in both periods were comparable, as shown in Table 3 above. Ante-partum admissions increased marginally, but this increase was not statistically significant (p=0.486).

Table 4: Comparison of Socio-demographic and obstetrics characteristics before and after introduction of free maternity services

			Free		Free	
		Maternity	Services	Maternity	Services	
		n	%	n	%	p-value
	Single	214	16.9	171	13.8	
	Married	1048	82.6	1068	85.9	
Marital status	Separated	1	.1	0	.0	0.150
	Divorced	1	.1	2	.2	
	Widowed	4	.3	2	.2	
Education	<pre><primary< pre=""></primary<></pre>	293	23.5	260	23.8	
level	≥Secondary	954	76.5	879	77.2	0.699
	Employed	319	25.6	344	28.0	
Employment	Self-employed	304	24.4	277	22.5	0.324
	Unemployed	623	50.0	609	49.5	
Attended	No	58	4.5	77	6.1	0.082
ANC	Yes	1219	95.5	1187	93.9	
ANC facility	KNH	365	31.2	489	42.4	<0.0001
attended	Other facility	805	68.8	664	57.6	
Referral	Booked for delivery at KNH	77	6.1	156	12.5	<0.0001
status	Referred from other facility	285	22.4	236	18.9	
	Self-referred	908	71.5	858	68.6	
Prognancy	Vaginal delivery	511	41.0	580	47.3	0.003
Pregnancy outcome	Caesarian section	700	56.1	625	50.9	
Outcome	Pregnant at discharge or death	36	2.9	22	1.8	

As demonstrated in Table 4, marital status, education level, employment and attendance of ANC did not change significantly after introduction of FMS p=0.150, p=0.699, p=0.324, p=0.082 respectively. Influx of mothers who attended ANC at other facilities significantly increased from 57.6% to 68.8%. Referral status also changed significantly (p=<0.0001). Referrals from other facilities increased from 18.9% to 22.4%, while those booked for delivery at KNH decreased from 12.5% to 6.1%.

Table 5: Comparison of co-morbidities before and after the introduction of free maternity services

		After Mate Serv	rnity	Before mate Serv	rnity	p value
		n=1,277	%	n= 1,264	%	
LIIV/ Info ation	No	1246	97.6	1227	97.1	0.435
HIV Infection	Yes	31	2.4	37	2.9	
A a	No	1255	98.3	1236	97.8	0.372
Anemia	Yes	22	1.7	28	2.2	
Diabataa	No	1267	99.2	1250	98.9	0.398
Diabetes	Yes	10	.8	14	1.1	
Renal	No	1273	99.7	1262	99.8	0.421
disease	Yes	4	.3	2	.2	
Cardiac	No	1268	99.3	1259	99.6	0.292
disease	Yes	9	.7	5	.4	
Chronic	No	1269	1269 99.4		98.9	0.191
hypertension	Yes	8	.6	14	1.1	

It is evident from Table 5 above that co-morbidities across both periods did not change significantly. Incidence of HIV decreased from 2.9% to 2.4% (p=0.435). Anemia, diabetes and chronic hypertension also decreased p=0.372, p=0.398 and p=0.191 respectively. Renal and cardiac disease increased, but the increase was not significant (p=0.421, p=0.292).

Table 6: Incidence of Severe maternal outcomes before and after the introduction of free maternity services

		Afte	r FMS	Before FMS		
		n	%	n	(%)	p-value
Matawal Dooth	No	1,266	(99.1)	1,242	(98.3)	0.05
Maternal Death	Yes	11	(.9)	22	(1.7)	
Maternal Near Miss	No	1,229	(96.2)	1,207	(95.5)	0.342
	Yes	48	(3.8)	57	(4.5)	
Maternal near miss mortality ratio		4.	4	2.	3	

In Table 6, the incidence of severe maternal outcomes was compared. Before the introduction of free maternity Services, 22 maternal deaths (1.7 %) and 57 near misses (4.5 %) were recorded. Both of these outcomes reduced during free maternity era to 11 deaths and 48 near misses, representing 0.9% and 3.8% respectively. The reduction in maternal deaths was statistically significant (p=0.05) while reduction in maternal near misses was not (p=0.342). The maternal near miss mortality ratio increased from 2.3 to 4.4 after introduction of free maternity services.

