

INTRODUCTION

For every maternal death there are many others who suffer serious life-threatening complications of pregnancy, referred to as 'near miss' morbidity. Mantel et al. (1998) identified 5 times as many 'near misses' as maternal deaths. In fact, for the over 500,000 mothers who die annually world-wide, and mostly in developing countries, there are more than 8 million who suffer severe maternal morbidity (WHO 2004). These women who survive serious complications of pregnancy are referred to as 'near misses'.

It is estimated that 80% of complications of pregnancy and maternal deaths are avoidable, even in resource poor countries. Studies, including those by Kassar et al. in Egypt (1995), and Bouvier-Colle et al. in France (2001) have shown that the quality of care provided to pregnant women is critical and that appropriate emergency obstetric care can save many lives. In the past, maternal audit using deaths have traditionally been used to improve maternal health outcomes. Confidential Enquiries into Maternal Deaths in the United Kingdom, Malaysia and other countries have resulted in continuous improvements of maternal health in those countries (WHO 2004; Rowe et al. 2005). Martey et al. (1993) in Ghana and Mbaruku and Bergstrom (1995) in Tanzania reported on the use of maternal mortality review to identify avoidable factors and improve on services. In Tanzania there was a 50% reduction in maternal mortality over a 3 year period of intervention following implementation of the maternal death reviews.

Over the last decade, review of 'near-misses' or severe maternal morbidity is emerging as a useful outcome measure for evaluating and improving maternal health services and it may reflect the standard of obstetric care (Stones et al. 1991; Fitzpatrick et al. 1992). Since then, other studies have been done by Baskett and Sternadel (1998), Ronsmans and Fillipi (2000) among others. Recently, 'near miss' studies have also been done in the developing countries. It has been suggested that as in the developed countries, the evaluation of 'near miss' maternal morbidity in developing countries may provide a very sensitive indicator of obstetric care.

LITERATURE REVIEW

Maternal mortality current status

Maternal mortality has been declining in the developed countries, but this is not so for developing countries. According to 2005 estimates from WHO, maternal mortality ratios are now 5 to 210 per 100,000 live births in most developed countries whereas they range from 400 to 1000 per 100,000 live births in Africa and Asia (WHO, 2007). The WHO estimates that over 585,000 maternal deaths occur world-wide yearly and 99% of these occur in developing countries. Maternal mortality has not shown a consistent decrease in Zambia. The Zambia Demographic and Health Surveys (ZDHS) of 1996, 2001-2002 and 2007 have reported the estimated maternal mortality ratios (calculated using a direct sisterhood method) to have been 649, 729 and 591 per 100 000 live births respectively (Central Statistical Office et al 1997, 2003, 2009).

Causes and determinants of maternal mortality and morbidity

Causes of maternal mortality and morbidity in the developing countries differ from those in the developed countries. There are numerous contributing factors in the developing countries. Thaddeus and Maine (1990) categorized these factors into three 'delays':

- a) delays in the decision to seek care
- b) delays in getting to a health facility
- c) delays in the provision of adequate care.

Other barriers include fear, shame and harmful traditional practices. Common causes of maternal mortality and morbidity include postpartum haemorrhage, ruptured uterus, unsafe abortion, obstructed labour, postpartum infection and pre-eclampsia/ eclampsia.

Quality of obstetric care

The WHO has estimated that 15% of all pregnancies develop complications which require rapid and skilled intervention if the woman is to survive, and also without life-long disabilities (WHO 1994). The probability of a woman dying from a pregnancy complication depends not only on the woman's capacity to cope with a complication, but also on the action and care she receives.

One such proven and effective action is provision of emergency obstetric care (EmOC). This refers to provision of effective and timely interventions when obstetric emergencies arise either suddenly or as a result of poorly managed complications of pregnancy. Common obstetric emergencies include: convulsions (in eclampsia), haemorrhage, (antepartum or postpartum with shock), severe sepsis, respiratory distress and sudden loss of consciousness.

Emergency obstetric care facilities should be able to provide basic emergency obstetric care (administration of antibiotics, oxytocics and anticonvulsants, manual removal of the placenta, removal of retained products and assisted vaginal delivery with vacuum or forceps) as well as facilities for blood transfusion and caesarean section.

The ability of a facility to deal with emergencies will depend on its readiness for an emergency, availability of drugs and emergency equipment and health care

provider's knowledge of emergency conditions and their treatments. The prognosis of a patient with an emergency condition is directly related to the time between occurrence and initiation of treatment for the emergency condition. Parameters which have been used to assess quality of obstetric care include: availability of EmOC facilities, duration of time taken to treat a patient with a complication of pregnancy, availability of resources such as drugs, blood, equipment and skilled staff (PMMN 1995).

Effect of quality of obstetric care on maternal mortality

According to De Brouwere and Lerbeghe (2001), there is evidence that when quality of obstetric care is improved, maternal mortality reduces. The dramatic drop in maternal mortality between 1870 and 1930 in the developed countries (Europe and USA) was closely associated with improvements in the quality of obstetric care. The maternal mortality ratios of these countries dropped from 500 to 900 per 100,000 live births in 1850 to less than 100 per 100,000 live births by 1950.

Sri Lanka, Malaysia and Seychelles which are considered as developing countries, have also managed to reduce their maternal mortality ratios to levels near those of developed countries (WHO 2007). This came about after improvements in the quality of obstetric care as evidenced by increased skilled attendance at delivery and increase in blood transfusion facilities, among other interventions. Similarly in Senegal, the maternal mortality rate was reduced following improvements in life saving interventions (Dumont et al. 2000).

Institutional figures at the University Teaching Hospital (UTH) also showed that poor quality of obstetric care was responsible for most maternal deaths - Hickey and Kasonde (1977) found that avoidable hospital factors were present in 52% of causes of maternal mortality. These hospital factors included poor intrapartum assessment, failure to correct anemia, missed diagnosis of ruptured ectopic pregnancy and inadequate anaesthetic staff.

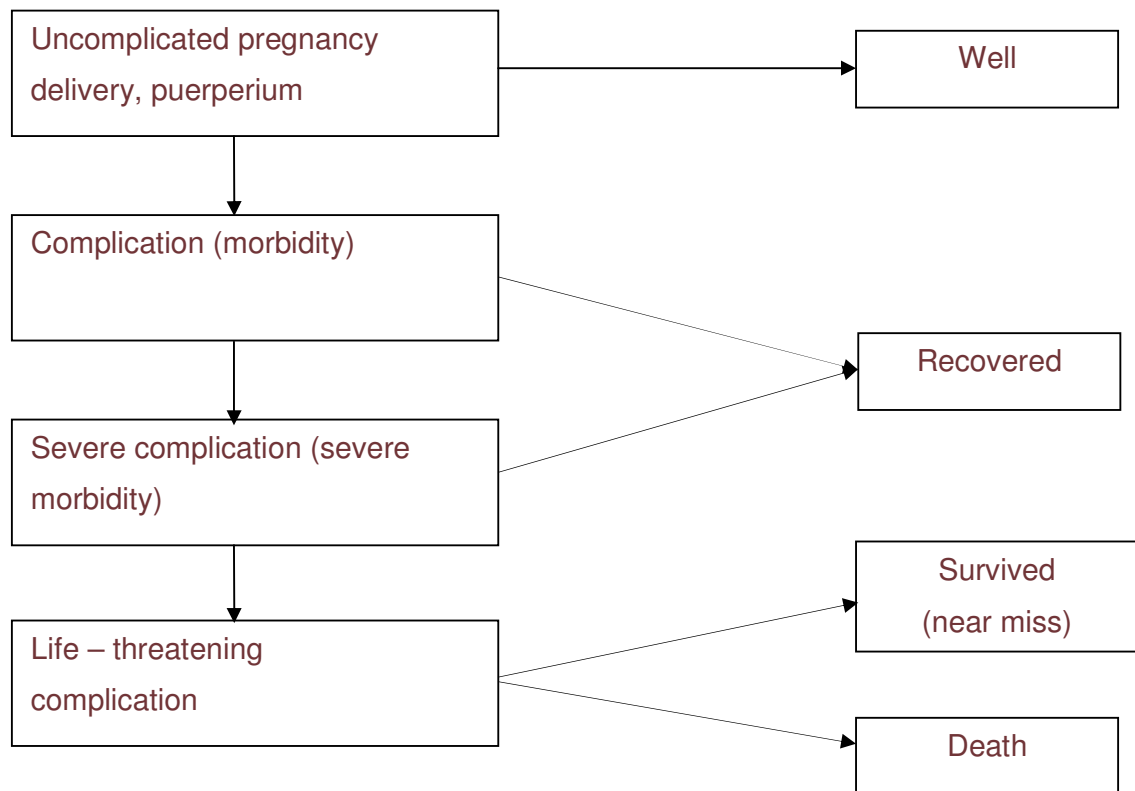
Maternal mortality and maternal morbidity

Maternal morbidity refers to complications arising during pregnancy, delivery or the puerperium. These complications can be acute or chronic. Chronic complications or morbidity include: loss of fertility, obstetric fistulae, chronic anaemia, stress incontinence, chronic pelvic pain, emotional depression and maternal exhaustion.

