

# DESCRIPTIVE STUDY OF MATERNAL OUTCOMES IN A NEAR-MISS COHORT AT KAGADI DISTRICT HOSPITAL, UGANDA

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## **DEDICATION**

Jane Nabwami

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## ACRONYMS

CPD	Cephalopelvic disproportion
PPH	Postpartum haemorrhage
MNMR	Maternal near miss incidence ratio
MMR	Maternal mortality ratio
MDG	Millennium development goals
WHO	World health organisation
ICU	Intensive care unit
HREC	Human research ethics committee
UK	United Kingdom
HELLP	Haemolysis, elevated liver enzymes, low platelets
IRB	Institutional review board
UCT	University of Cape Town
US	United States
RCT	Randomised control trial

## Abstract

**Background:** An understanding of pregnancy related morbidity (obstetric near miss) provides valuable information that can be used in reduction of maternal mortality. This study aims to (i) Describe the prevalence and short term outcomes of obstetric near misses (ii) Evaluate the level of care through comparative analysis of obstetric near misses and maternal mortality in Kagadi district hospital, Uganda

**Methods:** A facility based retrospective review of obstetric near miss cases and maternal deaths that occurred between 1<sup>st</sup> January 2015 and 31<sup>st</sup> December 2015. Obstetric near miss case definition was based on disease-specific criteria including: haemorrhage, hypertensive disorders of pregnancy, dystocia, infection and anaemia. Main outcome measures included the frequency of near-miss in each disease specific group, duration of hospital stay and maternal death. Secondary outcome measures included distribution of referral categories, caesarean section rate, hysterectomy and foetal outcomes measures i.e live births, still births, abortions, neonatal deaths. A comparative analysis of obstetric near miss and maternal mortality was done to determine the maternal near miss incidence ratio (MNMR), maternal mortality ratio (MMR) and Mortality indices. The maternal near miss to mortality ratio for the period of study was calculated.

**Results:** There were 7169 admissions to the maternity ward with 4366 deliveries, 752 near misses and 12 maternal deaths. The prevalence of maternal near misses was 10.7%. Maternal near miss and maternal mortality ratio were 177.1 per 1000 and 282 per 100,000 live births respectively. The near miss to mortality ratio was 63:1. Dystocia (69.3%) was the most common near miss event, followed by haemorrhage (19.5%), infection (5.2%), anaemia (4.5%) and hypertension (1.5%). The mortality indices were 27.3%, 4.1%, 2.9%, 2.5% and 0.2% for hypertension, haemorrhage, anaemia, infection and dystocia respectively. Most complications developed at home (46.7%) while 36.5% and 16.5% occurred at the study site and other public facilities respectively. The mean duration of hospital stay was 3.6 days. The caesarean section rate was 12% of all hospital deliveries and 6 near misses had hysterectomy. Foetal outcomes were 78.4%, 14.2%, 5.6% and 1.8% for live births, abortions, fresh still births and neonatal deaths respectively.

**Conclusion:** There is a high occurrence of near miss events at the health facility. Dystocia is the leading cause of obstetric near miss but hypertension and haemorrhage are associated with poor maternal outcome. Although most obstetric complications develop at home, a comparative analysis of morbidity and mortality at the health facility shows substandard care. In order to improve the quality of care there is need for advocacy for hospital delivery, development evidence management based protocols and routine audit of near miss.

# CHAPTER ONE

## INTRODUCTION

### 1.1 Background:

There is no standard definition of obstetric near miss; however, this can be easily understood as any woman who survives a life-threatening acute pregnancy complication. This could be due to “luck” or by receiving timely/appropriate care. Obstetric near misses share many characteristics with maternal deaths; both may be used as a marker of the health system. Recent data have shown that obstetric near misses are more common than deaths, and can therefore supplement investigations of maternal mortality.(1) Given this close link to maternal mortality, an investigation of near misses can provide an understanding of determinants of maternal death.

Uganda is a low income country with significant health system challenges. Despite investing in work towards the Millennium Development Goals, in Uganda the maternal mortality ratio is still twice the target, at 438/100,000 live births.(2) The burden of obstetric near miss is poorly understood as little research has been done. In keeping with other low income settings, the bulk of Uganda’s health resources tend to cluster in urban areas. It is not clear how rural facilities perform with regard to many indicators of the health system’s performance. There are no published data on determinants of maternal death in this setting.

There are several useful markers of maternal near misses and deaths. None of these have been studied in rural Uganda.

- *MNMR (maternal near miss incidence ratio)*: number of maternal near miss cases per 1,000 live births.
- *Maternal near miss to mortality ratio*: proportion of maternal near miss cases to maternal deaths; higher ratio indicating better care.
- *Mortality index* is the number of maternal deaths divided by the sum of maternal near miss and maternal deaths; expressed as a percentage. The lower the mortality index, the fewer women with life threatening conditions dies (better care) and the higher the index, more women die (lower quality care).
- *MMR (maternal mortality ratio)*: the number of maternal deaths cases per 100,000 live births.

The purpose of this study was to determine the prevalence and short term outcomes of obstetric near misses in a rural district in Uganda, in order to establish a base line for

future investigations. The study adds to existing knowledge, provides information that supplements the maternal mortality reviews to enable development of strategies to reduce maternal deaths and indeed increase survival (near miss)

## **1.2 Problem statement**

In low and middle income countries, near miss review as a tool for monitoring maternal health care is poorly utilised probably due to the high maternal mortality rates which can mask the more common obstetric near misses. In Uganda, maternal mortality remains high (438/100,000 live births)(2); however, lessons learned from community verbal autopsies and facility based maternal death audits help provide some insight into the problem. Little emphasis is placed on the audit of the more common obstetric near misses yet these could provide valuable supplementary information towards the reduction of maternal mortality.(1)

## **1.3 Justification**

This study described the prevalence and short term outcomes of obstetric near misses among pregnant women admitted in a rural district hospital in Uganda. This information provided a practical framework that can be used to reduce maternal mortality, provide room for further research and guide policy makers in the distribution of the limited resources.

## **1.4 Aim and Objectives**

The aim of this study is to describe the prevalence and short term outcomes of obstetric near miss in a rural district hospital in Uganda.

In order to achieve this aim, the study has the following objectives;

- To determine the short term outcomes of obstetric near misses in the hospital
- To comment on the quality of care through comparative analysis of maternal deaths and obstetric near miss
- To determine the prevalence of obstetric near miss at the hospital

## CHAPTER TWO

### 2.0 Literature Review

The Millennium Development Goals were developed in 2000; amongst them was goal 5 with a target to reduce maternal mortality by 75% by 2015.(3) However, this target has not been achieved yet in many countries including Uganda, where the target maternal mortality was expected to be reduced to 131/100,000 live births from 506/100,000. To work towards this, there is need for timely recognition and treatment of emergency obstetric complications; such recognition would be greatly helped by carefully examining women who survive these complications.(4)

In 2009, the World Health Organization formulated a definition for obstetric near miss, based on clinical, laboratory and management criteria.(5) The definition requires laboratory investigations and facilities which are not easily available in many resource limited settings; a disease based criteria would be ideal in these settings. The WHO definition built upon Mantel's 1998 description of obstetric near miss based on five disease specific criteria, based on management and/or clinical signs and symptoms:(6)

- haemorrhage at any pregnancy state (leading to transfusion, caesarean section or hysterectomy),
- hypertensive disorders of pregnancy (eclampsia or severe pre-eclampsia with a minimum diastolic pressure of 110 mmHg),
- puerperal sepsis (peritonitis, septicaemia, offensive vaginal discharge),
- dystocia resulting from prolonged labour, obstructed labour or malpresentation (leading to ruptured uterus or impending uterine rupture, caesarean section, instrumental delivery or perineal lacerations)
- Severe anaemia (haemoglobin < 6 g/dl).

Despite being a major public health problem, maternal deaths are rare especially within hospitals hence the study of those who survive (obstetric near misses) is useful in examining the quality of health care that is being provided.(7)

The prevalence and short-term outcomes of obstetric near misses has not been documented in many hospitals. This lack of data on which women are at high risk of maternal death has affected the distribution of scarce resources.(3) There is no universal definition of a near miss. Some studies utilize the organ system criterion while others use the management or disease specific criteria. Despite the lack of a universal definition, some studies on obstetric near misses have been conducted.

A recent systemic review of 30 studies by Say et al (2004) aimed at determining the world wide prevalence of obstetric near miss found that the prevalence ranged between 0.80 to 8.23% in studies using disease specific criteria, 0.38 to 1.09% in organ specific criterion and 0.01 to 2.99% in management based criteria studies. In this study a pooled estimate of effect could not be established due to heterogeneity caused by variation in case definition.(8) This study shows that regardless of the criteria used, it is likely that the global prevalence of near miss is less than 10% of all hospital deliveries.

Similarly a multinational prospective cohort study in six African countries including Bukina Faso, Cote d'Ivoire, Mauritania, Niger and Senegal by Prual et al (2000) showed that the prevalence of near misses was 6.7% of all hospital deliveries. This study used the disease specific criteria and had a large sample size of 19,694 hospital admissions, but excluded abortions - a category which is an important cause of morbidity and mortality.(9)

Other smaller studies have reported conducted in some hospitals have shown similar findings. A prospective study by Prual et al (1998) reported that prevalence of severe maternal morbidity was 5.68% of all deliveries in Niger. This study also used the disease specific criteria and classified obstetric complications in eight categories.(10) On the contrary a study in a teaching hospital in Benin by Filippi et al (1998) reported a higher prevalence on near miss. This study reported that near misses accounted for 8.23% of all hospital deliveries although case definition was based on algorithms developed for specific disease categories.(11). A higher prevalence of near misses has been reported in some studies. In a retrospective facility based study in Nigeria by Oladapo et al (2005) near misses occurred in 17% of hospital deliveries.(12). Likewise some studies in Uganda by Okong et al(2006) estimate that the prevalence of near misses is 33% of all hospital deliveries.(13)

In other middle income and developed countries, lower prevalence of obstetric near miss has been reported. A retrospective study in Malaysia by Sivalingam et al (1999) showed that near misses were prevalent in 1.23% of all hospital deliveries. This study used the disease specific criteria including hypertension, massive haemorrhage and organ failure.(14) Similarly low prevalence of near miss has been reported in the United Kingdom. A case control retrospective study in UK by Waterstone et al (2001) reported that the prevalence on near miss was 1.20% of hospital deliveries. This study used the disease specific criterion based on the obstetric complications including severe eclampsia, eclampsia, HELLP syndrome, haemorrhage, sepsis and uterine rupture.(15)

The literature shows that there is variation in definition of near miss and thus prevalence varies among hospitals. Despite this studies show that there is a higher prevalence of obstetric near miss in low income settings.