The maternal mortality ratio was calculated as follows:

Maternal Deaths X 100,000 Live Births

Before Free Maternity Services: 22 X 100, 000 = 1982

1110

After Free Maternity Services: 11 X 100, 000 = 962

1143

As illustrated above, the ratio after introduction of free maternity services was 962, compared to before free maternity at 1982 maternal mortalities, per 100,000 live births.

Table 7: A comparison of maternal complications before and after Free maternity services

		After free	maternity	Before	e free	
		serv	ices	maternity	services	
		n	%	n	%	p-value
Dro Folomosio	No	1200	94.0	1130	89.4	<0.0001
Pre-Eclampsia	Yes	77	6.0	134	10.6	
Ante-partum	No	1211	94.8	1224	96.8	0.012
Haemorrhage	Yes	66	5.2	40	3.2	
Postpartum	No	1234	96.6	1220	96.5	0.875
Hemorrhage	Yes	43	3.4	44	3.5	
Dunturad Litarua	No	1269	99.4	1238	97.9	0.002
Ruptured Uterus	Yes	8	.6	26	2.1	
Falamasia	No	1217	95.3	1214	96.0	0.358
Eclampsia	Yes	60	4.7	50	4.0	
Prolonged/	No	1184	92.7	1206	95.4	0.004
Obstructed labor	Yes	93	7.3	58	4.6	
Canaia ar continamia	No	1247	97.7	1236	97.8	0.821
Sepsis or septicemia	Yes	30	2.3	28	2.2	

Subsequent to the introduction of FMS, pre-eclampsia and ruptured uterus were observed to decrease significantly, p=<0.001 and p=0.002 respectively, as displayed in Table 7. An increase was seen in ante-partum hemorrhage and prolonged labour. APH increased from 40 (3.2%) to 66 (5.2%), p=0.012, and prolonged labour increased from 58 (4.6%) to 93 (7.3%). The changes in both were statistically significant. No significant changes were observed in PPH (p=0.875), eclampsia (p=0.358) or sepsis (p=0.821) across both periods.

Table 8: A comparison of neonatal morbidity and mortality before and after free maternity services

		After	FMS	Before	Before FMS		
		n	%	n	(%)		
Birth outcome	Live birth	1,143	(94.9)	1,110	(92.3)	0.009	
	Still birth	61	(5.1)	92	(7.7)		
Admitted NBU	No	1,075	(84.2)	1,080	(85.4)	0.376	
	Yes	202	(15.8)	184	(14.6)		

Table 8 represents neonatal morbidity and mortality among all women studied. A statistically significant reduction in adverse birth outcomes was observed after the introduction of free maternity services, where still births decreased from 92 (7.7%) to 61 (5.1%), (p=0.009). Although the proportion of admissions in the NBU increased after introduction of FMS, this change was not statistically significant (p=0.376).

Table 9: Association between Severe maternal Outcomes and neonatal morbidity

		A	fter free r	maternity	Before free maternity			
			servi	ces	services			
			dmission	n to NBU	Admission to NBU			
			No	Yes	No	Yes		
		n	%	n %	n (%)	n (%)		
Maternal Death	No	1,071	(84.6)	195 (15.4)	1,066 (85.8)	176 (14.2)		
	Yes	4	(36.4)	7 (63.6)	14 (63.6)	8 (36.4)		
p-value			<0.00	001	0.0	03		
Maternal Near Miss	No	1,046	(85.1)	183 (14.9)	1,035 (85.7)	172 (14.3)		
	Yes	29	(60.4)	19 (39.6)	45 (78.9)	12 (21.1)		
p-value			<0.00	001	0.155			

The association between severe maternal outcomes and neonatal morbidity is demonstrated in Table 9. Following a maternal death, the proportion of neonates admitted to the NBU increased from 36% to 63.6%, which was statistically significant (p= <0.0001). The same trend was seen with the occurrence of a near miss, with admissions to NBU increasing from 12 (21.1%) to 19 (39.6%), (p=<0.0001). There was no significant change in admissions to NBU for babies born to mothers who did not experience a near miss.