Acute complications can be severe from which a woman can either recover or die. If the woman dies, she is referred to as a maternal death where as if she recovers, she is referred to as a 'near miss' (Stones et al. 1991).

Thus, morbidity during pregnancy represents part of a continuum between the extremes of normal health and death. 'Near miss' represents one of two possible outcomes of a severe life-threatening complication of pregnancy, as illustrated in the following schema:

Pregnancy continuum between extremes of normal and death



Adapted from Beyond the Numbers: Reviewing maternal deaths and complications to make pregnancy safer (WHO 2004, p. 105).

Maternal mortality and 'near miss' maternal morbidity are intimately related because either event can result from pregnancy complications. The causes and factors which predispose pregnant women to severe morbidity or 'near misses' are similar to those that predispose them to maternal mortality as described in the three delays model (Thaddeus and Maine, 1990). As reported by Nyaphisi et al. (1996) based on a Commonwealth Regional Health Community Secretariat report on maternal mortality in Lesotho, Malawi, Uganda and Zambia, the same factors (the three delays) associated with maternal mortality were also found in women who had pregnancy complications but did not die.

Bouvier-Colle et al. (1997) in a review in France found that the risk factors which predisposed obstetric patients' admission to ICU, also predisposed them to severe maternal morbidity and deaths. These factors include low socio economic status, being in the age range 20-34 years, high parity (above 5) and lack of booking at the hospital offering emergency treatment. In a Ugandan study (Kaye et al. 2003), 'near misses' were associated with nulliparity and being less than 20 years old.

Definition of 'near miss' or severe maternal morbidity

There is currently no standard definition of 'near miss' such as there is for a maternal death because it is difficult to determine exactly at which point a woman becomes a 'near miss'. Locally appropriate and acceptable definitions are encouraged, and have been used by various researchers. For instance, the West African 'near miss' audit network used the following definition for the case review of 'near misses': 'any pregnant or recently delivered woman (within 6 weeks of termination of pregnancy) in whom immediate survival is threatened and who survives due to chance or hospital care she receives' (Fillipi 1998).

Mantel et al. (1998) defined a 'near miss' as 'a patient with an acute organ system dysfunction which if not treated appropriately, could result in death'.

Baskett and Sternadel (1998) proposed to define maternal 'near miss' cases as those women requiring critical care or transfer to an intensive care unit.

In a study in Benin, a 'near miss' was defined as 'a severe life-threatening obstetric complication necessitating an urgent medical Intervention in order to prevent the likely death of the mother' (Ronsmans and Fillipi 2000).

Criteria used to describe 'near misses'

Various researchers have described severe maternal morbidity or 'near miss' using 3 different criteria:

- 1. Clinical diagnostic criteria of morbidity from obstetric complications.**

Using clinical signs and symptoms to make an obstetric diagnosis. Such criteria focus on the major causes of maternal mortality i.e. haemorrhage, hypertensive disorders and sepsis (Bouvier-Colle, Varnoux and Groupe MOMS-B 2001).

- 2. Criteria based on organ system dysfunction.** Mantel et al. (1998) in

their criteria used dysfunction in the organ/system; e.g. cardiac, vascular, immunological (sepsis), respiratory, renal, liver, cerebral, metabolic and coagulation.

- 3. Criteria based on management** such as :

- A. Admission to an intensive care** unit regardless of the medical reason for the admission. Bouvier-Colle et al. (1996) found that 93% of women whose condition was considered as life- threatening were admitted to an intensive care unit.

Other studies have identified women at risk of severe maternal morbidity admitted to the intensive care unit (Lapinsky 1997; Dias De Souza et al. 2002).

- B. Major Interventions**, such as:

- i. Emergency post partum hysterectomy
- ii. Massive Blood transfusion
- iii. Hospitalization for 4 days or more
- iv. Anaesthetic accident.

Emergency postpartum hysterectomy (Nasrat et al. 1999) was used as a 'near miss' criterion in a study in Saudi Arabia.

Finally, combinations of multiple criteria for 'near miss' (Geller et al. 2002) have also been used.

Prevalence of 'near misses' world-wide

In a systematic review by Say et al. (2004) to determine the prevalence of severe acute maternal morbidity ('near miss') world-wide, it was found that most designs were cross-sectional and mostly conducted in tertiary hospitals. Many of the studies used response to an event such as admission to an intensive care unit as the classification criteria. Prevalence varied greatly for the 3 criteria: 0.80-8.23% for clinical diagnostic specific criteria, 0.38%-1.09% for organ system based criteria and 0.01 %-2.99% for management based criteria. It was also noted that although management based criteria yielded lower rates of prevalence yet they gave less variation in the results. Wilson and Salihu (2007) found that serious forms of maternal morbidity occur in about 1% of women in the United States compared to about 3% in some developing countries.

Prevalence of 'near misses' or severe maternal morbidity in Zambia

Few studies have been done on maternal morbidity in Zambia, let alone specifically addressing severe morbidity. In a study comprising factors associated with maternal deaths versus pregnant women who do not die conducted in 3 centres in Zambia in 1990, the same factors (the three delays) causing deaths were also found in women who did not die (Nyaphisi et al. 1996).

In a study on postpartum health among rural Zambian women in 2003, 84% of 620 subjects had at least one health problem (Lagro et al. 2003). 17% had abnormal high vaginal swabs and 93% of symptomatic women did not seek care. It was recommended that mass screening and treatment of genital tract infections postnatally would help to identify women with problems early.

In a similar study in 2006, it was found that only 42% of women delivering at a district hospital attended postpartum care at 6 weeks (Lagro et al 2006). It was suggested that hospital attendance could be increased if maternal and child health services were integrated, and if patients delivering at home were made more welcome when they attended hospital.

In a retrospective descriptive study on postpartum maternal morbidity requiring hospital admission at the UTH in 2005, high case fatality rates of severe complications were found (Vallely et al, 2005). The ratio of maternal mortality to severe maternal morbidity was 1: 11. Puerperal sepsis was identified as the leading cause of direct postpartum morbidity and malaria was the leading cause of indirect causes. The researchers found that up to 1.7% of the postpartum population in Lusaka require hospital level care for moderate to severe postpartum morbidity. It was also observed that despite large accessibility to health services, there was lack of efficiency of maternal health services.

Advantages of 'near- miss' studies / reviews

Enquiries into maternal health care have traditionally focused on maternal deaths. Methods of enquiry include:

1. Community based maternal death reviews or verbal autopsy.
2. Facility based maternal death reviews.
3. Confidential enquires into maternal deaths.
4. Clinical audit.
5. Surveys of severe maternal morbidity ('near misses'). The identification and assessment of cases in which pregnant women survive severe obstetric complications. (Local definitions are used to identify cases since there is no universally applicable definition).

It is advantageous to conduct surveys of severe maternal morbidity or 'near misses' for the following reasons:

1. Cases of severe maternal morbidity occur in larger numbers than maternal deaths and therefore it is possible to quantify avoidable factors. (Bewley and Creighton 1997; Mantel et al. 1997; Kaye et al. 2003, Bouvier-Colle et al. 1997)
2. Survivors can be reviewed on the care they received. (Bouvier-Colle et al. 1997; Geller et al. 2002)
3. Review of women who survive may be less threatening to health care providers than death, and therefore more acceptable. (Fillipi, 1998; Ronsmans and Fillipi, 2000)
4. Joint monitoring of maternal deaths and severe maternal morbidity makes integration of the two possible since death is the last step on a continuum of adverse events (Geller et al. 2002). This integration will help to

determine possible risks for death and identify effective preventive measures.

Disadvantages of 'near miss' studies/reviews

1. Lack of uniform or standard criteria for defining a 'near miss'. This makes it difficult to make regional comparisons. Drife (1993) while acknowledging the importance of maternal 'near miss' reviews especially in developed countries where the maternal mortality is now very low, also points out the difficulty in ascertaining cases for 'near miss' reviews. Case ascertainment requires reviewing a large number of registers and case notes.
2. 'Near miss' cases in the community cannot be identified accurately because of poor recall of obstetric events by most women after discharge from hospital.
3. Consent must be obtained if women who have survived are going to be interviewed, in addition to case note review.

Effect of quality of obstetric care on 'near misses' or severe maternal morbidity

1. Timing of care

In women who develop obstetric complications, timing of emergency treatment with appropriate care could reduce severe morbidity. In a study on 'near misses' to explore adequacy of care in France between 1995 and 1996, it was found that 62% of all study patients received adequate care while 14% received insufficient care and 24% had totally inadequate care (Bouvier-

Colle, Varnoux and Groupe MOMS-B 2001). The delivery to diagnosis of haemorrhage time was greater than 45 minutes in 21% of cases while the diagnosis to placental evacuation time was greater than 15 minutes in 49% of the cases. In 85% of cases no prostaglandins were used when oxytocics were ineffective. Factors associated with substandard care included lack of a 24 hour on-site anaesthetist at the hospital and low volume of deliveries in the facility.

A four months prospective observational study was conducted in facilities providing emergency obstetric care in Benin, in order to determine the quality of obstetric care (Saizonou et al 2006). This was done by examining availability and timeliness of emergency obstetric care. Out of 557 'near misses', 61% had immediate care given within 30 minutes, 42% had emergency surgery (caesarean section and laparotomy) within 1 hour and 10% of those requiring blood transfusion got it within 1 hour while 12% of those who needed blood did not get it. Only 47% of hypertensive patients and 60% of those with sepsis got their treatment within 1 hour. It was concluded that there was need to improve provision of emergency obstetric care.