Maternal outcomes are linked to the health system. An understanding of maternal outcome enables identification of health system gaps. A wide variation of maternal outcomes is reported in the literature but most of these relate to severe maternal morbidity (near miss) or maternal mortality. Maternal outcomes result from complications during pregnancy, labour or puerperium. They can also result from interventions or treatments like caesarean section, hysterectomy or from omissions or the lack of treatment that results in morbidity or mortality. Maternal outcomes therefore are a result of obstetric complications, service delivery or a combination of these factors.(9) The common outcomes reported in most studies include; frequency of obstetric complications, maternal death, caesarean section rate, hysterectomy, and foetal outcomes including live births, neonatal death, still births and abortions.(6, 9, 11, 16-22) Multiple studies document these outcomes in different contexts but few have reported these outcomes in a near miss cohort.

Mantel et al (1998) undertook a multi-centre pilot study in Pretoria, South Africa involving 147 near misses and 30 maternal deaths; they found that hypertension, haemorrhage, abortions and puerperal sepsis were the most frequent obstetric complications initiating undesirable maternal outcomes. The undesirable maternal outcomes including hysterectomy, hypotension and pulmonary oedema caused severe acute maternal morbidity. These initiating obstetric complications and associated maternal outcomes were linked to the unsatisfactory service delivery and missed opportunities in the provision of care.(6)

Fillipi et al (1998) in a retrospective cross sectional study in Benin involving 7320 women admitted at a maternity hospital and found that eclampsia, haemorrhage, puerperal sepsis and dystocia due to obstructed labour or CPD were the most frequent obstetric complications. In the study mortality was highest in cases with puerperal sepsis (21%), haemorrhage (9.2%), eclampsia (4.7%) and dystocia (3.6%). Mortality was related to weakness in the health system mainly delays in admission and providing appropriate intervention.(11) Similarly a multi country population based survey of a cohort of 20326 women in West Africa by Prual et al (2000) showed that haemorrhage, obstructed labour, eclampsia and sepsis were the most frequent complications among near misses. The mortality was however high in cases with sepsis (33.3%), uterine rupture (30.4%) and haemorrhage (5.6%) due to unsatisfactory quality of obstetric care.(9)

Cochet et al's (2003) descriptive study of women with severe acute maternal morbidity (near miss) found that abortions and haemorrhage were the leading obstetric complications(18) however this study used organ specific criteria hence these findings can only be compared with studies in which similar criteria has been used.

Kaye et al (2003) studied Mulago National Referral Hospital, the main referral hospital in Uganda, and examined 983 women referred to the hospital. They showed that 11% were obstetric near miss and that 17 out of the 983 died. In this study postpartum haemorrhage and hypertension in pregnancy caused most of the morbidities and mortalities.(17) Similarly, a systemic enquiry conducted in four referral hospitals in Uganda by Pius Okong et al (2006), found that haemorrhage was a major cause of morbidity however other causes like puerperal sepsis and abortions identified. In this study the obstetric care in the referral hospital was found to be substandard justifying the need for near miss audit.(13)

Oladapo et al's (2005) retrospective facility based review of near misses found a maternal death to near miss ratio of 1:48 over a three year period in a tertiary facility in Sagamu, Nigeria. In this study the commonest causes of near misses were hypertension in pregnancy and haemorrhage with mortality indices of 37.5% and 28.6% respectively. In this study poor maternal outcomes were related to poor health service utilisation and the substandard quality of care provided at the tertiary hospital.(16) Similarly a one year facility based retrospective study in Syria by Yara et al (2007) using disease specific criteria identified 901 near misses and 15 maternal deaths among women admitted at a maternity university hospital. In the study the most frequent complications were hypertension and haemorrhage although sepsis and haemorrhage were the leading causes of mortality.(20)

Saima et al (2010) undertook a cross sectional study in a tertiary hospital in Karachi, Pakistan that used disease specific criteria identified 111 near misses among 1508 hospital deliveries. In this study haemorrhage (34.2%), hypertension (29.1%) and ruptured uterus (11%) were the most frequent complications. In the study mortality was high among cases with sepsis. Up to 31.33% of near misses stayed for more than 7 days and ICU admissions were required in 42.3% of cases. The other maternal outcome reported was the hysterectomy rate that was low (3.6%). Like in other studies, these maternal outcomes were related to weakness in the health system.(23) Similarly a retrospective study in maternity hospital at Kasala, Sudan by Ali et al (2011) that used disease specific criteria identified 205 near misses and 40 maternal deaths. In the study haemorrhage, infection, hypertension, anaemia and dystocia were the most frequent obstetric complications although infection caused majority of the deaths.(19)

Most studies conducted in developed countries report similar maternal outcomes although the complications are less frequent and maternal death is rare. It is difficult to compare the occurrence of maternal outcomes reported in the developed countries to those in low and middle income countries because of differences in criterion used to define near miss. The management specific criteria including admission to ICU and emergency hysterectomy is used to define near miss in most of the studies conducted in developed countries.

As an example, Brace et al (2004) did a cross sectional study in Scotland and reported that near misses occurred in 3.8 per 1000 deliveries. In this study obstetric haemorrhage occurred in 50% of the near miss cases. The definition of near miss case was based on pathophysiologic features rather than clinical experience so there was case mix and as a result other categorical causes of near miss could not be specified.(24) On the contrary a 5 year retrospective study in a university hospital in United States by Baski et al (2001) identified 39 near misses who had emergency hysterectomy due to post-partum haemorrhage, uterine rupture or placenta praevia.(25). Similar studies in Japan and United Kingdom report that most obstetric complications are due to post-partum haemorrhage uterine rupture with some women undergoing emergency hysterectomy(26, 27)

Other studies in the developed countries define near miss based on ICU admission. In these studies, maternal mortality and morbidity is mainly due to hypertension and haemorrhage. Bewley et al's (1997) 2 year near miss enquiry of women admitted to ICU at a tertiary hospital in United Kingdom found that 30 near misses were due to haemorrhage and severe eclampsia. In the study more than half of the complications that led to ICU admission were due to substandard care.(28) Similarly a retrospective cohort study in UK by Murphy et al (2002) showed that hypertension (32%), haemorrhage (24%) and cardiac disease (24%) were the leading causes of ICU transfer.(29)

The available literature shows that the prevalence and short term outcomes differ in different settings. This is due to the lack of universal criteria for definition of near miss. The literature shows a higher prevalence of obstetric complications in low and middle income countries. These obstetric complications are a major determinant of maternal outcome. Many studies emphasize the need to address health system gaps in order to prevent maternal morbidity and mortality.

## CHAPTER THREE

### METHODOLOGY

#### 3.1 Study design:

This was a retrospective chart review, using standardised methods as described by Gilbert and Lowenstein.(30)

#### 3.2 Study Setting

All rural districts in Uganda were available to be selected: using a random number generator, Kibaale district was chosen for the study site. It is a typical rural district, with a population of 681,000(2)

This study was carried out at Kagadi hospital, located in Kibaale district, western Uganda 245km west of the capital city, Kampala. It is a 120 bed public hospital, offering comprehensive emergency obstetric services – it serves as the district referral point. There are 2 senior medical officers and 3 medical officers, 15 (midwives) at the hospital. In 2014, the hospital recorded a total of 3401 deliveries and 20 maternal deaths.(31) The maternity ward is very busy with an average of 30 admissions per day. There is a “waiting shade” for women with high risk pregnancies.

#### 3.3 Study population

The population of study were all the pregnant women who were admitted to the maternity ward at Kagadi Hospital between 1<sup>st</sup> January 2015 and 31<sup>st</sup> December 2015.

#### 3.4 Sampling

Inclusion criteria: All records of pregnant women admitted in Kagadi Hospital with ANY of the following clinical signs/symptoms or diagnoses.(6)

- a) Haemorrhage at any pregnancy state (leading to transfusion, caesarean section or hysterectomy),
- b) Hypertensive disorders of pregnancy (eclampsia or severe pre-eclampsia with a minimum diastolic pressure of 110 mmHg),
- c) Puerperal sepsis (peritonitis, septicaemia, offensive vaginal discharge),
- d) Dystocia resulting from prolonged labour, obstructed labour or malpresentation (leading to ruptured uterus or impending uterine rupture, caesarean section, instrumental delivery or perennial lacerations)

e) Severe anaemia (haemoglobin < 6 g/dl).

Exclusion Criteria: All records that do not fit inclusion criteria were excluded.

All records with incomplete data were removed from the analysis (complete case analysis) utilising the statistical package SPSS.(32) A total of 23 medical records with incomplete data were removed.

This study used the disease specific criteria because of simplicity and ease of extraction of required data from case notes. Other criteria are based on organ dysfunction thus require laboratory investigations that are not usually done in a resource limited settings like Kagadi hospital. The International Classification of Diseases (ICD 10) were used to define maternal mortality.(33) Maternal mortality was reported as frequencies or proportions of women who die while pregnant or within 42 days of termination of pregnancy.

### **3.5 Data Collection and management**

Using standardized data abstraction forms (appendix 1, appendix 2), data were extracted from in patient medical records and hospital registers taking care not to include personal/patient identifiers (anonymity). The abstraction forms had clear definition of variables. Four hospital staff (Registered Midwives) were trained on data abstraction prior to the study using practice/hypothetical medical records. The midwives collected the data using the abstraction forms following the inclusion and exclusion criteria.