Table 10: Association between Severe maternal outcomes and neonatal mortality

		After f	ree mate	ernity se	ervices	Before free maternity services			
	_	Live birth		St	ill birth	Live	Live birth		l birth
		n	%	n	%	n	(%)	n	(%)
Maternal	Yes	8	(80.0)	2	(20.0)	16	(72.7)	6	(27.3)
Death	No	1,135	(95.1)	59	(4.9)	1094	(92.7)	86	(7.3)
p-value			0.0	031		<0.0001			
Maternal	Yes	31	(67.4)	15	(32.6)	33	(58.9)	23	(41.1)
Near Miss	No	1,112	(96.0)	46	(4.0)	1,077	(94.0)	69	(6.0)
p-value			<0.0	0001		<0.0001			

It is evident from table 10, that there was a reduction in the number of still births born to mothers who died, after the introduction of FMS. In both the pre and post free maternity era, a strong association was observed between poor birth outcomes and maternal deaths, p=<0001 and p=0.031 respectively. However, the proportion of still births reduced from 6 (27.3%) to 2 (20%).

Amongst mothers who experienced a near miss, the proportion of still births reduced from 23 (41.1%) to 15 (32.6%) after FMS was introduced. In spite of this reduction, maternal near miss continued to be associated with poor neonatal outcomes p=<0001, both before and after FMS.

Table 11: Association between maternal complications and severe maternal outcomes

		A	fter free	mater	nity	Ве	fore fre	e mate	rnity	
			serv	/ices			serv	vices		
		Mat	ernal	Mater	nal Near	Mat	ernal	Maternal Near		
		De	eath	N.	1iss	D€	eath	Miss		
		No	Yes	No	Yes	No	Yes	No	Yes	
Dro Eclamacia	No	99.1	.9	96.4	3.6	98.6	1.4	96.2	3.8	
Pre-Eclampsia	Yes	100.0	.0	93.5	6.5	95.5	4.5	89.6	10.4	
p-value		0.3	399	0.	.193	0.	010	<0.	0001	
Antepartum	No	99.1	.9	96.5	3.5	98.3	1.7	95.8	4.2	
Haemorrhage	Yes	100.0	.0	90.9	9.1	97.5	2.5	87.5	12.5	
p-value		0.4	0.437		0.019		0.709		0.013	
Postpartum	No	99.2	.8	97.5	2.5	98.8	1.2	96.3	3.7	
Hemorrhage	Yes	97.7	2.3	60.5	39.5	84.1	15.9	72.7	27.3	
p-value		0.2	291	<0.0001		<0.0001		<0.0001		
Ruptured Uterus	No	99.1	.9	96.6	3.4	98.2	1.8	96.0	4.0	
Ruptureu Oterus	Yes	100.0	.0	37.5	62.5	100.0	.0	69.2	30.8	
p-value		0.	791	<0	.0001	0.	493	<0.	0001	
Eclampsia	No	99.2	.8	97.4	2.6	98.4	1.6	96.1	3.9	
Eclampsia	Yes	98.3	1.7	73.3	26.7	94.0	6.0	80.0	20.0	
p-value		0.	489	<0	.0001	0.	019	<0.	0001	
Prolonged/	No	99.1	.9	96.2	3.8	98.2	1.8	95.4	4.6	
Obstructed labor	Yes	100.0	.0	96.8	3.2	100.0	.0	96.6	3.4	
p-value		0	351	0.	.779	0.299		0.	690	
Sepsis or	No	99.1	.9	96.6	3.4	98.6	1.4	95.8	4.2	
septicemia	Yes	100.0	.0	80.0	20.0	82.1	17.9	82.1	17.9	
p-value		0.	605	<0	.0001	<0.	0001	0.	001	

As shown in Table 11, in the period where maternity services were not free, pre-eclampsia (p=0.01, p<0.0001), postpartum haemorrhage (p<0.0001 for both), eclampsia (p=0.019, p<0.0001) and septicemia (p<0.0001, p=0.001) were associated with both death and near-miss respectively. This changed after introduction of free maternity services as PPH (p<0.0001), eclampsia (p<0.0001) and sepsis (p<0.0001) are the only complications which remained associated with near-miss.

Complications that were associated with near miss during both periods were APH (p=0.013, p=0.019), and ruptured uterus (both p<0.0001). Prolonged labour was not associated with undesirable maternal outcomes in any of the periods.