Gohou et al (2004) in Cote d'Ivoire, reported that in a study which was conducted to document the frequency of severe obstetric morbidity, and the intervals between admission or decision and life-saving surgery, the decision to delivery time was 4.8 hours. Reasons for delay included huge case loads and lack of policy for prompt treatment.

In another Cote d'Ivoire study in 2005, aimed at identifying dysfunction in the care of female patients with severe maternal morbidity, Toure et al. (2005) showed that there was delay to receive care ranging from 80 minutes to 5 days, and it was concluded that there was inadequacy of quality of obstetric care.

2. Availability of medical supplies

Medical supplies including drugs, blood products and other equipment are cardinal in the provision of high quality of obstetric care. Most 'near miss' studies in the developing countries reported instances of non availability of medical supplies. The South African 'near miss' study in 1998, reported by Mantel et al. (1998) found that there was need to improve resources for the management of haemorrhage, which was a major cause of severe maternal morbidity.

Khosla et al. (2000) in a study in India, noted that tragic consequences in 'near miss' situations due to haemorrhage could have been successfully averted with the ready availability of blood and prompt operative intervention. Inadequate resources for the management of haemorrhage and hypertensive diseases of pregnancy were also noted in a study conducted in a tertiary hospital in Nigeria in 2005 (Oladapo 2005).

3. Skilled attendants at delivery

A skilled attendant refers to a health care provider with midwifery skills such as a midwife, a nurse and a doctor. Such an attendant at delivery is the

single most critical intervention for ensuring safe motherhood through timely delivery of emergency obstetric and newborn care when life-threatening complications arise. Most deliveries in developing countries are not conducted by skilled attendants (UNFPA, 2007). A 'near miss' study in India reported deliveries by un-trained village midwives (Khosla et al, 2000) while another study in West Africa (Gohou et al, 2004) reported huge case loads as contributing factors to inadequate care.

4. Mode of delivery

Most 'near miss' studies showed that up to 50% or more of deliveries were by caesarean section (Murphy and Charlett 2002; Nasrat et al 1999; Dias de Souza et al 2002).

5. Fetal outcome

In South Africa, Mantel et al (1998) reported that more than 20% of the 'near misses' had early pregnancy losses, while Oladapo (2005) showed that there were 37% stillbirths in his Nigerian study.

There is sufficient evidence that appropriate emergency obstetric care can prevent most maternal morbidities. Audits or reviews are useful ways of finding out what factors hinder the provision of such care and can also assist in finding remedial interventions.

STUDY JUSTIFICATION

This study aims to determine the nature and magnitude of severe maternal morbidity conditions or 'near misses' at UTH, and to what extent these were affected by the quality of obstetric care (timing of treatment, availability of resources) in 'near misses'. It is being done as a follow up study on previous studies in Zambia which have been done on mild to moderate, and moderate to severe postpartum morbidity (Lagro et al 2003; Lagro et al 2006; Vallely et al 2005). In contrast to those studies which focused on postpartum and postnatal morbidity, the current study will include both antepartum and postpartum severe morbidity.

RESEARCH QUESTION

RESEARCH QUESTION: What is the extent and nature of life-threatening maternal complications in pregnant and recently delivered women on admission to the UTH?

HYPOTHESIS: Life-threatening maternal complications in pregnant and recently delivered women on admission to the UTH constitute a large part of the overall admissions.

OBJECTIVES

MAIN OBJECTIVE: To determine the extent of and describe the type of life-threatening maternal complications in pregnant and recently delivered women on admission to the UTH.

SPECIFIC OBJECTIVES

1. To determine the magnitude and types of life-threatening maternal complications in pregnant and recently delivered women ('near miss' morbidity) admitted at the UTH.
2. To describe the characteristics of women (demographic and pregnancy related) that have a 'near miss' at UTH.
3. To assess the timing and management of 'near miss' morbidity at the UTH.
4. To determine the use of blood transfusion and major surgery in the management of 'near miss' morbidity patients.
5. To describe the fetal outcome of patients with 'near miss' morbidity.
6. To determine the inpatient duration of stay of patients with 'near miss' morbidity.

METHODOLOGY

1. Research design

The study was prospective cross-sectional descriptive study involving case file review of patients admitted as a life-threatening complication in pregnancy or the puerperium (as defined below in case definition) and survived to discharge. These patients, termed 'near misses' or severe maternal morbidity were admitted in the Department of Obstetrics and Gynaecology of the University Teaching Hospital, Lusaka in 2007 over a 3 month period from 1st September to 30th November 2007.

2. Research setting

Lusaka has a population of over 1.5 million people. The University Teaching Hospital is the largest public health institution in the country, has a bed capacity of 1,800 and is a national referral centre as well as a teaching centre for various health professions including medical students, postgraduate doctors, nurses, midwives, and paramedicals.

There are twenty three health centers in Lusaka, in addition to UTH, that provide antenatal and postnatal services. Ten of these have trained midwives that provide twenty four hour labour and delivery services. Chainama clinic also offers twenty four hour labour and delivery services. However, all these centers refer patients with pregnancy problems (antenatal, intrapartum or puerperal) to UTH which has 24 hour anaesthetic cover for the operating theatres and on-site blood transfusion availability. About 25% of all deliveries in Lusaka occur at the UTH.

Labour Ward High Dependency Unit (HDU)

Labour ward has the equivalent of an obstetric intensive care unit where patients with complicated pregnancy conditions requiring critical care are admitted. There is an admission policy which allows women fulfilling the following criteria to be admitted to this unit:

A. Severe medical conditions in pregnancy, e.g:

- i. cerebral malaria, malaria with liver/renal involvement
- ii. respiratory diseases and Acute Respiratory Disease Syndrome (ARDS)
- iii. Hypertensive Disorders of Pregnancy (HDP) with organ involvement

B Severe infection:

- i. Postpartum/postarbotal septicemia

C Severe blood loss (APH/PPH) requiring massive blood transfusion

- i. Hypovolaemic shock
- ii. Coagulopathy

Patients whose condition deteriorate and require assisted ventilation are transferred to the Main Intensive Care Unit for specific medical management.

Antenatal patients with severe complications and with gestation determined to be viable (above 28 weeks) or non-viable, are admitted to this unit, as are puerperal patients – e.g. those with severe PPH, eclampsia. However, some patients requiring critical care may also be admitted in the acute bays of the

general obstetric and gynaecology wards for lack of space in the HDU. Such patients were also captured in this study.

3. Case definition

In order to capture the most cases that had a life-threatening complication but did not die (i.e. a 'near-miss'), the case definition was adapted to include:

- A. A clinical diagnostic criteria of morbidity from obstetric complications focusing on the major causes of maternal mortality i.e. haemorrhage, hypertensive disorders, abortion and sepsis (Bouvier-Colle, Varnoux and Groupe MOMS-B 2001).
- B. A criteria based on management such as admission to an intensive care unit for patients whose condition was considered as life threatening (Bouvier- Colle et al (1996).
- C. Major Interventions, such as:
 - i. Emergency post partum hysterectomy
 - ii. Immediate blood transfusion

Case Definition and inclusion criteria

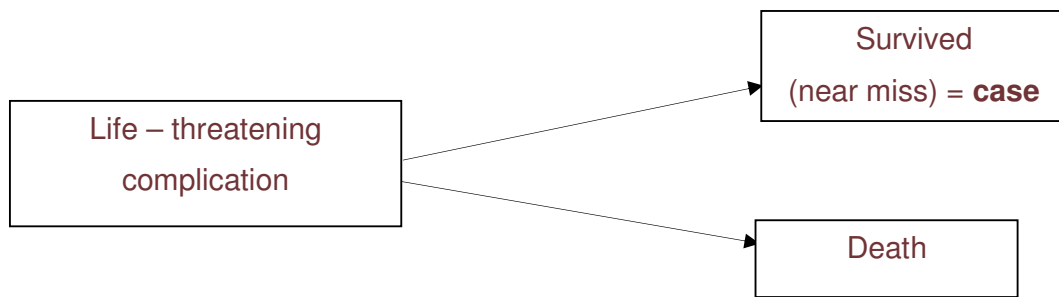
1. Admitted to or requiring admission to the UTH obstetric and gynaecology intensive care unit (High Dependency Unit) for an acute complication
and
2. Pregnant or within 42 days of delivery or termination of pregnancy (either postnatal or after a miscarriage/termination of pregnancy)
and

3. Requiring an immediate major intervention, including:
 - i. Eclampsia
 - ii. Severe pre-eclampsia (SBP> 160mmHg, DBP >110mmHg)
 - iii. Patients with congestive cardiac failure (but not asymptomatic cardiac disease)
 - iv. Patients with acute renal complications e.g. oliguria and anuria
 - v. Hypovolaemic shock requiring at least 4 units of blood
 - vi. Respiratory complications requiring assisted ventilation
 - vii. Requiring immediate intervention like emergency laparotomy (e.g. for ruptured uterus)

Exclusion criteria:

- A. patients that died –these were noted for purposes of calculating the case fatality
- B. patients who had not been pregnant in the previous 42 days
- C. patients routinely cared for in the obstetric and gynaecology intensive care unit as a precaution even though they were not in a decompensated state – e.g. patients in labour that had cardiac disease and well controlled diabetes mellitus.