Main outcome measures included;

- The frequency of near-miss in each disease specific group (Mantel Criteria)
- Duration of hospital stay
- Maternal death

Secondary outcome measures included

- Distribution of referral categories
- Caesarean section rate
- Hysterectomy
- Foetal outcomes measures i.e live births, still births, abortions, neonatal deaths occurring at the hospital. Foetal outcomes occurring outside the hospital are not documented in the medical records thus these were not be considered.

A comparative analysis of obstetric near miss and maternal mortality was done to determine the maternal near miss incidence ratio (MNMR), maternal mortality ratio

(MMR) and Mortality indices. The maternal near miss to mortality ratio for the period of study was calculated.

The investigators monitored the data collection by holding regular meeting with abstractors to resolve data collection conflicts and irregularities and were regularly at a daily basis review the filled abstraction forms. The abstraction forms were stored under key and lock in the hospital data office with access limited to the researchers. Filled data abstraction forms were entered into a computer using Microsoft Excel and this was password protected. The investigator also regularly carried out independent data collection on thirty random samples of medical records thereby assessing the interrater reliability of the data.

### **3.6 Statistical analysis**

The data were exported into SPSS software for analysis. Descriptive statistics were used in the analysis and data was presented as frequencies, ratios and percentages. MNR, MNMR, was calculated using live births as the denominator.

### **3.7 Ethical consideration**

Data was collected and extracted from health facility medical records. The information collected was anonymous with no patient identifiers. Informed consent was not necessary because no information was obtained directly from participants and interviews were not conducted. A waiver of informed consent was obtained from the ethics committees.

In addition to HREC approval at UCT, was given ethics approval from IRB of Lacor Hospital in Uganda. Authorization from the district (district health officer) and hospital superintendent were obtained.

The data abstraction forms and other documents were kept by the abstractors who are hospital staff, and investigator at all times. The abstraction forms and data logs were kept within the hospital premises in locked drawers during the study and for two years after conclusion of the study. The data was transcribed into an Excel database and SPSS was password protected. The abstraction forms will be destroyed after the study (shredded) 2 years after conclusion of the study. There are no anticipated risks due to this study.

### **3.8 Dissemination plan**

This will involve a formal presentation of study findings at the hospital and/or district plus the publication of the findings in a suitable journal.

## **CHAPTER FOUR**

### **RESULTS**

#### **4.1 Aim of the study**

The study aimed at describing the prevalence and short term outcomes of obstetric near miss in a rural district hospital in Uganda.

#### **4.2 Objective One: The prevalence of maternal near miss at Kagadi hospital**

During 1st Jan – 31st Dec 2015, there were 7169 hospital admissions with 752 maternal near miss and 12 maternal deaths. There were 4366 deliveries with 4244 live births and 122 still births and the Maternal Near Miss incidence Ratio (MNMR) was 177.1 per 1000 live births. The total mortality index was 1.57% (Near Miss/Fatality ratio 63:1). The Maternal Mortality Ratio (MMR) was 282.7 per 100,000 live births. The prevalence of maternal near miss at Kagadi hospital was **10.7%**.

##### **4.2.1 Demographic characteristics of the maternal near miss**

The age of maternal near miss ranged between 10 – 49 and the most frequent age group was 15 -19 (38.7%), 20 - 24 (28.2%). The majority of near misses were prime gravida (49.5%) with complications commonly occurring after 36 weeks of gestation (84.6%). A total of 94.1% of near misses had no previous still births. Among the MNM that delivered, 86.7% delivered by caesarean section while 13.3% had vaginal delivery. 351 near misses (46.7%) developed complications at home, 275 (36.5%) at Kagadi hospital, 124 (16.5%) at other public health facility and 2 (0.3%) at private hospital/clinic

**Table 1: Demographic Characteristics of Maternal Near Miss at Kagadi Hospital during 2015**

Characteristic	Number N (%)
<b>Age Of Patients(Years)</b>	
10-14	4(0.5)
15-19	291(38.7)
20-24	213(28.2)
25-29	128(17.0)
30-34	54(7.2)
35-39	49(6.5)
40-44	10(1.3)
45-49	3(0.4)
<b>Gravidity</b>	
1	365(49.5)
2	162(21.9)
3	62(8.4)
4 or more	148(20.1)
<b>Gestational Age(Weeks)</b>	
1-12	81(11.0)
13-28	9(1.2)
28-36	24(3.3)
>36	623(84.5)
<b>Previous live born babies</b>	
0*	363(52.6)
1-3	244(35.7)
4 or more	82(12.0)
<b>Previous still births</b>	
0**	540(94.1)
1-3	23(4.0)
<b>Complications development</b>	
Home	351(46.7)
Other Public health facility	124(16.5)
Kagadi hospital (Public)	275(36.5)
Private Clinic/Hospital	2(0.3)

\*Indicates those with 1st time deliveries (Primigravidae)

\*\* Indicates those with no still birth

#### **4.3 Objective Two: Short term outcomes of obstetric near misses in the hospital**

The main outcome measures included; frequency of near miss in each disease specific group, duration of hospital stay and maternal deaths. The secondary outcome measures included caesarean section rate, hysterectomy and foetal outcome (live births. Fresh still births, neonatal deaths and abortions)

### 4.3.1 Frequency of near-miss in each disease specific group

During the study period, dystocia disease category had the highest number of near misses (N = 521) with MNMR of 112.8 per 1000 live births. The dystocia resulted from contracted pelvis/CPD (31.2%), obstructed labour (30.5%), malpresentation (16.7%), prolonged labour (9.8%), uterine rupture (8.7%) and impending rapture (3.1%).

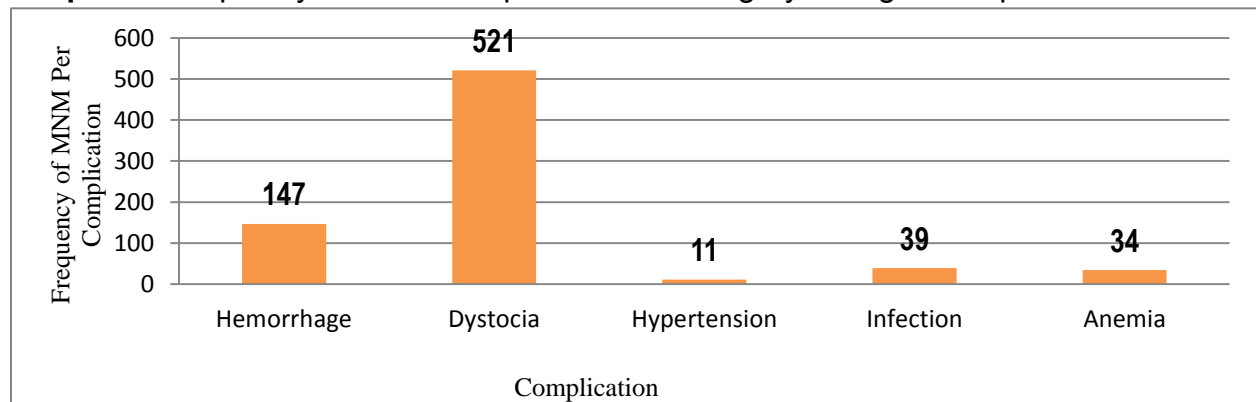
The second leading cause of near miss events was haemorrhage with MNMR 34.6 per 1000 live births. A total number (N = 147) had haemorrhage commonly due to abortions (58.5%) and post-partum haemorrhage (22.4%). Late pregnancy bleeding abruption placentae and placenta previa accounted for 6.1% and 5.4% respectively while other causes of haemorrhage were due to ectopic pregnancy (4.8%).

The third leading cause of near miss was infection (N=39) with MNMR 9.2 per 1000 live births. The infections were due to puerperal sepsis (87.3%), chorioamnionitis (2.5%) and other infections including malaria (10.2%).

The disease category of anaemia was the 4<sup>th</sup> leading cause of near miss with at total number (N =34) and MNMR 8.0 per 1000 live births.

Hypertensive disorders occurred in a total eleven mothers (N=11) with MNMR 2.6 per 1000 live births. The causes of hypertension were mainly due to eclampsia (90.9%) and severe eclampsia (9.1%).

**Graph 1:** Frequency of near miss per disease category at kagadi hospital.



### 4.3.2 Duration of hospital stay

During the study period the mean duration of hospital stay for maternal near miss was 3.6 days +- 1.73SD

### 4.3.3 Maternal deaths

The total mortality index was 1.57% (Near miss/Fatality ratio 63:1). The maternal mortality ratio (MMR) was 282.7 per 100,000 live births.

The mortality indices were highest in categories of hypertension (27.3%) and haemorrhage (4.1%). Dystocia, anaemia and infection disease categories had mortality index of 0.2%, 2.9% and 2.5% respectively.