Table 12: Multi-variate analysis (logistic regression) for factors associated with free maternity services

	Coefficient	nt S.E. of p-value OR 95% C.I. for				for OR
		coefficient	t		Lower	Upper
Pre-eclampsia	596	.149	.000	.551	.411	.738
Ante-partum Haemorrhage	.525	.206	.011	1.690	1.130	2.529
Prolonged Labour	.495	.174	.004	1.641	1.167	2.307
Ruptured Uterus	-1.270	.408	.002	.281	.126	.625

In a multivariate analysis of the independent correlates of free maternity services displayed in table 12, Pre-eclampsia and ruptured uterus were observed to have a negative correlation with FMS. After FMS, patients were less likely to have Pre-eclampsia and ruptured uterus, odds ratios 0.551 (95% CI: 0.411-0.738), and 0.281 (95% CI: 0.126-0.625). Patients were 1.6 times more likely to experience Ante-partum hemorrhage and prolonged labour, odds ratios 1.690 (95% CI: 1.1130-2.529) and 1.641 (95% CI: 1.167-2.307) respectively, compared to their counterparts before FMS.

DISCUSSION

The socio-demographic profile of mothers managed at KNH did not change appreciably after the introduction of free maternity service. It was however observed that patients who attended ANC elsewhere and those booked for delivery in other facilities increased in KNH after FMS was introduced. The mean number of ANC visits also increased. This is validated in the systematic review by Dzakapasu et al where they established that fee exemptions generally result in increased facility deliveries and ANC visits.(19)

In this study, the incidence of maternal mortalities decreased from 22 (1.7%) to 11 (0.9%) after the introduction of free maternity services (FMS). Near misses decreased from 48 (4.5%) to 11 (3.8%). This puts joint morbidity and mortality at 6.2% before free maternity, which subsequently reduced to 4.7%. The percentage before free maternity is higher than that documented by Owiti et al at KNH, which was at 4.7%. (34) However it is in keeping with the estimation by Say et al in their systematic review at 0.8-8.23%.(12) These changes, though not statistically significant, point to an encouraging trend of decreasing severe maternal outcomes, despite the increased numbers of women attended to at KNH.

The maternal mortality ratios were 1982 mortalities per 100,000 live births before FMS and 962 per 100,000 live births after. This is a 52% reduction. This trend was also observed in Ghana (23). The MMR in the Volta region reduced from 1439.4 to 911.2 after a fee exemption policy was introduced. In the central region it reduced from 953.5 to 856.1. This study recorded higher values for MMR in both periods compared to Ghana. This is likely to be because the Ghanaian study used total births instead of live births for the denominator, in the calculation of the MMR. The MMR was also higher than in other studies done at KNH. Owiti et al recorded 829.7 and Oyieke et al at 921.5 per 100,000 live births. (38)

In this study, it was not possible to determine the direct cause(s) for the observed trend in MMR. This is unlike in Ghana where clinical record reviews and health worker interviews were a part of the study. These revealed that there was an increase in utilization of health facilities for delivery, with health workers needing to work between 7-17 additional hours per week. The decline in MMR was attributed to two reasons: Firstly, that the workforce that was motivated and thus able to cope with the extra work, thereby maintaining the quality of care. They also found that some facilities had been working below capacity, and therefore were able to absorb the increased workload, without being stretched beyond capacity. (23) These reasons may also explain the reduction in MMR, in the KNH setting.

This reduction in maternal mortalities is further reflected in the near miss to mortality ratio which increased from 2.3 to 4.4. This confirms that there are 4.4 women with a near miss who survive for everyone who dies, compared to 2.3 women before FMS. Owiti et al had a higher ratio of 4.7, with Murage et al having found a ratio of 7.(34,35). The increase in the ratio is largely due to the reduction in mortalities. It infers increasing quality of care, in the context of a health system, as more women are surviving life threatening complications, who previously would have died (16).

In this study, it was observed that Pre-eclampsia reduced while obstructed labour increased. In Ghana, no clear pattern of the causes was seen in the pre and post exemption phase, however pre-eclampsia and obstructed labour increased. (23) The Ghanaian study demonstrated that the fee exemption resulted in an increased number of women with complications seeking care. A three-fold increase of these women was noted in one of the facilities, which is a teaching hospital, with a concurrent drop in referrals. It is therefore possible that the fee exemption in Kenya has opened the door for women with complications to access care at KNH, and would explain the increased numbers seen with certain complications.