Definition of case fatality: Case fatality was defined as those women with life-threatening conditions that died from the conditions. Based on the schema that had been previously described in the literature review, the numerator is 'near miss' and the denominator is all cases with life-threatening complications (cases of 'near miss' which are the subject of this study plus those that died) expressed as a percentage:



$$\text{Case fatality} = \frac{\text{Near miss}}{\text{Near miss} + \text{died}} \quad (\text{Expressed as a percentage})$$

4. Sampling

The target population is all women at any stage of pregnancy and up to 42 days, admitted for obstetric reasons in Lusaka during the stipulated period. **The study sample** is, of those admissions during the stipulated period, all patients that meet the case definition of a 'near miss' morbidity by virtue of having had a life-threatening complication and survived (described above in section 3).

Sample size estimation

During the preparation of the proposal it was noted, over different weekly periods that between 1-2 per 100 admissions met the case-definition of life-threatening complications and survived ('near miss') – i.e. 1-2% of admissions. Despite different case definitions from the literature, the WHO systematic review (Say et al, 2004) and other authors (Wilson and Salihu, 2007) estimate the prevalence of 'near miss' to be up to 3%. This higher assumption was used.

The sample size question was thus formulated as follows: *Assuming that 3% of admissions are life-threatening and survive as cases of 'near miss', what sample is needed to estimate the proportion of 'near miss' cases out of all admissions to within 5% of the true population?* (The level of precision required is such that at the 95% confidence level, the confidence interval is no wider than 5%, i.e. 0.05).

The formula to calculate the sample size N for a single proportion based on the above assumptions is as follows:

$$N \geq \frac{z^2}{w^2} \times pq \quad (\text{from: Bland, 2000}),$$

p= unknown proportion, assumed to be 3% (0.03);

q= 1-p

w=half width of margin of error (5%=0.025 on either side);

z=1.96

$$N \geq \frac{1.96^2 \times 0.03 \times (1-0.03)}{.025^2}$$

$N \geq 178.9$, rounding off to 179

Adding 10% for non-response and missing cases: **$N \geq 197$**

Sampling technique. Based on observations of previous admissions if every patient meeting the case definition was designated as a study subject, it was estimated that it would take up to 3 months to obtain the sample size. This was taken as the recruitment interval.

5. Data Collection

A. Timing and site

All patients meeting the case definition in the Department of Obstetrics and Gynaecology of the University Teaching Hospital, Lusaka in 2007 over a 3 month period from 1st September to 30th November 2007.

B. Data source(s)

Patients meeting the case definition were identified daily by inspection of the labour ward admission and delivery books, gynaecology emergency admission book, and the admission log of patients admitted to the High Dependency Unit (HDU) of the labour ward.

C. Data collection methods

A daily review was made of registers identifying patients that potentially had a life-threatening complication. If the patient met the criteria of the

cases definition of a 'near miss', the details were abstracted from the patients case records.

An adapted data collection tool was used for the abstraction of details. (See appendix). This was based on the WHO document: Beyond the Numbers: Reviewing maternal deaths and complications to make pregnancy safer (2004). In addition, although meant for maternal death review, the Ministry of Health document: 'Beyond the Numbers; Maternal Death Review Forms; Community Data Collection Instruments' also had questions that were applicable for morbidity review. (MOH 2005).

The forms were filled in by trained data collectors (medical students).

6. Data QA/QC Handling and Analysis

The data collectors had been briefed on how to fill-in the data collection tool and any ambiguities had been cleared. To ensure all cases were captured, the various registers were checked daily (as described in 5B above).

All data was entered into an Excel spreadsheet by both a data entry assistant and the author, and compared. Based on this double entry, any discordant entries were corrected by verifying with the original data capture instrument. Values found to be implausible or on out of range checks and missing data were similarly verified from the original data capture instrument. Finally, an independent assessor (Consultant Obstetrician Gynaecologist) verified each filled-in case record instrument to ensure they met the case definition and subsequently verified the data for accuracy, particularly the coding for the

'near miss' (see Appendix items 10 and 11). The data was imported from the Excel spreadsheet for subsequent analysis using SPSS version 11.5.

Data analysis:

Data was tabulated as simple frequency distributions using appropriate class divisions when more than 2 variables were involved (e.g. age 15-19, 20-24 years etc). Although this was a descriptive study, for illustrative purposes only and using SPSS, comparisons were made of variables (e.g. age, gravidity/parity, blood pressure, days in hospital) for the cases with different conditions that qualified as 'near miss'. An appropriate test statistic was used (predominantly a non-parametric, mentioned in the Results) being mindful of the fact that numbers were small and conditions for normal distribution were not generally met. Statistical significance was set at 5% ($p < 0.05$).

7. Ethical Considerations

All data were abstracted from the case files without identifying the case subjects. A sequential numerical identifier was assigned to each case and at the end of the data abstraction no link existed between the case and the numerical identifier. All abstract forms were kept securely in a locked cabinet accessible to the author and data entry person only.

Approval to conduct the study was obtained from the University Teaching Hospital Management. Before the onset of data collection, human subject approval to conduct the study was obtained from the University of Zambia Research Ethics Committee.

RESULTS

Extent of 'near miss' morbidity during the study period

During the 3 months study period from 1st September to 30th November 2007 there were 5672 patients admitted in the Department of Obstetrics and Gynaecology. Of these, 1419 were in early pregnancy or in the puerperium and admitted via the gynaecology wards and 4253 via the obstetric admission ward. Of the total 5672 admissions, 205 patients had a life-threatening complication of pregnancy or the puerperium and subsequently survived and were classified as meeting the criteria for 'near-miss' (morbidity). (Those cases initially considered as cases but then died were excluded as not meeting the case-definition of a near miss). The 205 cases of 'near misses' constituted 3.6% of all admissions during this interval. (Table 1).

Table 1. Summary of data obtained during study (1st September 2007 to 30th November 2007)

Admissions	
Early pregnancy admissions (gynaecology wards)	1419 (25.0%)
Obstetric admissions (labour ward)	4253 (75.0%)
Total	5672 (100%)
'Near miss' (NM)	205
NM as a proportion of all admissions (as a %)	3.6%

In tables 2 and 3 in the subsequent pages, the types of admissions in the gynaecology and obstetrics wards, respectively, are further described.

Source of 'near miss' cases – Gynaecology ward admissions (N=1419)

The vast majority of the 1419 admissions in the gynaecology admission wards during the 3-month study period (Table 2 - early pregnancy or postnatal admissions), were due to miscarriage or complications of unsafe abortion (1189). Of these abortions, 16 met the case definition of a 'near miss' in that they were all critically ill on admission, required resuscitation, including blood transfusion and antibiotics. Similarly, not all conditions required immediate care for a life-threatening complication; e.g. of 71 cases of ectopic pregnancy, 10 met criteria for a 'near miss' in that they had shock, needed immediate laparotomy and 5 had blood transfusions.

Table 2. Gynaecology Admissions (pregnancy and puerperium).

Dept of Obstetrics and Gynaecology, UTH, Sept-Nov 2007

(source – UTH gynaecology wards monthly returns)

	Gynaecology emergency and inpatient ward admissions (Sep-Nov 2007)
Abortion (spontaneous or unspecified)	1189
Delivery complicated by retained products/placenta (postnatal)	12
Ectopic pregnancy	71
Anemia in pregnancy	26
Malaria in pregnancy	42
Sepsis in puerperium	20
HIV	11
PTB	7
Hypertension	34
Infectious hepatitis	1
Meningitis	1
Pneumonia	1
Injury, assault (in pregnancy)	4
Total pregnancy related admissions	1419

Source of 'near miss' cases – Labour ward admissions (N=4253)

Of the 4253 reviews through the labour ward, not every one of the 4253 women admitted went on to deliver (Table 3) during the 3-month study period. Some were admitted to the antenatal ward and subsequently discharged to deliver later. However, of the 3634 that delivered, 19% were by caesarean section and there were 94% live births. Overall, in the 3 month period 6% of births were stillborn.

Of the 704 caesarean sections, almost 30% (210) were due to cephalopelvic disproportion – listed as failure to progress in the first (or rarely second) stage of labour. Had facilities for caesarean section not been readily available, these cases could lead to obstructed labour with serious maternal morbidity or resultant maternal death. However, caesarean section by itself was not part of the case-definition.

Table 3. Labour ward admissions and delivery statistics.