**Table 2: Comparison of Near-miss events and primary causes of maternal deaths at Kagadi Hospital between Jan – Dec 2015**

Complications/Diseases	Total N (%)	Mortality n (%)	MNM/1000 Live Births	Mortality index- %age
Haemorrhage	147(19.5)	6(50.0)	34.6	4.1
Early				
Ectopic Pregnancy	7(4.8)	0		
Abortion	86(58.5)	0		
Other haemorrhage	4(2.8)	1		
Late				
Abruptio	9(6.1)	0		
Placenta Previa	8(5.4)	1		
PPH	33 (22.4)	4		
Dystocia	521(69.3)	1( 8.3)	122.8	0.2
Obstructed Labour	159(30.5)	0		
Prolonged Labour	51(9.8)	0		
CPD(Contacted	163(31.2)	0		
Pelvis)				
Mal	87(16.7)	1		
Presentation/breech				
Impending Rapture	16(3.1)			
Uterine Rapture	45(8.7)			
Hypertension	11(1.5)	3(25.0)	2.6	27.3
Eclampsia	10(90.9)	2		
Severe Eclampsia	1(9.1)	1		
Infection	39(5.2)	1(16.7)	9.2	2.5
Puerperal Sepsis	34(87.3)	0		
Chorioamnionitis	1(2.5)	0		
Others <sup>α</sup>	4(10.2)	1		
Anaemia	34(4.5)	1(8.3)	8.0	2.9
Total <sup>β</sup>	752	12	177	37.0

<sup>α</sup> Others Included malaria primary cause of maternal deaths

<sup>β</sup> Summary statistics (Totals) for MNM, Mortality Mortality(%),MNM/1000 Live births, Mortality Index

#### 4.3.4 Secondary outcome measures

541 near misses (70%) delivered by caesarean section with a caesarean section rate of 12% in all hospital deliveries. A total of 86 (11.1%) near miss had vaginal delivery. A total 8 near miss (1%) had laparotomies with 6 (0.8%) undergoing hysterectomies. 81 of the near miss (10.7%) had abortions managed with evacuation or misoprostol. Blood was transfused in 39 (4.8%) of near miss. Foetal outcomes included 575 (78.4%) live born, 104 (14.2%) abortions, 41 (5.6%) fresh still births and 13 (1.8%) neonatal deaths

**Table 3: Secondary Short term Outcomes of Maternal Near Miss at Kagadi Hospital 2015**

Outcome	Number N (%)
Intervention	
Evacuation	69(70.4)
Laparotomy	8(8.2)
Misoprostol	12(12.2)
Others (Repair)	9(9.2)
Hysterectomy	6
Blood transfusion	39
Foetal outcome	
Abortion	104(14.2)
Live born	575(78.4)
Fresh still birth	41(5.6)
Type of delivery	
Vaginal Delivery	86(13.3)
Caesarean Section	541(86.7)

#### 4.4. Objective Three: Comment on the quality of care through comparative analysis of maternal deaths and obstetric near miss

The total mortality index was 1.57% (Near Miss/Fatality ratio 63:1).The Maternal Mortality Ratio (MMR) was 282.7 per 100,000 live births. The prevalence of maternal near miss at Kagadi hospital was 10.7% and the Maternal Near Miss incidence Ratio (MNMR) was 177.1 per 1000 live births.

## CHAPTER FIVE

### DISCUSSION

#### 5.1 Near Miss Prevalence and Maternal Mortality Ratio

This retrospective chart review is one of the few studies that document maternal near miss in rural Uganda. The concept of obstetric near miss as initially described by Stones et al (34) is increasingly being utilized by scientists and policy makers as an adjunct to maternal mortality and a maker of a health system. With the understanding of obstetric near miss, the quality of obstetric care can be accessed and where possible measures to prevent progression of complications from severe maternal morbidity to mortality instituted.

A comparison of hospital based prevalence of obstetric near miss is difficult because of the wide spectrum of maternal morbidity in different settings. Secondly there is variation in definition of near miss with some studies using disease specific criteria, organ specific criteria or management criteria. The disease specific criterion was used in our study because it is easy to interpret, can be applied retrospectively and allows determination of quality of care for specific disease(s). The other criteria – organ specific and management criteria require laboratory and haemodynamic investigations; are less prone to bias (8) but the disease specific criteria was utilized in our study because most of the laboratory investigations and haemodynamic investigations are not available at Kagadi hospital. The disease specific criterion is however limited by the fact that it can ignore other important conditions like pulmonary embolism which cause maternal death. Secondly applying it retrospectively is challenging because the severity of different diseases cannot be objectively determined for example women with early pregnancy bleeding due to abortions have different consequences from those with late pregnancy bleeding with normal or low haemoglobin (anemia); therefore classifying them as “haemorrhage” is indeterminate and can be confusing because they actually have different thresholds.

Similarly, the comparison of facility based maternal mortality ratio is difficult because not all women deliver or die in the hospitals.

With this in mind our findings show that the prevalence of obstetric near miss in Kagadi hospital was 10.7%. This means that health workers at the hospital are faced with 1 woman with life threatening obstetric complication in every 10 who utilise the obstetric services. The MNMR 117.1 per 1000 live births and maternal mortality ratio 282.7 per 100,000 live births. The total mortality index was 1.57% (near miss to fatality ratio 63:1).

Previous studies in rural African hospitals in various findings but prevalence range between 1 – 25% of hospital deliveries. A multinational prospective cohort study in six African countries including Bukina Faso, Cote d'Ivoire, Mauritania, Niger and Senegal by Prual et al (2000) showed that the prevalence on near misses was 6.7% of all hospital deliveries. This study used the disease specific criteria and had a large sample size of 19,694 hospital admissions but excluded abortions disease category which is an important cause of morbidity and mortality.(9) Other smaller studies have reported conducted in some hospitals have shown similar findings. A prospective study by Prual et al (1998) reported that prevalence of severe maternal morbidity was 5.68% of all deliveries in Niger. This study also used the disease specific criteria and classified obstetric complications in eight categories.(10) On the contrary a study in a teaching hospital in Benin by Filippi et al (1998) reported a higher prevalence on near miss. This study reported that near misses accounted for 8.23% of all hospital deliveries although case definition was based on algorithms developed for specific disease categories.(11) A higher prevalence of near misses has been reported in some studies. In a retrospective facility based study in Nigeria by Oladapo et al (2005) near misses occurred in 17% of hospital deliveries.(12)

The country level prevalence of obstetric near miss is about 33% with near miss to fatality ratio 2.5:1 as show by studies by Okong et al (2006)(13). The current maternal mortality ratio in Uganda is 438 per 100,000 live births.(22) Our results are lower than those reported in Uganda but share similarity to those reported in previous studies in rural Africa. Our findings are different from those reported in middle income and developed countries. In other middle income and developed countries, lower prevalence of obstetric near miss has been reported.(8)

A retrospective study in Malaysia by Sivalingam et al (1999) showed that near misses were prevalent in 1.23% of all hospital deliveries. This study used the disease specific criteria including hypertension, massive haemorrhage and organ failure.(14) Similarly low prevalence of near miss has been reported in the United Kingdom. A case control retrospective study in UK by Waterstone et al (2001) reported that the prevalence on near miss was 1.20% of hospital deliveries. This study used the disease specific criterion based on the obstetric complications including severe eclampsia, eclampsia, HELLP syndrome, haemorrhage, sepsis and uterine rapture.(15)

A recent systemic review by Say et al (2015) including studies from 1998 – 2013 showed that the prevalence of obstetric near miss ranged from 0.80 – 8.23% internationally while ranges of 0.05 – 14.98% are reported in Africa.(8)

In comparison to national figures, the lower prevalence of obstetric near miss at Kagadi hospital means that less women experience severe acute maternal morbidity. It also means that fewer women are likely to die from these life threatening complications.

The lower maternal mortality ratio and mortality index indicates better quality care at Kagadi hospital. This could be attributed to the availability of free emergency obstetric care services, advocacy for maternal health and established ambulance systems provided by “saving mothers giving life” projects in the region.(35)

In an international context, the prevalence of obstetric near miss and maternal mortality ratio at Kagadi hospital is relatively high. According to the millennium development goals (MDGs) 2015, MMR was to be reduced by 75% by 2015 so in Uganda we expected a MMR of 162 /100,000 live births by 2015(22) so the MMR of 282.7/100,000 live births at Kagadi hospital is relatively high. This high institutional MMR could be related to poor health service utilization.

Our findings on prevalence of obstetric near miss and maternal mortality ratio at Kagadi hospital provide an understanding of local morbidity and mortality patterns. The results provide an insight into the quality of obstetric care, strengths and weakness of the health system. These findings can be used in planning and preparedness for these life threatening acute morbidities. The findings can also be used to formulate facility based guidelines or protocols that enable early detection, minimize delays and ultimately prevent maternal mortality.

## **5.2 Near Miss Events and Maternal Outcomes**

The concept of “obstetric near miss” has been limited by lack of universal criteria for definition of a near miss(7) despite the fact that near misses shares many characteristics with maternal death. Near miss events are proxy measures of health service delivery. Service delivery a major building block of an effective and efficient health system.(36) The assessments of maternal outcomes in near miss cohort are advantageous in identifying health system gaps.

### **5.2.1 Social demographic characteristics**

Our findings show that the age of near miss ranged from 10 – 49 and the most frequent age groups were 15 – 19 (38.7%) and 20 -24 years (28.2%). The majority of near misses were prime gravida (49.5%) with complications occurring after 36 weeks of gestation. Most of these complications occurred at home (46.7%). The complications occurring at the study site Kagadi hospital constituted 36.5% while those at other public health facility and private clinics/hospital accounted for 16.5% and 0.3% respectively. These findings mean that near miss events are associated with individual and health facility factors. These individual and health facility factors interact in a complex manner influencing functionality of the health care system. Our study shows that obstetric complications are associated with age, parity, gestation age and the location of the mothers at onset of the complications. Thaddeus et al describes “three delay model” including the delay in seeking care (delay 1), delay in reaching health facility (delay 2)

and delay in providing appropriate intervention at the health facility (delay 3).(37) In our study most of the complications occurred at home which is probably due to delay in seeking care. However, some complications occurred at Kagadi hospital and this could be related to delays in providing appropriate intervention at the health facility. The delay in providing appropriate intervention is probably due to a number of factors including low partograph use, lack of essential medicines or services and human resource constraints. We speculate that there decreased utility of partographs at the health facility yet this a tool has been shown to be cost effective and efficient in preventing complications.(38) A study examining the use of partograph to monitor labour at Kagadi hospital is warranted. We also speculate that delays in providing appropriate intervention at the health facility could be related to human resource factors such as staff absence, poor working conditions, low pay and low morale or related to lack of essential medicines and supplies. Similarly, a study to determine causes of delayed intervention(s) at the health facility is recommended.

Other studies in Uganda have shown similar results with complications occurring in nulliparous women aged 15 – 19 years(39) and with women delaying to seek health care and developing complications at home(40) Most women develop complications because they cannot access health services because of poorly developed transport systems and referral chains. Some others women develop complications due poor obstetric services and delays at health facilities.(41) Understanding of individual and health care system factors in the casual chain of obstetric near miss is extremely important in the improvement of maternal and foetal outcomes. Our study provides an insight on individual and health system factors in casual chain of near miss. This information can be used by policy makers to improve the quality of obstetric care in the region.