Various maternal complications were assessed for their association to severe maternal outcomes. Pre-eclampsia was significantly associated with mortality and near miss before FMS. This association was no longer significant after FMS. Eclampsia that was previously associated with mortality and near miss, was only associated with near miss after FMS. This is significant as hypertensive disease is a major contributor to poor maternal outcomes. Hemorrhage, both ante partum and postpartum, remain a major cause of maternal near miss in our setup. PPH that was previously associated with death is now only associated with near miss. Certain practices that were put in place after introduction of free maternity may have directly impacted this. All gravid women now get at least one ultrasound in the course of the pregnancy (more than one if indicated), meaning that patients who are at a higher risk for APH and PPH can be identified early, and mitigative measures put in place. The blood transfusion unit has also implemented an aggressive policy in conjunction with the reproductive health unit to increase availability of blood products. All women requiring transfusion and those scheduled for an elective cesarean section must have at least two people donate blood at the unit. In view of this, gravid women or mothers requiring life saving transfusion are able to receive it expeditiously.

Ruptured uterus is a potentially fatal event, both for the mother and the baby. This was demonstrated in previous studies done at KNH which showed the contribution of ruptured uterus to maternal deaths at 3% between 1995-1999 (38), and 7.6% of near miss morbidity in 2009 (34).

In this study, it was associated with near miss in both periods, but not with mortality. After FMS, 8 (60%) of those who had a ruptured uterus had a near miss, compared to 5 (30%) before FMS. However, the absolute numbers of those who got a ruptured uterus decreased significantly from 26 to 8, p=0.002.

Contribution of sepsis to maternal deaths was recorded at 11% by Say et al. At KNH (34), the contribution of sepsis to SMO's was found to be 6%. Rates of sepsis in this study did not change significantly across both periods. While previously associated with both maternal death and near miss, after FMS it is only associated with near miss.

Contextual factors that may have contributed to the decreased mortality seen with these maternal complications are the introduction of an extra maternity theater that is operational 24hours. This helped off load the solitary theater used before free maternity services were introduced, where a junior registrar was the surgeon on call. This new theater is in addition, manned by senior registrars, thus availing additional expertise in the course of the day in the decision making and management of the complicated cases that would present in theater.

The pattern of birth outcomes was noted to change after the introduction of free maternity services. Live births increased marginally, with still births decreasing from 92 (7.7%) to 61 (5.1%) among all women studied. These changes were statistically significant; p=0.009.

In mothers who experienced a severe maternal outcome before FMS, the still birth rate was much higher, at 6 (27.3%) and 23 (41.1%) for maternal deaths and near misses respectively. This is higher than that recorded in previous studies (34,35). After FMS, 1 in 5 babies born to mothers who died also demised, and 1 in 3 of those whose mothers had a near miss also died. Even though this represents a reduction from the pre free maternity era, it is still unacceptably high. Also noteworthy is that these only represent ante or intra-partum deaths. Those that happened later in the neonatal period were not documented, and as such the actual figure for neonatal mortality would be much higher.

In both periods, there is a clear association between severe maternal outcomes and poor neonatal outcomes. This is because the fetus is dependent on the mother for sustenance, and maternal compromise leads to fetal compromise.

Babies who were born to mothers who had an SMO were highly likely to be admitted to NBU, compared to those who did not. This was true both before and after free maternity. The rate before FMS is in keeping with Owiti's study that recorded 30%. The rate of admission to NBU nearly doubled after the introduction of FMS, for babies born to mothers who had an SMO. This is in keeping with the increased number of live births and points to increased morbidity, and increased need for supportive care among these neonates.

The rate of admission to NBU was however constant across both periods, in those born to mothers who did not experience an SMO. Even though these neonates were not followed up for the duration of their admission to determine further outcomes, the reduction in still birth rate points to improved quality of care.

CONCLUSION

This study demonstrates that there have been major achievements with the introduction of free maternity services. Severe maternal outcomes have reduced, even though the reduction is not statistically significant. Gains have been made in the management of Pre-eclampsia, as it is no longer significantly associated with severe maternal outcomes. Progress has also been made in eclampsia, PPH, and sepsis management as they're no longer significantly associated with death, but only with near miss. APH and ruptured uterus continue to be associated with near misses, and present multiple opportunities to improve on care.