Dept of Obstetrics and Gynaecology, UTH, Sept-Nov 2007

(source – UTH labour ward monthly returns)

	Adm	SVD	CS	LB	FSB	MSB
Oct	1433	999	253	1320	29	38
Nov	1449	957	246	1244	49	31
Dec	1371	974	205	1193	54	40
3-month Totals	4253	2930 (81%)	704 (19%)	3757 (94.0%)	132 (3.3%)	109 (2.7%)
		3634 (100%)		3998 (100%)		

(Adm = admission; SVD=spontaneous vaginal delivery; CS=caesarean section;

LB= live birth; FSB=fresh stillbirth; MSB=macerated stillbirth)

Types of 'near miss' cases

Using a clinical diagnostic classification for tabulation of the results, the 205 identified cases of 'near-miss' morbidity (as outlined in Table 4 overleaf) were grouped in 4 main categories:

1. haemorrhage
2. abortion
3. hypertensive disorders of pregnancy (HDP - which include severe pre-eclampsia and eclampsia)
4. 'others'

Most cases of 'near miss' were due to hypertensive disorders of pregnancy (HDP) (129, 62.9%), followed by haemorrhage (43, 21.0%). About two-thirds of the haemorrhage cases were in the antepartum period (27 of 43 cases; 62.8%) as opposed to the postpartum period (16 of 43; 37.2%). The 16 cases of abortion admissions that met the criteria for 'near miss' represented 7.8% of all cases of 'near miss'. The 'other' cases (n=17; 8.3%) included 10 cases of ectopic pregnancy with the rest detailed as a note to Table 4.

Case fatality: Table 4 also outlines the case fatality (as defined in the Methods section) for the different conditions during the study period. In addition to the 43 cases of 'near miss' cases classified as haemorrhage there were an additional 9 haemorrhage-related deaths. The case fatality was therefore $9/(43+9) = 17.3\%$. However, the breakdown by whether it was antepartum or postpartum showed that case fatality after postpartum haemorrhage was substantially higher than after antepartum haemorrhage (30.4% vs. 6.9%). Of the 17 'other' cases, 10

were cases of ectopic pregnancy (that came in critical condition) and none died. The case fatality of the rest is not described in detail as numbers were small. However, of the 7 cases of puerperal sepsis that were considered life-threatening, 5 died. However these were initially admitted in a non life-threatening condition and progressively worsened. Their HIV status was not recorded.

Overall case fatality of life threatening- conditions was 11.3% and if only direct causes were considered, it was 10.7%.

Table 4. Type of ‘near miss’ and case fatality

		Near miss cases	Maternal deaths	Case fatality= [Near miss / (near miss cases + maternal deaths)] as a %
Diagnosis on Admission		N (%)	N (%)	%
Haemorrhage		43 (21.0)	9 (34.6)	9/(43+9)= 17.3%
<i>Antepartum Haemorrhage</i>	27 (13.2)		2	2/(27+2)=6.9%
<i>Postpartum Haemorrhage</i>	16 (7.8)		7	7/(16+7)=30.4%
Abortions		16 (7.8)	4 (16)	4/(16+4)=20%
HDP: Pre-eclampsia and Eclampsia		129 (62.9)	*6 (23.1)	6/(129+6)=4.4%
Others**		17 (8.3)	7 (26.9)	7/(17+7)=41.2%
Total		205 (100)	26 (100)	26/(205+26)=11.3%
<i>Total direct***</i>		200	24	24/(200+24)=10.7%

* 6 maternal deaths due to HDP: 1 had pre-eclampsia and 5 had eclampsia

** ‘Others’ (n=17) included:

10 cases of ectopic pregnancy; (no ectopic related death in study period)

2 cases of asthma in pregnancy; (no asthma related death in study period)

2 cases of puerperal sepsis; (there were 5 other cases that died; 5/(2+5)=71.4%)

1 case of cardiac failure; (one other with cardiac failure died in study period)

1 case of diabetic ketoacidosis; (No diabetic ketoacidosis related death in study period)

1 case of pneumonia; (1 other pneumonia-related related death in study period)

*** **Total Direct:** Haemorrhage (n=43), HDP (n=129), Abortion (n=16), Puerperal sepsis (n=2). Ectopic pregnancy (n=10) = 200 cases of ‘near miss’. Direct Deaths = 24.

Description of 'near miss' patients

Residence and age of 'near miss' patients

Overall, the cases were distributed across all residential areas (Table 5), though there was variation by type of 'near miss'. Less than half (32%) of the 'near miss' patients with haemorrhage were from high density areas and about a quarter (25.6%) were from low density areas. A sizeable number were from peri-urban areas (14%). Most of the patients with abortions (68.8%) came from low density areas while none came from a high density area. Of the 'near miss' patients with hypertensive disorders of pregnancy, 45% were from high density areas, 15.5% from low density and 7% came from peri-urban areas.

16.6% of the patients classified as 'near miss' were aged less than 20 years old and 16.1% were above 35 years old. The age range was from 15 to 45 years with mean age of 27 years. Of the 129 'near miss' patients with HDP, 36 (28%) were in the age group 25-29 though there was a sizeable number that were young, aged 15-19 years (n= 30; 23.3%).

Using ANOVA (non-parametric Kruskal Wallis statistic test as the conditions for normalcy were not met), cases of 'near miss' that had haemorrhage were significantly older than those that had HDP (mean 29.0 vs. 25.8; median 29 vs. 26 years).

Similarly, those with HDP were significantly younger than those classified 'others' – (mean 25.8 vs. 30.7; median 26 vs. 31 years).

Table 5. Residence and age of ‘near miss’ patients

	Haem	Abort	HDP	Others	All
Residence	n (%)	n (%)	n (%)	n (%)	N (%)
High Density	14 (32.6)	0 (0)	58 (45.0)	3 (17.6)	75 (36.6)
Medium Density	12 (27.9)	4 (25)	47 (36.4)	7 (41.2)	64 (31.2)
Low Density	11 (25.6)	11 (68.8)	20 (15.5)	7 (41.2)	49 (23.9)
Peri-urban inhabitant	6 (14.0)	1 (6.3)	9 (7.0)	0 (0)	16 (7.8)
Missing	-	-	1 (.8)	-	1 (0.5)
Total	43 (100)	16 (100)	129 (100)	17 (100)	205 (100)
Age of Patient					
Haem vs. HDP and					
HDP vs. other					
sig diff (p<0.05)					
(ANOVA nonparametric					
Kruskall Wallis)					
Mean (SD)	29.0 (6.4)	27.0 (6.0)	25.8 (6.6)	30.7 (5.1)	27.0 (6.55)
Median (IQR)	29 (24-35)	26 (23.5-29.5)	26 (20-30)	31 (27-34)	27 (22-31)
Min to max (range)	16-42 (26)	20-45 (25)	15-41 (26)	21-41 (20)	15-45 (30)
	n	n	n	n	N (%)
15 – 19 years	4 (9.3)	-	30 (23.3)	-	34 (16.6)
20 – 24	8 (18.6)	7 (43.8)	27 (20.9)	2	44 (21.5)
25 – 29	11 (25.6)	5 (31.3)	36 (27.9)	5	57 (27.8)
30 – 34	9 (20.9)	3 (18.8)	18 (14.0)	6	36 (17.6)
35 and above	11 (25.6)	1 (6.3)	17 (13.2)	4	33 (16.1)
Missing	-	-	1 (.8)	-	1 (0.5)
Total	43 (100)	16 (100)	129 (100)	17	205 (100.0)

Past history and booking status of 'near miss' patients

Out of the 205 cases, 71 were primigravidas and so previous complications of pregnancy did not apply. Of the remaining 134, 40 (29.9%) had a complication in a previous pregnancy (Table 6). None of those with an abortion had a previous complication in their previous pregnancy. A majority of the cases (193, 94.1%) did not book at UTH but were emergency referrals. Most of the cases of 'near miss' (170, 82.9%) had attended antenatal clinic.

Table 6. Past history and booking status of 'near miss' patients

	Haem	Abort	HDP	Others	All
Maternal Complications in Previous Pregnancy					
	n (%)	n (%)	n (%)	n (%)	N (%)
<i>(Primigravidas n=71)</i>	10	4	55	2	<i>n/a (71)</i>
Complications	12 (36.4)	0 (0)	23 (31.1)	5 (33.3)	40 (29.9)
No Complications	20 (60.6)	12 (100)	49 (66.2)	9 (60)	90 (67.2)
Missing/non response	1 (3.0)	-	2 (2.7)	1 (6.7)	4 (3.0)
Total	33 (100)	12 (100)	74 (100)	15 (100)	134 (100.0)
Booking Status					
	n	n	n	n	N (%)
Referral	40	16	121	16	193 (94.1)
UTH booked	1	-	8	1	10 (4.9)
Missing/ non response	2	-	-	-	2 (1.0)
Total	43	16	129	17	205 (100.0)
Antenatal Care Attendance					
	n	n	n	n	N (%)
Attended	41	1	121	7	170 (82.9)
Not Attended	1	-	6	-	7 (3.4)
Missing/non response/ (n/a for abortion)	1	15	2	10	28 (13.7)
Total	43	16	129	17	205 (100.0)

Gravidity, parity and gestation of 'near miss' patients

About a third of the 'near miss' patients were in their first pregnancy whereas less than a quarter were in their 5th or 6th pregnancy (Table 7). Among the 43 patients with haemorrhage, the highest number were in their 5th or 6th pregnancy (n=16; 37.2%). By contrast, 55 (42.6%) of the patients with HDP were primigravid. Though the exact week gestation was not available in most cases, it was noted whether the pregnancy was less than or greater than 28 weeks. By definition, the haemorrhage cases were >28 weeks and the abortion cases were <28 weeks. Only 6 of the 129 (4.7%) cases of HDP were <28 weeks gestation.