### **5.2.2 The near miss disease specific categories**

Using the disease specific criteria to define near miss, our study showed that dystocia was the leading cause of morbidity. Dystocia results from CPD, obstructed labour, malpresentation and prolonged labour. Dystocia can lead to ruptured uterus or impending uterine rupture hence it necessitates interventional strategies including caesarean section, instrumental delivery, laparotomy or hysterectomy depending on the clinical presentation. A total of 69.3% dystocia related near miss events resulted from prolonged labour; obstructed labour or malpresentation that lead to ruptured uterus, impending uterine rupture, caesarean section, and instrumental delivery or perianal lacerations. Amongst cases with dystocia, 31.2% were due to contracted pelvis/CPD, 30.5% due obstructed labour, 16.7% due to malpresentation, and 9.8% due prolonged labour, 87% uterine rupture and 3.1% impending rupture. The high proportions of CPD and Obstructed labour show the impact of these two conditions on maternal morbidity in this community.

Obstructed labour is a leading cause of obstetric fistula; a serious and debilitating condition that can be prevented if mothers in labour are managed appropriately.(42) The understanding of the frequency of dystocia in Kagadi hospital should therefore provide a platform for both preventive and interventional strategies for this condition. The high frequency of dystocia also shows weakness in early detection of CPD especially during antenatal care. The high proportion of mothers with obstructed labour demonstrates key delays in seeking or reaching health facilities. It is likely that a large majority of women delay at home at onset of labour only to present at the health facilities with these life threatening complications of dystocia. The mortality index for Dystocia was 0.2% the lowest among all disease specific categories showing effectiveness in managing this condition at the hospital. The findings of our study show that dystocia is a leading cause of near miss events (69.3%) but this is different from other studies utilizing disease specific criteria that report dystocia accounting for 15% near miss.(16, 43, 44) The disparity is probably due to differences demographic characteristics, variations in definition and identification of near miss a major limitation in comparison of near miss data across hospitals.(7, 8, 45) Secondly most of these studies do not investigate obstructed labour, CPD, prolonged labour and malpresentation as causes of dystocia. On the contrary a study conducted in western Uganda supports our findings because it shows that dystocia is a leading cause of maternal morbidity with up to 63.3% due to CPD, 36.4% due to malpresentation causing obstructed labour. In this study the prevalence of obstructed labour was estimated at 10% of all deliveries but this probably an underestimate because most of the records documented secondary causes of morbidity ignoring primary causes of dystocia especially CPD.(39) Other studies in Africa report that dystocia is a common cause of morbidity and mortality and that obstructed labour due to CPD or malpresentation occurs in 1 – 7% of all hospital deliveries.(19, 46) To prevent adverse maternal and foetal outcome, women with dystocia require transportation to health facilities and provision of emergency obstetric care. Our findings therefore emphasize the need for increased access and availability of emergency obstetric services to manage dystocia and associated complications.

Our findings show that haemorrhage was the second leading cause of morbidity (19.5% of near misses). During the study period at Kagadi hospital, this disease category was the leading cause of mortality with up to 50% of all maternal deaths attributed to haemorrhage. Although haemorrhage disease category was a leading cause of death, the mortality index (4.1%) was low indicating a relatively good quality care. This could be attributed to availability of blood transfusion services, staff trainings and support from MCH projects at the hospital. Haemorrhage occurred during early pregnancy and was due to abortions (58.5%) and ectopic pregnancy (4.8%). Late pregnancy haemorrhage was due to abruptio and placenta praevia causing 6.1% and 5.4% of haemorrhage respectively. Amongst all records of mothers who experienced haemorrhage, 22.4% developed PPH. The high proportions of abortions and PPH as shown in our study

emphasises need for continued vigilance in management and prevention of these conditions. In Uganda the recent estimate of incidence of abortions are 54 per 1000 women of reproductive age while that of East African region is 36 per 1000 women.(47) However, results from our study show that 104 (14.2%) of foetal outcomes were abortions of which 70.4% underwent manual vacuum aspiration while 12.2% were managed with misoprostol. The practise of termination of pregnancy (abortion) is currently illegal in Uganda. Induced abortions are commonly done in unsafe environments by untrained practitioners. This can lead to undesirable maternal outcomes including pain, bleeding, infection, secondary infertility or death. Secondly unsafe abortions may necessitate resources for ICU admission, blood transfusion, antibiotics and medical expertise that may not be readily available. This strains the limited resources and affects care of patients with other conditions. In 2009 the cost of managing un safe abortion was estimated at 130 US dollars and post abortion care at 14 US dollars, giving a total cost of 144 US dollars per patient.(48) This has a huge implication on the health system financing in Uganda given the limited resources. Our findings demonstrate a need for mitigation of unsafe abortions by providing family planning, post abortion care and lawful termination of pregnancy at the health facility.

During the study period 22.4% of all causes of haemorrhage were due to post-partum haemorrhage. PPH was the second leading cause of haemorrhage a finding similar to those shown in other studies on obstetric near miss.(16, 17, 44, 49) PPH is a major cause of maternal morbidity with up to 30% total maternal deaths due to this condition(50). Our results show that a large proportion of women at Kagadi hospital are at increased risk of PPH. The causes of PPH are related to poor management of third stage of labour which involves the use of uterotonic drugs, controlled cord traction and uterine massage.(51) The components of active management of third stage of labour can be achieved when women deliver from hospitals equipped with uterotonic medicines like oxytocin and under the care of skilled birth attendants. PPH is a preventable condition that requires the identification of risk factors, active management of third stage of labour and replacement of blood volume. (52) In our study up to 90% of near misses with PPH received blood transfusion. Our findings show that most of the complications occurred at home or in other primary health facilities where the likelihood of uterotonic drugs or skilled birth attendants is low. Our findings therefore emphasize a need to avail uterotonic drugs and blood transfusion services at the hospital. The results also demonstrate a need for skilled birth attendants who are trained in active management of third stage of labour. Because a large number of PPH did not occur at Kagadi hospital, there is need to advocate for hospital delivery and to distribute uterotonic to lower health facilities or communities. A 2006 RCT by Derman et al demonstrated that community distribution of a uterotonic drug (misoprotol) was significantly associated with decrease in rate and severity of post-partum haemorrhage in low resource settings.(53) Community distribution of uterotonic drugs is a WHO

recommendation for prevention of postpartum haemorrhage.(54) We therefore recommend for community distribution of uterotonic drugs in the community, increased access and availability of emergency obstetric services to manage and prevent obstetric haemorrhage.

Infection disease category accounted for 5.3% of near miss cases and was mainly due to puerperal sepsis (87.3%), chorioamnionitis (2.5%) and other infections including malaria (10.2%). In our study the infection mortality index was 2.5%. Because of the complexity, infection classifications and the broad nature of this disease category it's difficult to compare our results with those from other studies. Some studies measure fever and do not distinguish between puerperal sepsis and chorioamnionitis or other infections including malaria and HIV. With this in mind, our findings were similar to those reported in studies in Benin that showed prevalence of infection among near miss of 5.4%(10, 11). On the contrary studies in Bukina Faso report a lower proportion (0.5%) of infection in deliveries complicated by fever and (3.3%) is reported in Philippines and India(55, 56). A study in rural Sudan which reported a high proportion (19.5%) of infections among near miss.(44) A one year multicentre cross sectional 2010 study by Pfitscher et al examining the role infection on severe maternal morbidity found that infection was an alarming but yet preventable cause of morbidity. This study identified multiple risk factors to infection including place of delivery, mode of delivery and HIV infection.(57) Similarly a study in Uganda by Okong et al demonstrated the role of HIV in severe maternal morbidity.(58) In our retrospective chart review we could not determine the magnitude of some of these risk factors to infections because of poor documentation. It was however noted that most of the complications occurred at home or in other primary health facilities. Because delivery at home predisposes women to puerperal sepsis and chorioamnionitis, strategies like health education to encourage women to deliver at the hospital should be implemented. Health system changes need to be made to ensure the availability of antibiotics, standardized management protocols and adherence to infection control practices both at Kagadi hospital and other primary health facilities. Our findings show low proportions of infections and this could be due to prophylactic use of antibiotics, infection control practises and availability of standardized management protocols at the hospital. Despite a low frequency of infection, there is need for early identification, effective management and prevention of infection at this health facility.

Hypertension disease category occurred in 1.5% of near miss cases. Up to 90.9% of near misses with hypertension were due to eclampsia while 9.1% were due to severe eclampsia. This disease category had the highest mortality index (27.3%) and was the second leading cause of mortality with up to 25% maternal deaths due to this condition. These findings are surprising since the condition had a low occurrence. The results reflect poor quality care of mothers with hypertension in pregnancy at Kagadi hospital.

Multiple studies show that among women with severe maternal morbidity, hypertension is associated with worst maternal and foetal outcomes(6) Our findings are different from those shown in Mulago national referral, Uganda were 17.6% of cases with severe maternal morbidity were attributed to hypertension.(17) Likewise other studies in Kenya, Tanzania and India report a range of 0.1 - 0.2% of pregnancies associated with hypertension(59) and a range of 0.17 – 0.93% in Asia.(9) The disparity could be related to social demographic characteristics and variation in case definition. In our study majority of near missed were primigravidae (49.5%) which is a major risk factor for pre-eclampsia.(60) The other risk factors for hypertension in pregnancy including social economic class, family history of hypertension, pre-existing hypertension among others could not be assessed due to methodological constraints. Our findings reflect need for early detection and effective management of this condition. This can be achieved through antenatal screening, staff trainings, provision of essential medicines like magnesium sulphate and the utilization of evidence based management protocols/guidelines at the health facility. This will reduce the high mortality due to this condition thereby improve the quality of care.