Neonatal outcomes in the context of severe maternal outcomes are brought to the fore in this study. The extra burden placed on the health system by FMS, is demonstrated with the significant increase of neonates admitted to the new born unit, for babies born to mothers who experience a severe outcome.

RECOMMENDATIONS

- I. There should be continued prioritization on the management of Pre-eclampsia, eclampsia, APH, PPH, ruptured uterus and sepsis to prevent mortality and morbidity associated with near misses at KNH.
- II. Studies should be done jointly by obstetricians and neonatologists, to determine the causes for increased early neonatal morbidity, in the context of severe maternal outcomes, in the era of free maternity services.
- III. Outcomes in the entire neonatal period were beyond the scope of this study. With increasing admissions to NBU, it is important to determine how these neonates fare in the neonatal period as well as long term sequelae. This is a vital area for future research, as effects of SMO's on future milestone developments, cognitive developments, learning capabilities and quality of life is yet to be documented in our setting.
- IV. Other countries should adopt a fee exemption policy for maternal care, as implementation of the same has been shown to have a positive effect on maternal and neonatal outcomes.

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STUDY TIMELINES

	2015		_	2016			2017
	February - July	August	September- January 2016	February- August	September- October	November	February
Proposal							
Development							
Proposal							
Presentation							
Ethics							
Committee							
Review							
Data							
Collection							
Data							
Analysis							
Results							
Presentation							
Publication							

BUDGET

	Item	Amount (Kes)	
1	Personnel		
	Statistician	65,000	
	Research Assistants x 4 pax	120,000	
2	Operational Costs		
	Printing/ Photocopy	45,000	
	Internet	10,000	
	Telephone	2,000	
	Transport/Meetings	2,000	
	Training of research assistants	3,000	
3	Other Costs		
	Record retrieval fees	2,000	
	KNH/UoN ERC fees	2,000	
	Dissemination & Publication	10,000	
		261,000	

ΑF	PPEN	IDIX 1: DAT	TA ABSTRA	CTION TOOI	_		
St	udy N	No:				Date:	
	The	-				comes at Kenya free maternity s	
Pa	art I:	Eligibility					
1.	Is th	ne woman:	Gravid≥ 28	weeks			
			Within 42 d	ays postpart	um 🗆		
Pa	art II:	Socio dem	ographics				
In	dicat	e all times	using the 24	hour clock	, and dates	in this format d	ld/mm/yyyy
2.	Age	(years)					
3.	Mar	ital Status					
		Singl	e 🗆		Widowe	d □	
Married		ed 🗆		ed 🗆			
		Divor	ced 🗆				
4.	Cou	inty of resid	ence				
5.	Lev	el of Educat	tion				
	Prin	nary		Secondary	/ 🗆	Tertiary	
6.	Emp	oloyment sta	atus				
	Emp	oloyed□		Unemploy	ed □		
Pa	art III:	Obstetric	History				
7.	Pari	ty					
8.	Obs	tetric Histor	ТУ				
		Date	Place	GA** at	Mode of	Maternal	Neonatal
		(Year)	Home or HF*	delivery	Delivery	Complications	Outcome
	'	1					
		2					
	-	3					
	1	1	I	1	1	1	1

^{*}HF-Health Facility GA** Gestational age

9.	ANC attendance		Yes		No				
10.	If yes, facility attended:		KNH		Other	facility			
11.	Number of visits								
12.	Date of first visit/	/							
13.	Gestational age at first	visit	(in co	mpleted	d week	s)		40	
14.	ANC Profile								
	Hemoglobin:	Blood	group:	:		VDRL	:	I	HIV:
PΑ	ART IV: INDEX ADMISS	SION							
15.	Date of Admission	/.	/						
16.	Time of admission								
17.	Referral status								
	Referred from other fac	cility							
	Self referred								
	Booked for delivery at I	KNH							
18.	Gestational age at adm	nission	(in con	npleted	weeks	s)	/4	10	
19.	Gestational age calcula	ated by	Dates	;			Quicke	ning	
			Ultras	ound			Fundal	Height	
			First o	linic vi	sit estir	nate	I		
20.	Date of discharge or de	eath	/.	/					
21.	Time of discharge or de	eath	/.						
22.	Duration of admission hours)		da _y	ys	or		hours (if less t	han 24
PΑ	RT V: MATERNAL OU	тсом	E						
23.	Maternal death*								
24.	Maternal Near miss*								
25.	Other **								