Table 7 Gravidity, parity and gestation of ‘near miss’ patients

	Haem	Abort	HDP	Others	All
Gravidity					
Haem vs. HDP and HDP vs. Other sig diff (p<0.05).					
ANOVA nonparametric Kruskal Wallis					
Mean (SD)	3.8 (2.4)	3.0 (1.5)	2.5 (1.8)	3.5 (1.7)	2.9 (2.0)
Median (IQR)	3 (2-5)	3 (1.5-4)	2 (1-3)	4 (2-5)	2 (1-4)
Min to max (range)	1-9 (8)	1-5 (4)	1-8 (7)	1-7 (6)	1-9 (8)
	n	n	n	n	N (%)
1	10	4	55 (42.6)	2	71 (34.8)
2	5	2	23	5	35 (17.2)
3	8	3	19	1	31 (15.2)
4	5	4	14	3	26 (12.7)
5 or more	16 (37.2)	3	17	6	41 (20.0)
Missing/non response	-	-	1	-	1 (0.5)
Total	43 (100)	16	129 (100)	17	205 (100.0)
Parity					
Haem vs. HDP and HDP vs. Other sig diff (p<0.05).					
ANOVA nonparametric Kruskal Wallis					
Mean (SD)	2.7 (2.4)	1.9 (1.5)	1.5 (1.8)	2.4 (1.6)	1.9 (1.9)
Median (IQR)	3 (1-4)	2 (0.5-3)	1 (0-2)	3 (1-4)	1 (0-3)
Min to max (range)	0-8 (8)	0-4 (4)	0-7 (7)	0-5 (5)	0-8 (8)
	n	n	n	n	N (%)
0	10	4	57(44.2%)	2	71 (34.6)
1	6	2	21	5	34 (16.6)
2	7	4	19	1	31 (15.1)
3	5	3	14	3	25 (12.2)
4	6	3	7	5	21 (10.2)
5 or more	9	-	10 (8%)	1	20 (9.8)
Missing/non response	-	-	1	-	1 (0.5)
Total	43	16	129	17	205 (100.0)
Gestation					
	n	n	n	n	N (%)
Less than 28 weeks	-	16	6 (4.7)	11	33 (16.1)
More than 28 weeks	43	-	123	6	172 (83.9)
Total	43	16	129 (100)	17	205 (100.0)

Timings on admission and availability of resources

Almost half of the 'near miss' patients were reviewed in less than 30 minutes of their arrival in the admission room, though 22.5% were not seen till an hour later (Table 8). There was no obvious pattern of speed or delay by cause, though more cases of haemorrhage were seen in <30 minutes. The necessary treatment was available for most of the 'near miss' patients (n=166, 81%) but it was given promptly (in less than 30 minutes) in only over a third of cases (n=75, 36.6%).

Table 8. Timings on admission and availability of resources

	Haem	Abort	HDP	Others	All
Variable					
Time to be seen	n (%)	n (%)	n (%)	n (%)	N (%)
<30 mins	28 (65.0)	9 (56.3)	61 (47.3)	4 (23.5)	102 (49.8)
30-60 mins	6 (14.0)	4 (25.0)	36 (27.9)	10 (58.8)	56 (27.5)
>60 mins	9 (21.0)	3 (18.8)	31 (24.0)	3 (17.6)	46 (22.5)
missing	-	-	1	-	1
Total	43 (100)	16 (100)	129 (100)	17 (100)	205 (100)
Treatment available?*					
	n	n	n	n	N (%)
Yes	29	11	112	14	166 (81.0)
No	1	5	3	2	11 (5.4)
Missing	13	-	14	1	28 (13.7)
Total	43	16	129	17	205 (100.0)
Time treatment given after seen*					
	n	n	n	n	N (%)
<30 mins	13	2	54	6	75 (36.6)
30-60 mins	8	8	37	6	59 (28.8)
>60 mins	11	6	24	3	44 (21.5)
missing	11	-	14	2	27 (13.2)
Total	43	16	129	17	205 (100.0)

*percentage not calculated for each condition as large number of missing values

Condition when assessed on admission

Over two thirds of the cases did not have their pulse recorded on admission (n=126, 61.5%) (Table 9). Of those that did, most of those with haemorrhage had a tachycardia (n=15 of 28 with a pulse recorded). Nearly all patients had their blood pressure recorded on admission (only 14 of the 205 did not) but only less than a quarter had their temperature recorded.

In the group of patients with HDP, the mean systolic pressure was 168mmHg and the mean arterial pressure was 129.3mmHg. Note that this group included those with eclampsia whose blood pressure may not have been extremely high.

Table 9. Condition of ‘near miss’ patients when assessed on admission

	Haem	Abort	HDP	Others	All
Pulse Rate (/min)	n (%)	n (%)	n (%)	n (%)	N (%)
only available for:	28 (65.1)	9 (56.3)	33 (25.6)	9 (52.9)	79 (38.5)
0-59	-	2	-	1	3
60-79	1	-	7	-	8
80-99	12	2	19	5	38
100+	15	5	7	3	30
Not recorded/missing	15	7	96	8	126 (61.5)
Total	43 (100)	16 (100)	129 (100)	17 (100)	205 (100)
Blood pressure					
HDP vs. Haem, HDP vs. Abort, HDP vs. Other all sig different. (ANOVA nonparametric Kruskal Wallis)					
Systolic					
Mean Systolic (SD)	103 (24.6)	91.4 (31.1)	168 (22.3)	106.6 (16.4)	144.1 (41.6)
Min-max (range)	0-180 (180)	0-130 (130)	120-260 (140)	80-140 (60)	0-260 (260)
MAP	75.2 (25.7)	69.7 (23.5)	129.3 (15.9)	80.8 (12.0)	111.1 (31.6)
Min-max (range)	0-153.3 (153.3)	0-96.6 (96.6)	93.3-193.3 (100)	60-106.7 (46.7)	0-193.3 (193.3)
	n	n	n	n	N (%)
0-59 mmHg	1	1	-	-	2 (1.0)
60-89	7	2	-	1	10 (4.9)
90-139	24	11	4	12	51 (24.9)
140-159	4	-	31	1	36 (17.2)
160-179	1	-	47	-	48 (23.4)
180-260	-	-	44	-	44 (21.5)
Not recorded/missing	6	2	3	3	14 (6.8)
Total	43	16	129	17	205 (100)
Diastolic					
	n	n	n	n	N (%)
0-59 mmHg	13	4	-	1	18 (8.8)
60-89	20	10	5	12	47 (22.9)
90-139	4	-	114	1	119 (58.1)
140-159	-	-	7	-	7 (3.4)
Not recorded/missing	6	2	3	3	14 (6.8)
Total	43	16	129	17	205 (100.0)

Table 9. (Continued) Condition when assessed on admission

	Haem	Abort	HDP	Others	All
Temp taken	n (%)	n (%)	n (%)	n (%)	N (%)
Yes	12(27.9)	8 (50)	16 (12.4)	7 (41.2)	43 (20.9)
No	3 (69.8)	8 (50)	111(86.0)	10 (58.8)	159 (77.6)
Not recorded/missing	1 (2.3)	-	2 (1.6)	-	3 (1.5)
Total	43 (100)	16 (100)	129 (100)	17 (100)	205 (100.0)

Management / Delivery Characteristics and outcome

Nearly half (n=100; 48.8%) of the deliveries were attended by resident doctors while less than a fifth had attendance from senior doctors (n=36; 17.6%) (Table 10). Just over 40% of the patients (n=83) had a normal vaginal delivery and almost the same numbers were delivered by emergency caesarean section (n=85). Ten patients had laparotomy for ectopic pregnancy.

Table 10. Management / Delivery Characteristics and Outcome

	Haem	Abort	HDP	Others	All
Delivery conducted by	n	n	n	n	N (%)
Self	1	-	-	-	1 (0.5)
TBA	-	-	-	-	-
Student Midwife	1	-	1	-	2 (1.0)
Midwife	7	-	54	4	65 (31.7)
Medical Student	-	-	-	-	-
Doctor	21	16	50	13	100 (48.8)
Senior Doctor (*)	12	-	24	-	36 (17.6)
Other	1	-	-	-	1 (0.5)
Not recorded/missing	-	-	-	-	-
Total	43	16	129	17	205 (100)
Mode of Delivery					
	n (%)	n	n (%)	n	N (%)
Normal vaginal	13 (30.2)	-	66 (51.2)	4	83 (40.5)
Ventouse/Forceps	-	-	2	-	2 (1.0)
Vaginal breech	1	-	-	-	1 (0.5)
Emergency caesarean	28 (65.1)	-	55 (42.6)	2	85 (41.5)
Elective caesarean	-	-	3	-	3 (1.5)
Laparotomy (**)	-	-	-	10	10 (4.9)
Abortion (early) (9)	-	16	-	-	16 (7.8)
Not recorded/missing	1	-	3	1	5 (2.4)
Total	43 (100)	16	129 (100)	17	205 (100.0)

(*) Senior doctor refers to Senior Registrar and Consultant.