Our findings show that severe anaemia (haemoglobin <6g/dl) occurred 4.5% of near miss cases with a low mortality index of 2.9%. All near misses with severe anaemia received blood transfusion. Our results are different from those reported in other studies. Studies in Uganda have estimated that anaemia accounts for 32.2% of obstetric complications.(61, 62) On the contrary a 2007 study by Pragti et al in India reported that 22% of cases of severe maternal morbidity were due to severe anaemia.(63) Our results could be an underestimate of frequency of anaemia disease category because of misclassification. Some medical records showed near misses with haemorrhage disease category as well as associated severe anaemia. It was therefore difficult to classify these near misses in either of two of the disease categories using our criteria. Similar misclassifications could also have occurred with the infection disease category because conditions like puerperal sepsis and malaria can also cause severe anaemia. With this in mind the low frequency and mortality index of severe anaemia in our study means that fewer women are likely to die from this life threatening condition. The low mortality index also reflects good quality care possibly due to the fact that all cases had blood transfusion. Despite the low frequency and mortality index of severe anaemia at Kagadi hospital, there is need for vigilance in managing this life threatening condition. Policy makers need to ensure the continued availability of blood transfusion services in the region because severe anaemia is a major cause of maternal morbidity and mortality.

### **5.2.3 Secondary outcome measures**

The secondary outcome measures determined during our study included; duration of hospital stay, caesarean section rate, hysterectomy, distribution of referral categories and foetal outcome measures. These outcome measures and the information on complications development provide an insight on health service utilization.

Our findings show that 46.7% of the complications occurred at home, 36.5% at Kagadi hospital while 16.5% and 0.3% occurred at other public and private hospitals/clinic respectively. Because most of the complications occurred at home, this is an indicator of poor health service utilization. The barriers to health service utilization in Uganda have been reported in some studies(17, 64) but we speculate that this could be lack of transport, long distances, lack of knowledge or the lack of trust in the quality of care provided at the health facilities. Some complications occurred at Kagadi hospital possibly due to delays in providing appropriate intervention possibly as a result of staff demotivation, the lack of skills or deficiencies essential drugs and supplies. The small proportion of complications occurring in other public and private health facilities could be a maker of an efficient referral system. The proportions of near misses that developed complications within or outside the hospital show a need to strengthen referral systems.

Our results show a total of 752 near misses of which 541 delivered by caesarean section, 86 delivered by vaginal delivery, 69 had evacuation, 12 managed with oral misoprostol, 8 had laparotomies with 6 undergoing hysterectomy. A total 30 near misses were referred to other regional and tertiary hospitals. Amongst those that were admitted, the mean duration of hospital stay was 3.6 days and the caesarean section rate was 12% of all hospital deliveries. The results also show that the caesarean section rate among all near miss deliveries was 86.7%; meaning that among near misses at Kagadi hospital, caesarean section is the commonest mode of delivery hence an extremely important lifesaving intervention. The high caesarean section rate could be due to the fact that Kagadi hospital is a referral facility that receives complicated cases from other health facilities. The caesarean section rate of 12% of all hospital deliveries at Kagadi hospital is within the WHO recommended range of 10 – 15%.(65) Caesarean section rates above 15% carry a risk of complications in the proceeding pregnancies. Despite the fact caesarean section is a lifesaving intervention; the benefits for its use must be weighed against harm. Since the caesarean section rate of all hospital deliveries at Kagadi is less than 15%, this is an indicator of good quality care.

Hysterectomy is a lifesaving intervention especially among near misses with uterine rupture or atonic uterus. Our findings show that 6 near misses (0.8%) underwent this surgical procedure. Similar findings have been reported in other studies with rates

ranging from 0.2 – 1.5%(66) Hysterectomy requires skilled surgical team and necessitates availability of blood transfusion services. Our results therefore emphasize the need for skilled surgical team and blood transfusion services in order to carry out this life saving intervention.

Our findings show that 78.4% foetal outcomes were live births, 14.2 % abortions, 5.6% still births and 1.8% neonatal deaths. There is need for quality improvement in order to improve these foetal outcomes.

### **5.3 Limitations of the Study**

- (i) The definition of near miss (severe maternal morbidity) is linked to a particular health care system hence no universal definition exists. The definition depends on both the obstetric condition(s) and provisions of care. A woman who experiences an obstetric complication during labour, delivery or post-partum is regarded a “near miss”. Likewise near miss definition can be made when there are obstetric interventions such as caesarean section, omissions (absence of interventions) or a combination of these factors. In our study we also had difficulty in defining a near miss. We used a modified disease specific criteria ensuring that only severe maternal morbidity was included and that cases were dependent on the health care provided at the health facility. Our criterion was pragmatic, dependent on interventions and investigations that can be provided at the hospital. Our criterion ensured that a subset of obstetric complications were investigated hence it is likely that other direct causes of morbidity like pulmonary embolism were undermined or ignored.
- (ii) There was a likelihood of dependant misclassification because some diagnoses are not clear cut. Exemplified by this is the fact that medical records showed some near misses with haemorrhage also had severe anaemia. It was therefore difficult to classify these near misses in either of two of the disease categories using our criteria. Similar misclassifications could also have occurred with the infection disease category because conditions like puerperal sepsis and malaria can also cause severe anaemia. Because of misclassification there is a likelihood of over or underestimating the frequency of the different obstetric complications. The use of a different criteria such as organ specific criteria is there recommended in future studies.
- (iii) The other major limitation to our study relates to its methodology (retrospective chart review). Some of the medical records were unavailable, incomplete, poorly documented or inaccurate in coding diagnoses. This created scarcity of morbidity

or mortality data and created difficulties in assessing severity of obstetric complications and not to mention the care provided. Because of these inconsistencies there was a probability that we underestimated the near miss cases. In order to minimize these inconsistencies, data collection was done by experienced midwives who had been trained in data abstraction before the study. Secondly an explicit disease specific criterion was used and important variable defined precisely to allow data collection using the standardized abstraction forms. Periodic meetings were also held to resolve discrepancies and assess agreement. Data collection was monitored by the investigator who also double checked the data before data entry with the help of the statistician. Because of the limitations of retrospective chart review, prospective studies are recommended in future.

- (iv) In our study we intended to comment on the quality of care by comparatively analysing maternal morbidity and mortality. It would therefore have been important that we audit morbidity and mortality but we relied on clinical diagnoses that were documented in the medical records. There is a probability that the diagnoses were inaccurate because there are no regular maternal morbidity and mortality audits held at the hospital. Secondly a comprehensive assessment of quality of care was not achieved because no interviews were done. To comment on quality of care, subsequent near miss studies should therefore incorporate audits and interviews.
- (v) The study was done in one out of four health facilities offering emergency obstetric services in the district therefore we recommend that future studies include all health facilities in the district.

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## CHAPTER SIX

### CONCLUSIONS AND RECOMMENDATIONS

#### 6.1 Conclusions

There is a high occurrence of near miss events among pregnant women admitted at Kagadi hospital. These life threatening near miss events are mainly due to dystocia caused by obstructed labour and CPD. Near misses also occur following abortion, post-partum haemorrhages, infections, hypertension and anaemia. Our results show survival of women with these life threatening complications in spite of the unsatisfactory quality of care. Although most women survive, those with haemorrhage and hypertension are more likely to die. Our study highlights some of the health system failures including access, referral and utilization of maternal health services. The study provides information on maternal outcomes in a near miss cohort. This information will guide policy makers to improve the quality of maternal health care.

#### 6.2 Recommendations

Based on the findings of the study we recommend;

- (i) Audits of both severe maternal morbidity and maternal mortality
- (ii) Advocacy for hospital delivery and strengthening emergency referral systems
- (iii) Improvement of antenatal, family planning and post natal care services
- (iv) Improvement of post abortion care plus advocacy for safe abortion
- (v) Improvement medical records documentation
- (vi) Training of staff in emergency obstetric care with focus on dystocia, haemorrhage and hypertension.
- (vii) Development and utilization of evidence based guidelines and protocols
- (viii) Provision of essential drugs, supplies and equipment

## Appendix 1: Research Protocol

### Descriptive study of maternal outcomes in a near-miss cohort at Kagadi District Hospital, Uganda

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This study is in partial fulfilment of the award of a Masters of Philosophy in Emergency Medicine of University of Cape Town

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## Abstract

**Background:** An understanding of pregnancy related morbidity (obstetric near miss) provides valuable information that can be used in reduction of maternal mortality. This study aims to (i) Describe the prevalence and short term outcomes of obstetric near misses (ii) Evaluate the level of care through comparative analysis of obstetric near misses and maternal mortality in Kagadi district hospital, Uganda

**Methods:** A facility based retrospective review of obstetric near miss cases and maternal deaths that occurred between 1<sup>st</sup> January 2015 and 31<sup>st</sup> December 2015. Obstetric near miss case definition will be based on disease-specific criteria (Mantel) including: haemorrhage, hypertensive disorders of pregnancy, dystocia, infection and anaemia. Main outcome measures will include the frequency of near-miss in each disease specific group, duration of hospital stay and maternal death. Secondary outcome measures will include distribution of referral categories, caesarean section rate, hysterectomy and foetal outcomes measures i.e live births, still births, abortions, neonatal deaths. A comparative analysis of obstetric near miss and maternal mortality will be done to determine the maternal near miss incidence ratio (MNMR), maternal mortality ratio (MMR) and Mortality indices. The maternal near miss to mortality ratio for the period of study will be calculated.

**Results:** The results of the study will include quantitative information on deliveries, obstetric near miss cases, surgical interventions, and maternal mortality. MNMR, MMR and mortality indices will be calculated. Additionally the frequency and categories of complications responsible for obstetric near miss at the hospital will be reported.

**Discussion:** Findings of this study will provide baseline data on prevalence and short term outcomes of obstetric near miss cases in Kagadi Hospital. This will provide valuable information on obstetric care and supplement maternal death enquiries. The information will also help identify women at high risk of maternal death, guide resource distribution, training and facilitate further research.