*If the answer to this section is 'Maternal death' or 'Near miss', proceed to part VI
**If the answer to this section is 'Other' proceed to part VII

PART VI: DIAGNOSIS OF MATERNAL COMPLICATION

26. Indicate the applicable criteria

26a	Near Miss Criteria	Present			
	Shock				
	Cardiac arrest				
	Acute cyanosis				
	Gasping				
	Tachypnoea (respiratory rate >40bpm)				
	Bradypnoea (respiratory rate <6bpm				
	Oliguria non responsive to diuretics				
	Failure to form clots				
	Jaundice in pre-eclampsia				
	Prolonged unconsciousness (>12hours)				
	Stroke				
	Status epilepticus				
	Global paralysis				
	Severe acidosis				
	Hypoperfusion (lactate >5 mmol/l)				
	Severe hypoxemia (SPO ₂ <90% for ≥60 minutes				
	Or PaO ₂ /Fio ₂ <200				
	Severe acute azotemia (Creatinine ≥300µmol/l or				
	≥3.5mg/dl)				
	Severe acute thrombocytopenia (Platelets < 50,000/ml)				
	Severe acute hyperbilirubinemia				
	(bilirubin>100 μmol/l or >6·0mg/dL)				
	Use of continuous vasoactive drugs				
	Cardiopulmonary resuscitation				
	Intubation and ventilation not related to anaesthesia				
	Dialysis for acute renal failure				
	Massive transfusion of blood / red cells (≥ 5 units				
	Hysterectomy following infection or haemorrhage				
26b	Demised				

77	Ihhh	clinical	diadr	2122	MOC:
//		(.111 11(CHACH	10315	was

A.	Pre-Eclampsia	F.	Ruptured Uterus
В.	Eclampsia	G.	Prolonged/Obstructed labor
C.	Antepartum Haemorrhage	H.	Sepsis or Septicemia □
D.	Post partum Hemorrhage		
E.	Ectopic pregnancy		

PART VII: COMORBIDITIES 28. Indicate any other illnesses the patient had a) HIV Infection e) Cardiac disease f) Chronic hypertension b) Anemia c) Diabetes g) Other co-morbidity d) Renal disease PART VIII: PREGNANCY OUTCOME 29. What was the pregnancy outcome? a) Vaginal delivery b) Caesarean section

Emergency

i.

		ii.	Elective			Indi	cation		
30.	With refer	ence to	question	29, ir	which	facil	lity did this occur?		
	KNH		Ot	her fa	cility 🗆				
PA	RT IX: FE	TAL O	UTCOME						
31.	Date of de	elivery		/					
32.	Time of d	elivery							
33.	Time from hours)			elivery	(days)		Or hours (if less t	han 24
34.	Gestation	at deliv	very (in co	omplet	ed wee	eks)	/40		
35.	If <37 cor	npleted	weeks, v	vere co	orticost	teroic	ds given? Yes□	No	
36.	Order of p	oregnar	ncy: Singl	eton/T	wins/T	riplet	ts		
37.	Live birth		St	ill birth	ı 🗆				
38.	Birth weig	ıht (gra	ms)						
39.	Apgar sco	ore	1 minute				5 minutes		
40.	Admitted	to NBU	Υe	es 🗆	N	lo			
41.	Date of a	dmissio	n		/	/			
42.	Admissio	n diagn	osis						

Indication.....