(**) Laparotomy excludes caesarean and/or subsequent hysterectomy

Blood transfusion and hysterectomy

Forty seven (22.9%) of all the 'near miss' patients required a blood transfusion as part of their immediate management (Table 11). Among the 'near miss' patients due to haemorrhage, 23 (53.5%) had blood transfusion and all 16 cases of abortion categorized as 'near miss' patients had a blood transfusion. A hysterectomy was required in 8 of the 43 cases of haemorrhage (18.6%) - and all of those had required a blood transfusion.

Table 11. Blood transfusion and Hysterectomy

	Haem	Abort	HDP	Others	All
Immediate					
Transfusion need:					
	n (%)	n	n	n	N (%)
Transfused	23 (53.5)	16	2	6	47 (22.9)
Not transfused	20 (46.5)	0	127	11	158 (77.1)
Not recorded/missing	-	-	-	-	-
Total	43 (100)	16	129	17	205 (100)
Hysterectomy					
	n (%)	n	n	n	N (%)
Done*	8* (18.6)	0	0	0	8 (3.9)
Not done	35 (81.4)	16	129	17	197 (96.1)
Not recorded/missing	-	-	-	-	-
Total	43 (100)	16	129	17	205 (100)

*Of the 8 that had a hysterectomy, 5 had a ruptured uterus, 1 had a previous caesarean and 1 with a vaginal delivery (that had a PPH). The remaining 1 had a caesarean following antepartum haemorrhage due to placenta previa.

Fetal outcome of index pregnancy

Of the viable pregnancies (i.e. gestation above 28weeks), 140 (68.3%) had live births versus 31 (15.1%) who had stillbirths (Table 12). Despite small numbers, the outcome in those with haemorrhage was worse than those with HDP (62.8% vs 84.5% live births).

The mean duration of stay in hospital was 4.6 days with a range of 1-55 days. There was no significant difference in length of stay when comparing type of 'near miss'.

Table 12. Fetal outcome of index pregnancy and duration of inpatient stay

	Haem	Abort	HDP	Others	All
Fetal outcome of index pregnancy					
	n (%)	n	n (%)	n	N (%)
Early pregnancy loss	-	16	2 (1.6)	10	28 (13.7)
Live birth	27 (62.8)	-	109 (84.5)	4	140 (68.3)
stillbirth	14 (32.6)	-	15 (11.6)	2	31 (15.1)
Missing/not recorded	2 (4.6)	-	3 (2.3)	1	6 (2.9)
Total	43 (100)	16	129 (100)	17	205 (100)
Days in Hospital					
no sig diff between any groups. (ANOVA nonparametric , Kruskal Wallis)					
Mean (SD)	4.8 (8.6)	3.3 (1.3)	4.9 (4.2)	4.0 (1.7)	4.6 (5.1)
Median (IQR)	3 (2-4)	3 (2-3.5)	4 (2-6)	3 (3-6)	3 (2-5)
Min to max (range)	1-55 (54)	2-6 (4)	1-30 (29)	2-7 (5)	1-55 (54)
	n	n	n	n	N (%)
1	2	0	2	-	4 (1.95)
2	12	5	34	2	53 (25.9)
3	13	7	22	8	50 (24.4)
4	5	1	14	2	22 (10.7)
5-9	5	1	38	5	49 (23.9)
10+	2	2	11	-	15 (7.3)
Missing/not recorded	4	-	8	-	12 (5.9)
Total	43	16	129	17	205 (100)

DISCUSSION

Extent of 'near miss' cases

During the 3 months study period, September to November 2007, 5672 patients were admitted in the Department of Obstetrics and Gynaecology. Of these, 25% (1419) were admitted via the gynaecology wards (in early pregnancy or in the puerperium) and 75% (4253) were obstetric admissions. 205 cases (3.6% of all the cases admitted) had a life-threatening complication of pregnancy or the puerperium and fulfilled the case definition used in this dissertation for a 'near miss'. These patients nearly died but survived a severe complication during pregnancy, delivery or the puerperium.

The WHO is still in the process of establishing a uniform set of identification criteria and a standard definition for 'near miss' cases. At the moment it is difficult to make comparisons across studies from different regions because of the different definitions used. Nevertheless, Say et al. (2004) reported in a systematic review by WHO that many 'near miss' studies used criteria of admission to an intensive care unit – as was a criteria in this study. It also reported that the world wide prevalence for such criteria ranged from 0.01% to 2.99%. In another systematic review, Wilson and Salihu (2007) found that serious forms of maternal morbidity occur in about 1% of women in the United States compared to about 3% in some developing countries.

This study used a case definition that included clinical (e.g. severe pre-eclampsia); management (admission to intensive care unit) and intervention (e.g. blood transfusion for severe haemorrhage and caesarean hysterectomy). This

yielded the proportion of 'near miss' as 3.6% of admissions. It is not possible to compare our proportion to the general prevalence found across other studies world-wide because of the many differences in terms of geographic location, population and study methodologies used.

Types of 'near miss' patients

The two main clinical diagnoses in the 'near miss' cases were hypertensive disorders of pregnancy (n=129, 62.9%) and haemorrhage (n=43, 21%). The rest were due to abortions (16, 7.8%) and others (17, 8.3%). This demonstrated the large case load due to haemorrhage and HDP in this setting that progressed to life-threatening conditions and which required immediate resources to deal with them. This is consistent with Mantel et al. (1998) in South Africa and Amorim et al. (2008) in Brazil who found that haemorrhage and hypertensive disorders were the most common diagnoses associated with 'near miss' cases.

Determinants of 'near miss' patients

Residential area: The 'near miss' patients were distributed across all residential areas in Lusaka. It is noteworthy that 16 (7.1%) were referrals from peri-urban areas and would have had more difficult access to UTH. Although numbers are small, a large proportion (68.8%) of abortion 'near misses' were from low density areas. If area of residence is a proxy for socio-economic status, this indicates that those well off and residing in low density areas were heavily represented as cases. It is unclear why this may be the case, and could simply be fortuitous as the numbers are small and the duration of the study was short. Further, the abortions were not categorized by original type (spontaneous or induced) and it is plausible that those from low density areas just access the clinics and get referred earlier. A longer duration study would be required to establish this. By

contrast, HDP showed a gradient from high to low density areas and may simply reflect the higher numbers of women that are pregnant and come from high density areas.

Age: The age range of cases was from 15 to 45 years with mean age of 27 years (SD 6.5). 27.8% of these patients were in the age group 25-29 years which is the most active reproductive age group in Zambia. However, both the young (n=34, 16.6%) and also older women (n=33, 16.1%) were markedly represented. Since the ages of all 5672 admissions was not collected, age-specific rates cannot be provided. The mean age of those that had HDP (25.8, SD 6.6) was significantly less than those that had haemorrhage (29, SD 6.4) and reflects more of the primiparas having HDP and a significant number of older women with haemorrhage as anticipated. Even then both young and old were susceptible to being cases of 'near miss' as haemorrhage and HDP.

There is a wide variation of age range and mean age in various 'near miss' studies. In a Uganda study, Kaye et al. (2003) found that most of the 'near miss' cases were less than 20 years old. Chhabra et al. (2008) reported a mean age of 26.3 +/- 5 years in their study of 'near miss' in India.

Past history and booking status of 'near miss' patients

Maternal Complications in Previous Pregnancy. Of the 205 cases, 71 were primigravidas and of the remaining 134 multigravidas, 40 (29.9% with previous pregnancy or 19.5% of all cases) had a previous pregnancy complication (type not recorded). There was no pattern detected by type of 'near miss'.

Booking Status. A vast majority of the 'near miss' patients (94.1%) were emergency referrals to UTH, though a few had been initially booked at UTH. This highlights the importance of an effective and reliable referral system in the event that care is needed.

Antenatal Care Attendance. As is common in Zambia, and particularly in an urban setting – over 80% had attended antenatal care. There were 28 (13.7%) cases in which attendance was not determined (missing) and 7 had not attended. Of these 7, 6 had HDP and 1 had haemorrhage as the cause for the 'near miss'. Although 2 were from a peri-urban area, 4 were from high density areas and none from a low density area. Once again this highlights the need for antenatal attendance and also poor access by those from peri-urban areas and also most likely poorer patients in high density areas.

Gravidity, Parity and gestation of 'near miss' patients

Gravidity and parity. As would be expected, there was a close correlation between gravidity and parity. Nulliparity is an important risk factor for HDP and is also reflected in the numbers of cases (the highest number of cases of HDP was in nulliparous – n=57, 44.2%). However, there were also 10 (8%) with parity >5 or more. Those that had a 'near miss' due to haemorrhage had a significantly greater parity than those that had HDP (median 3 vs. 1; p <0.05)

Gestation (at time of admission). By definition all haemorrhage cases were >28 weeks and all abortion cases were <28 weeks gestation. However, 6 of the 129 cases with HDP (4.7%) were less than 28 weeks showing that severe pre-

eclampsia (all were multigravid and in fact 3 were older than 30 years) in these was perhaps a reflection of chronic hypertension which was then complicated by pre-eclampsia.