**Conclusion:** This information will help improve the quality of care.

## 1 Introduction

### 1.1 Background:

There is no standard definition of obstetric near miss; however, this can be easily understood as any woman who survives a life-threatening acute pregnancy complication. This could be due to “luck” or by receiving timely/appropriate care. Obstetric near misses share many characteristics with maternal deaths; both may be used as a marker of the health system. Recent data have shown that obstetric near misses are more common than deaths, and can therefore supplement investigations of maternal mortality.(1) Given this close link to maternal mortality, an investigation of near misses can provide an understanding of determinants of maternal death.

Uganda is a low income country with significant health system challenges. Despite investing in work towards the Millennium Development Goals, in Uganda the maternal mortality ratio is still twice the target, at 438/100,000 live births(2). The burden of obstetric near miss is poorly understood as little research has been done. In keeping with other low income settings, the bulk of Uganda’s health resources tend to cluster in urban areas. It is not clear how rural facilities perform with regard to many indicators of the health system’s performance. There are no published data on determinants of maternal death in this setting.

There are several useful markers of maternal near misses and deaths. None of these have been studied in rural Uganda.

- *MNMR (maternal near miss incidence ratio)*: number of maternal near miss cases per 1,000 live births.
- *Maternal near miss to mortality ratio*: proportion of maternal near miss cases to maternal deaths; higher ratio indicating better care.
- *Mortality index* is the number of maternal deaths divided by the sum of maternal near miss and maternal deaths; expressed as a percentage. The lower the mortality index, the fewer women with life threatening conditions dies (better care) and the higher the index, more women die (lower quality care).
- *MMR (maternal mortality ratio)*: the number of maternal deaths cases per 100,000 live births.

The purpose of this study to determine the prevalence and short term outcomes of obstetric near misses in a rural district in Uganda, in order to establish a base line for future investigations. The study will add to existing knowledge, provide information that will supplement the maternal mortality reviews and enable development of strategies to reduce maternal deaths and indeed increase survival (near miss)

### 1.2 Problem statement

In low and middle income countries, near miss review as a tool for monitoring maternal health care is poorly utilised probably due to the high maternal mortality rates which can mask the more common obstetric near misses. In Uganda, maternal mortality remains high (438/100,000 live births)(2); however, lessons learned from community verbal autopsies and facility based maternal death audits help provide some insight into the problem. Little emphasis is placed on

the audit of the more common obstetric near misses yet these could provide valuable supplementary information towards the reduction of maternal mortality(1)

### **1.3 Justification**

This study will describe the prevalence and short term outcomes of obstetric near misses among pregnant women admitted in a rural district hospital in Uganda. This information will provide a practical framework that can be used to reduce maternal mortality, provide room for further research and guide policy makers in the distribution of the limited resources.

### **1.4 Aim and Objectives**

The aim of this study is to describe the prevalence and short term outcomes of obstetric near miss in a rural district hospital in Uganda.

In order to achieve this aim the study has the following objectives;

- To determine the prevalence of obstetric near miss at the hospital
- To determine the short term outcomes of obstetric near misses in the hospital
- To comment on the quality of care through comparative analysis of maternal deaths and obstetric near miss

## **2 Literature review**

The Millennium Development Goals were developed in 2000; amongst them was goal 5 with a target to reduce maternal mortality by 75% by 2015(3). However, this target has not been achieved yet in many countries including Uganda, where the target maternal mortality was expected to be reduced to 131/100,000 live births from 506/100,000. To work towards this, there is need for timely recognition and treatment of emergency obstetric complications; such recognition would be greatly helped by carefully examining women who survive these complications.(4)

In 2009, the World Health Organization formulated a definition for obstetric near miss, based on clinical, laboratory and management criteria.(5) The definition requires laboratory investigations and facilities which are not easily available in many resource limited settings; a disease based criteria would be ideal in these settings. The WHO definition built upon Mantel's 1998 description of obstetric near miss based on five disease specific criteria, based on management and/or clinical signs and symptoms (6):

- haemorrhage at any pregnancy state (leading to transfusion, caesarean section or hysterectomy),
- hypertensive disorders of pregnancy (eclampsia or severe pre-eclampsia with a minimum diastolic pressure of 110 mmHg),
- puerperal sepsis (peritonitis, septicaemia, offensive vaginal discharge),
- dystocia resulting from prolonged labour, obstructed labour or malpresentation (leading to ruptured uterus or impending uterine rupture, caesarean section, instrumental delivery or perineal lacerations)
- Severe anaemia (haemoglobin < 6 g/dl).

Despite being a major public health problem, maternal deaths are rare especially within hospitals hence the study of those who survive (obstetric near misses) is useful in examining the quality of health care that is being provided(7).

The prevalence and short-term outcomes of obstetric near misses has not been documented in many hospitals. This lack of data on which women are at high risk of maternal death has affected the distribution of scarce resources(3). Nevertheless in low income settings some studies on obstetric near misses have been conducted. A study conducted in 2000 in Mulago National Referral Hospital, the main referral hospital in Uganda, examined 983 women referred to the hospital and showed that 11% were obstetric near miss and that 17 out of the 983 died. In this study postpartum haemorrhage and hypertension in pregnancy caused most of the morbidities and mortalities(17). Similarly, a systemic enquiry conducted in four referral hospitals in Uganda by Pius Okong et al (2006), found that haemorrhage was a major cause of morbidity however other causes like puerperal sepsis and abortions identified. In this study the obstetric care in the referral hospital was found to be substandard justifying the need for near miss audit(13).

Oladapo et al (2005) in a retrospective facility based review of near misses found a maternal death to near miss ratio of 1:48 over a three year period in a tertiary facility in Sagamu, Nigeria. In this study the commonest causes of near misses were hypertension in pregnancy and haemorrhage with mortality indices of 37.5% and 28.6% respectively(16). In contrast a study conducted in 2006 – 2007 in a hospital in Syria showed a relatively low mortality index (1.7%)(67) In 2013 a study conducted in Kasturba Hospital, India showed that the maternal near miss incidence ratio was 17.8/1000 live births, maternal death to near miss ratio of 1: 56 and mortality index of 14.9%. In the study the leading causes of near miss events were haemorrhage and hypertensive disorders as demonstrated in the other studies(49).

The available literature shows that the prevalence and short term outcomes differ in different settings. We do not have detailed information on this problem in rural Uganda.

### **3 Methodology**

#### **3.1 Study design:**

This will be a retrospective chart review, using standardised methods as described by Gilbert and Lowenstein(30).

#### **3.2 Study Setting**

All rural districts in Uganda were available to be selected: using a random number generator, Kibaale district was chosen for the study site. It is a typical rural district, with a population of 681,000 (2).

This study will be carried out at Kagadi hospital, located in Kibaale district, western Uganda 245km west of the capital city, Kampala. It is a 120 bed public hospital, offering comprehensive

emergency obstetric services – it serves as the district referral point. There are 2 senior medical officers and 3 medical officers, 15 (midwives) at the hospital. In 2014, the hospital recorded a total of 3401 deliveries and 20 maternal deaths(31). The maternity ward is very busy with an average of 30 admissions per day. There is a “waiting shade” for women with high risk pregnancies.

### **3.3 Study population**

The population of study will be all the pregnant women who were admitted to the maternity ward at Kagadi Hospital between 1<sup>st</sup> January 2015 and 31<sup>st</sup> December 2015.

### **3.4 Sampling**

Inclusion criteria: All records of pregnant women admitted in Kagadi Hospital with ANY of the following clinical signs/symptoms or diagnoses(6).

- a) Haemorrhage at any pregnancy state (leading to transfusion, caesarean section or hysterectomy),
- b) Hypertensive disorders of pregnancy (eclampsia or severe pre-eclampsia with a minimum diastolic pressure of 110 mmHg),
- c) Puerperal sepsis (peritonitis, septicaemia, offensive vaginal discharge),
- d) Dystocia resulting from prolonged labour, obstructed labour or malpresentation (leading to ruptured uterus or impending uterine rupture, caesarean section, instrumental delivery or perineal lacerations)
- e) Severe anaemia (haemoglobin < 6 g/dl).

Exclusion Criteria: All records that do not fit inclusion criteria will be excluded. All records with incomplete data will be removed from the analysis (complete case analysis) utilising the statistical package SPSS(32)

This study will use the Mantel criteria because of simplicity and ease of extraction of required data from case notes. Other criteria are based on organ dysfunction thus require laboratory investigations that are not usually done in a resource limited settings like Kagadi hospital. The International Classification of Diseases (ICD 10) will be used to define maternal mortality(33). Maternal mortality will be reported as frequencies or proportions of women who die while pregnant or within 42 days of termination of pregnancy.

### **3.5 Data Collection and management**

Using standardized data abstraction forms (appendix A, appendix B), data will be extracted from in patient medical records and hospital registers taking care not to include personal/patient identifiers (anonymity). The abstraction forms will have clear definition of variables. Four hospital staff (Registered Midwives) will be trained on data abstraction prior to the study using practice/hypothetical medical records. The midwives will collect data using the abstraction forms following the inclusion and exclusion criteria.

Main outcome measures will include;

- The frequency of near-miss in each disease specific group (Mantel Criteria)
- Duration of hospital stay
- Maternal death

Secondary outcome measures will include

- Distribution of referral categories
- Caesarean section rate
- Hysterectomy
- Foetal outcomes measures i.e live births, still births, abortions, neonatal deaths occurring at the hospital. Foetal outcomes occurring outside the hospital are not documented in the medical records thus these will not be considered.

A comparative analysis of obstetric near miss and maternal mortality will be done to determine the maternal near miss incidence ratio (MNMR), maternal mortality ratio (MMR) and Mortality indices. The maternal near miss to mortality ratio for the period of study will be calculated.

The investigator will monitor the data collection by holding regular meeting with abstractors to resolve data collection conflicts and irregularities and will regularly at a daily basis review the filled abstraction forms. The abstraction forms will be stored under key and lock in the hospital data office with access limited to the researchers. Filled data abstraction forms will be entered into a computer using Microsoft excel and this will be password protected. The investigator will also regularly carry out independent data collection on thirty random samples of medical records thereby assessing the interrater reliability of the data.

### **3.6 Statistical analysis**

The data will be exported into SPSS software for analysis. Descriptive statistics will be used in the analysis and data will be presented as frequencies, ratios and percentages. MNR, MNMR, will be calculated using live births as the denominator.