PART XI: CRITICAL INTERVENTIONS

Use of continuous vasoactive drugs

43. With reference to the clinical diagnosis, indicate the critical interventions and when they were administered.

Yes □

No

П

Α.	Severe	pre eclamp	sia and	eclamo	sia
/١.	CCVCIC	pre ecianip	Sia alla	CCIGITIF	JJIG

Was the woman still pregnant at discharge/death

i.	Date of diagnosis/
	Time of diagnosis/
ii.	Was magnesium sulphate given? Yes □ No □
	If yes, date of commencement/
	Time of commencement/
iii.	Time from diagnosis to critical interventiondays+hours

В.	Post partum Haemorrhage			
i.	Date of diagnosis/			
	a. Time of diagnosis/			
ii.	Was prophylactic oxytocin 10IU given a	after de	elivery? Yes	□ No □
iii.	Indicate intervention and time of intervention	ention		
		Date		Time
a)	Therapeutic oxytocin administration		//	/
b)	Prostaglandin administration		//	/
c)	B-lynch suture insertion		//	/
d)	Uterine artery ligation		//	/
e)	Hysterectomy		//	/
iv.	Time from diagnosis to critical intervent	tion	days+ .	hours
C.	Systemic infection or sepsis			
i	. If patient deliver via caesarian section	on, we	re prophylactic	antibiotics given?
	Yes 🗆 No 🗅			
ii	. Date of diagnosis/	¹		
	Time of diagnosis/			
iii	. Were intravenous antibiotics given a	after di	agnosis? Yes	□ No □
	If yes,			
	a) Date of administration	//		
	b) Time of administration/	'		
iv	. Time from diagnosis to critical interv	ention/	days	+hours

<i>ا</i> . ن	bstructed Labour
i.	Date of diagnosis/
	Time of diagnosis/
ii.	Was a cesarean section prescribed Yes □ No
iii.	If yes, indicate
	Date of cesarean section/
	Time of commencing cesarean section/
iv.	If uterine rupture occurred, indicate
	Date of laparatomy/
	Time of commencing laparatomy/
٧.	Time from diagnosis to critical interventiondays+hours
E. R	enal Dysfunction
i.	Renal dysfunction was secondary to
ii.	Date of diagnosis//
	Time of diagnosis/
iii.	Date of commencement of dialysis/
	Time of commencement of dialysis/
iv	. Time from diagnosis to critical interventiondays+hours
_	ritical Care Support
i.	Date of diagnosis/
	Time of diagnosis/
ii.	·
	Yes No
iii	
	Time of transfer/
iv	Time from diagnosis to critical interventiondays+hours+minutes

APPENDIX 2:KNH-UON / ETHICS AND RESEARCH COMMITTEE APPROVAL LETTER



UNIVERSITY OF NAIROBI COLLEGE OF HEALTH SCIENCES

P O BOX 19676 Code 00202 Telegrams: varsity (254-020) 2726300 Ext 44355

Ref: KNH-ERC/A/475

Dr.Grace Watau Njau Reg. No.H58/69089/2013 Dept.of Obs/Gynae School of Medicine College of Health Sciences University of Nairobi

Dear Dr. Njau

2 3 NOV 2015

KNH-UON ERC

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KENYATTA NATIONAL HOSPITAL

P O BOX 20723 Code 00202

Tel: 726300-9 Fax: 725272 Telegrams: MEDSUP, Nairobi

23rd November 2015

Revised research proposal: The pattern of severe maternal and neonatal outcomes at Kenyatta National Hospital, before and after the introduction of Free Maternity Services. A Quasi-Experimental study P599/09/2015)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH-UoN ERC) has reviewed and approved your above proposal. The approval periods are 23rd November 2015 – 22rd November 2016.

This approval is subject to compliance with the following requirements:

- a) Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
- All changes (amendments, deviations, violations etc) are submitted for review and approval by KNH-UoN ERC before implementation.
- c) Death and life threatening problems and serious adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH-UoN ERC within 72 hours of notification.
- d) Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH/UoN ERC within 72 hours.
- Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (Attach a comprehensive progress report to support the renewal).
- f) Clearance for export of biological specimens must be obtained from KNH/UoN-Ethics & Research Committee for each batch of shipment.
- g) Submission of an <u>executive summary</u> report within 90 days upon completion of the study. This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/or plagiarism.

Protect to Discover

For more details consult the KNH/UoN ERC website http://www.erc.uonbi.ac.ke

Yours sincerely,

PROF. M.L. CHINDIA SECRETARY, KNH-UoN ERC

The Principal, College of Health Sciences, UoN The Deputy Director CS, KNH C.C.

The Chairperson, KNH- UoN ERC
The Assistant Director, Health Information, KNH
The Dean, School of Medicine, UoN

The Chair, Dept.of Obs/Gynae, UoN

Supervisors: Dr.Francis X. Odawa, Dr. John Ong'ech