### **3.7 Ethical consideration**

Data will be collected and extracted from health facility medical records. The information collected will be anonymous with no patient identifiers. Information will not be obtained from participants directly and interviews will not take place so individual informed consent will not be necessary. A waiver of informed consent will be obtained from the ethics committees.

In addition to HREC approval at UCT, we will gain ethics approval from IRB of Mulago National Referral Hospital in Uganda and register with Uganda National Council of Science before conducting the study. Authorization from the district (district health officer) and hospital superintendent will be obtained. We will only be able to obtain such documentation once we have a provisional approval (subject to Ugandan approval) from UCT.

The data abstraction forms and other documents will only be kept by the abstractors who are hospital staff, and investigator at all times. The abstraction forms and data logs will be kept within the hospital premises in locked drawers during the study and for two years after conclusion of the study. The data will be transcribed into an Excel database and SPSS will be password protected. The abstraction forms will be destroyed after the study (shredded) 2 years after conclusion of the study. There are no anticipated risks due to this study.



## 5 Budget

Source of funding: TOTAL E&P Uganda (Sponsor of student's MPhil EM training)

No.	Item/Expenses	Number	Unit cost	Total
01	Research assistant training – Per diem for one day	4	200,000	800,000
02	Administrative fees; including processing of ethics – registration with Uganda National Council of Science and Technology and supervisor fees		Block	3,900,000
03	Allowance for research assistant; daily facilitation (lunch, airtime etc) @ 25,000 for 60 days	4	Block	6,000,000
04	Transport for all the activities; within the district and accommodation			1,800,000
05	Data entry and statistical analysis	1	2,000,000	2,000,000
06	Secretarial and stationery			200,000
07	Miscellaneous			500,000
<b>Total</b>				<b>UGX 15,200,000*</b>

\*Equivalent to ZAR 60,800

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## Appendix 2: Data Abstraction Tool

*Fill/tick applicable fields*

<b>Section A - Summary</b>	
Date of Admission	
Date of discharge	
Status at discharge	
Alive	
Dead	
Diagnosis	
Primary	
Secondary	
<b>Section B - Complications</b>	
Complication(s)	
1. Haemorrhage	
Early pregnancy	
Ectopic Pregnancy	
Abortion	
Others	
Late pregnancy	
Abruptio Placentae	
Placenta Previa	
Postpartum Haemorrhage	
Others	
2. Hypertension	
Eclampsia	
Severe Eclampsia	
3. Dystocia	
Obstructed Labour	
Prolonged Labour	
4. Uterine rapture	
5. Impending rapture	
6. Infections	
Pueperal Sepsis	
Chorioamnionitis	
Others	
7. Anaemia	
8. Indirect Cause/Other	
Cardiac	
Others	

<b>Section C - Complication Development</b>	
Home	
Other Public health facility	
Kagadi hospital (Public)	
Private Clinic/Hospital	
<b>Section D – POH/GH</b>	
• Age of patient	
10-14 years	
15-19 years	
20-24 years	
25-29 years	
30-34 years	
35-39 years	
40-44 years	
45-49 years	
50-54 years	
55-59 years	
• Gravity	
1	
2	
3	
more than 3	
• Gestational age (weeks)	
1 week – 12	
13-28	
28 -36	
>36	
• Previous Live born babies	
0	
1 to 3	
4 or more	
• Previous Still birth	
0	
1 to 3	
4 or more	
• Type of delivery	
Vaginal	
Ceasarian Section	
• Interventions/Special Procedures	
Hysterectomy	

Blood transfusion	
Other	
<b>Section E – Foetal Outcomes</b>	
Abortion	
Live born	
Fresh still birth	
Neonatal death	

### Appendix 3: Monthly indicators

	Number of admissions	Number of deliveries	Number of live births (LB)	Maternal Deaths (MD)	Maternal Near Misses (MNM)
January					
February					
March					
April					
May					
June					
July					
August					
September					
October					
November					
December					
TOTAL					

## Appendix 4: HREC approval - Uganda



# ST. MARY'S HOSPITAL LACOR

P.O. Box 180, GULU - UGANDA  
Tel: +256 - 471- 432310, Fax: +256 - 471-432665  
Email: [info@lacorhospital.org](mailto:info@lacorhospital.org) Website: [lacorhospital.org](http://lacorhospital.org)

11<sup>th</sup> January 2016

To **Micheal Suuna**  
Contact No. +256-701704802 or +256774704802  
Email: [suunamicheal@gmail.com](mailto:suunamicheal@gmail.com)

**Re: Study No. LHIREC 044/12/15, Study Title: Descriptive study of maternal outcomes in a near-miss cohort at Kagadi District Hospital, Uganda**

This is to inform you that Lacor hospital Institutional Research and Ethics Committee (LHIREC) reviewed the above research proposal on the 11<sup>th</sup> January 2016 and approved it.

Please note that your study protocol number with LHIREC is: **044/12/15**. Please be sure to reference this number in any correspondence with LHIREC. Also note that your study was first approved by LHIREC on 11<sup>th</sup> January 2016 and therefore approval expires at every annual anniversary of this approval date. The current approval is therefore valid 11<sup>th</sup> January 2017. If it is necessary to continue with the research beyond expiry date, a request for continuation should be made in writing to the secretary LHIREC.

Continued approval is conditional upon your compliance with the following requirements:

- 1) All protocol amendments and changes to other approved documents must be submitted to LHIREC and not be implemented until approved by LHIREC except where necessary to eliminate apparent immediate hazards to the study subjects.
- 2) Significant changes to the study site and significant deviations from the research protocol and all unanticipated problems that may involve risks or affect the safety or welfare of subjects or others, or that may affect the integrity of the research must be promptly reported to LHIREC.

You are required to submit a progress report after 6 months and at completion, termination, or if not renewing the project - send a final report within 90 days upon completion of the study to LHIREC.

You are also advised to register with Uganda National Council for Science and Technology (UNCST).

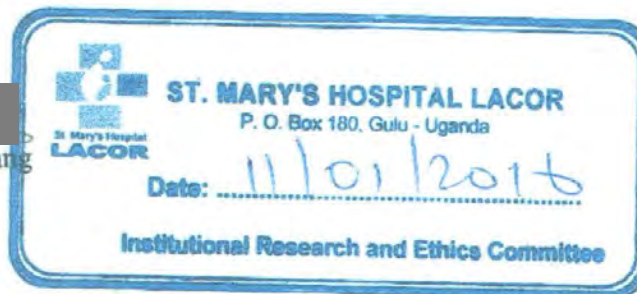
Below is a list of document approved with this application:

No.	Document Title	Language	Version	Version Date
1.	Proposal	English	N/A	N/A
2.	Data Abstraction tool	English	N/A	N/A
3.	Monthly indicators	English	N/A	N/A

Yours sincerely,

**Signed**

Dr. Martin David Ogwang  
Chairman LHIREC



## Appendix 5: District and Hospital Permission

Dr. Suuna Micheal

P.O. Box 25961 K'la

Tel. 0774704802

[suunamicheal@gmail.com](mailto:suunamicheal@gmail.com)

15<sup>th</sup> Feb 2016

To:  
The DHO Kibaale district

Through:

Medical supretendant  
Kagadi district hospital

RE: PERMISSION TO DO RESEARCH

*Permission Granted to Dr. Suuna Micheal  
to do Research of Near-miss maternal  
Outcomes in Kagadi Hospital.*



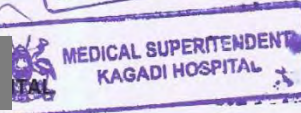
**Signed**

*15/2/2016*

*M. Micheal  
to carry out  
the research*

*15/2/16*

**Signed**



I am kindly requesting for permission to do research (descriptive study of maternal outcomes in a near miss cohort) - a retrospective chart review at Kagadi hospital, Uganda.

The research is partial fulfillment of a master's degree in emergency medicine which am currently pursuing at the University of Cape Town, South Africa.

This research has been approved by the ethics committee of St. Mary's Lacor (study no. LHIREC 044/12/15) and the HREC of the University of Cape Town (HREC. REF: 830/2015).

I will be grateful if my request will be grateful put to your due consideration.

NB: attached is proof of ethics approval and research proposal.

Regards

*Suuna Micheal*

Dr. Suuna Micheal

## Appendix 6: HREC approval UCT



**UNIVERSITY OF CAPE TOWN**  
**Faculty of Health Sciences**  
**Human Research Ethics Committee**



Room E52-24 Old Main Building  
Groote Schuur Hospital  
Observatory 7925  
Telephone [021] 406 6338 • Facsimile [021] 406 6411  
Email: [nosi.tsama@uct.ac.za](mailto:nosi.tsama@uct.ac.za)  
Website: [www.health.uct.ac.za/fhs/research/humanethics/forms](http://www.health.uct.ac.za/fhs/research/humanethics/forms)

17 November 2015

**HREC REF: 830/2015**

**Prof L Wallis**  
Emergency Medicine  
J Floor  
Old Main Building

Dear Prof Wallis

**PROJECT TITLE: DESCRIPTIVE STUDY OF MATERNAL OUTCOMES IN A NEAR-MISS COHORT AT KAGADI DISTRICT HOSPITAL, UGANDA (MPhil-candidate-Dr M Suuna)**

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee for review.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study subject to December 2015 data only being collected after December 31, 2015.

**Approval is granted for one year until the 30<sup>th</sup> November 2016.**

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.

(Forms can be found on our website: [www.health.uct.ac.za/fhs/research/humanethics/forms](http://www.health.uct.ac.za/fhs/research/humanethics/forms))

**Please quote the HREC REF in all your correspondence.**

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Yours sincerely

**Signed**

**PROFESSOR M BLOCKMAN**  
**CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE**

Federal Wide Assurance Number: FWA00001637.

Institutional Review Board (IRB) number: IRB00001938

This serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Convention on Harmonisation Good Clinical Practice (ICH GCP), South African Good Clinical Practice Guidelines (DoH