Timings on admission and availability of resources

Prompt review and management of cases that have life-threatening complications on admission is important. Only about half (49.8%) were reviewed within 30 minutes and about a quarter more than an hour later. Marginally more cases of haemorrhage were seen within 30 minutes (28 of 43, 65%), but even then, 9 (21.0%) were reviewed more than an hour later. Overall it was judged that treatment was available in the majority of cases (81%, though 13.7% of responses were missing). The need for prompt review cannot be overstated, but limitations of staff numbers and a heavy work load may account for some not being reviewed quickly.

Assessment on admission

More cases had their blood pressure measurement taken in the admission room whereas measurements for temperature and pulse were rarely taken – or if taken not recorded. Only 79 of the 205 cases (38.5%) had a pulse taken on admission and this was most frequently in cases of haemorrhage (65.1%) compared to HDP (25.6%). Similarly, temperature was not taken in 159 of the 205 cases (77.6%). By contrast only 14 (6.8%) did not have a blood pressure recording on admission. The blood pressure in cases of haemorrhage and abortion was significantly less compared to HDP.

Complete measurements of vital signs on admission are crucial in the management of these critically ill patients. It also helps to ascertain those patients already in a 'near miss' state on admission and those who deteriorate and become 'near miss' cases while already in hospital.

Management / Delivery Characteristics and Outcome

Review of the 205 cases of 'near miss' showed that most of the deliveries of the 'near miss' patients were conducted by midwives (31.7%) and resident doctors (48.8%). Although generally most deliveries are conducted by midwives, these complicated cases were more often delivered by doctors – mainly as a result of higher caesarean rates (41.5% of cases of 'near miss' had a caesarean section). Skilled attendants at delivery (midwives and others with midwifery skills) have been shown to improve maternal and neonatal outcomes, and it is one of the 3 strategies being used by UNFPA and other partners to improve maternal health in countries with high maternal mortality ratios (UNFPA, 2007). Most deliveries in developing countries are not conducted by skilled attendants resulting in poor outcomes.

Interestingly, all 16 cases of abortion that were classified as 'near miss' had a transfusion, reflecting the serious condition they had been admitted in. Although 53.5% of cases of haemorrhage were transfused, this may reflect resuscitation with other intravenous fluids and also unavailability of blood. Hysterectomy was carried out in 8 cases and all had haemorrhage. Of these 5 had a ruptured uterus, 1 had a previous caesarean and 1 with a vaginal delivery (that had a PPH). The remaining 1 had a caesarean following antepartum haemorrhage due

to placenta previa. The ability to perform a hysterectomy (usually due to atonic uterus) requires a skilled surgeon, theatre team and facilities and also blood transfusion access. These can be difficult to make available in all settings but are important in the management of life-threatening complications.

Fetal outcome

Of those who delivered, there were 14 of 43 cases of haemorrhage that resulted in a stillbirth (32.6%), and 15 cases of HDP resulted in a stillbirth (11.6%). These are much higher than stillbirth rates overall (6% during the study period as shown in Table 3).

Inpatient stay

Those patients that have a 'near miss' remain in hospital for a considerable length of time. The mean duration of stay in hospital was 4.6 days (SD 5.1) though this ranged widely (1-55 days). Also, 64 (31.2%) were inpatients for > 5 days with 15 (7.3%) being inpatients for >10 days. There was no significant difference among the different causes of 'near miss'.

Case fatality

The case fatality should be clarified and seen in the context of small numbers. Firstly, by definition, none of the 'cases' died. What is implied is that for the cause-specific 'life-threatening condition' under consideration (e.g. haemorrhage, abortion, HDP, and 'others') how many survived as a 'near miss' case and how many had died. Thus in addition to the 205 that met the study case definition of a 'near miss', there were 26 that died (see Table 4). The ratio of 'near miss' to

deaths in those with life-threatening conditions was therefore 205:26 about 8 to 1 (11.6% case fatality). However, this varied for the different conditions and it is acknowledged that numbers were small for some of the conditions and generalizations cannot be made. This is contrasted with the 17.3% reported by Oladapo et al. (2007) from a Nigerian teaching hospital where their 'cases' were defined as 'critically-ill patients'.

The 'cause-specific' case fatality, e.g. for haemorrhage (17.3%) was much higher than that for hypertensive disorders of pregnancy (4.4%). Similarly, of the 20 abortion patients with life-threatening complication (out of a total of 1189 patients admitted with abortion), 4 died (20%). There were 2 cases of puerperal sepsis classified as 'near miss', but during the study interval there were 5 deaths logged as due to puerperal sepsis. It is difficult to interpret this finding because of small numbers but it draws attention to the problem of puerperal sepsis as an important cause of morbidity and mortality. Out of a total of 71 cases of ectopic pregnancy, 10 were classified as life-threatening, all survived (zero case fatality) and hence remained 'near misses'.

STUDY LIMITATIONS

1. An organ system based definition approximates most closely to the true definition of a life-threatening complication or 'near miss' because only very severe end points are selected. However, technologies may not be available to make accurate diagnosis of organ failure e.g. O₂ saturation measurement, biochemistry, coagulation studies, etc. Hence the choice to use the criteria of intensive care admission and clinical diagnosis for this 'near miss' study.
2. The study could not assess non clinical factors as they are not usually found in medical records e.g. satisfaction of care (patients and relatives were not interviewed). Further, some data e.g. circumstances leading up to the life-threatening complication, was not recorded in the case records. In these circumstances interview of the patients and staff would have been helpful in collecting such data. In fact, the MOH instrument previously described for maternal death review includes this and could be adapted for morbidity. (MOH 2007)
3. Patients were only followed up to discharge from the obstetric intensive care unit or up to their death while inpatients. Following up patients for a longer period would determine whether they survived the puerperium and up to 42 days postpartum. However, this would have required community follow-up.
4. The period of data collection (September to November) was just before the rainy season. It is unclear whether any seasonal differences might have affected the type of cases.
5. Although data was collected as the cases occurred, there was still some missing data despite training of staff. Immediate QA/QC of the instruments, which was not done, could have picked up these omissions.

6. Complete data, as was obtained for 'near miss' cases, were not obtained from all those that died as the intent was not to study maternal mortality. However, had this data been collected, it would have allowed for a detailed comparison and identification of risk factors in cases of life-threatening complications leading to survival ('near miss') as opposed to death (maternal mortality).

CONCLUSION

This study has shown that 'near misses' constituted some 3.6% of life-threatening complications at UTH during the study period, which despite different case definitions is consistent with other studies in developing and developed countries. The case fatality for life-threatening complications was 11.6%. Although factors leading to survival or death were not studied, amongst the survivors ('near miss'), management of conditions like haemorrhage, abortion, HDP and other complications was not always done in under 30 minutes and in some cases took over 60 minutes both for immediate assessment and for initiating management.

Nevertheless, the fact that there were more cases of 'near miss' compared to those with maternal mortality, provides an opportunity to critically review factors that led to survival as opposed to death, and also to highlight aspects of care that could be improved. All this could be done in a less threatening manner than for maternal mortality audits in which the outcome is extreme.

RECOMMENDATIONS

This study will need to be followed up with a case-control study involving interviews with 'near misses' in addition to the review of case files of those who died, in order to obtain more complete data on determinants of survival.

There is need to include 'near miss' or severe maternal morbidity audit as a useful outcome measure for evaluating and further improving maternal health services at the UTH Department of Obstetrics and Gynaecology.

Interviews with survivors ('near misses') and care givers would yield more information on the strengths and weaknesses of the obstetric services at UTH, in order to further improve maternal health care.

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APPENDIX

Data Collection Instrument

adapted from:

World Health Organisation. 2004. Beyond the Numbers: Reviewing maternal deaths and complications to make pregnancy safer. WHO, Geneva.

and

Ministry of Health, Zambia. 2007. Beyond the Numbers; Maternal Death Review Forms; Community Data Collection Instruments, Lusaka, Zambia.

Default in all is 'not recorded' or 'not applicable' as relevant

1. Unique Study identification number
2. Residential area:
 1. High Density
 2. Medium Density
 3. Low Density
 4. Peri-urban area
3. Age: ----- (in years), and subsequently categorized as:
 1. 15 – 19 years
 2. 20 – 24
 3. 25 – 29
 4. 30 – 34
 5. 35 and above
4. Gravidity -----
5. Parity -----
6. Gestation actual ----- (weeks)
 1. Less than 28 weeks
 2. 28 weeks and above

7. Maternal complications in previous pregnancy (if not primigravida)
 1. Yes
 2. No

8. Attended antenatal care attendance in index pregnancy
 1. Yes
 2. No

9. Referral status to UTH
 1. Referred (from clinic or self-referral)
 2. (already UTH in-patient)

10. Diagnosis:
 1. Antepartum Haemorrhage
 2. Postpartum Haemorrhage
 3. Abortion
 4. Severe Pre-eclampsia and Eclampsia
 5. Sepsis
 6. Others -----
(inc ectopic pregnancy, ruptured uterus, etc)

11. Major intervention
 1. Immediate blood transfusion (Yes/No)
 2. Hysterectomy (as a caesarean or puerperal) (Yes/No)

12. Who conducted delivery
(regardless of whether delivered at UTH or not)
 1. Self
 2. Traditional Birth Attendant
 3. Student Midwife
 4. Midwife
 5. Medical Student
 6. Doctor (JRMO, SRMO, Registrar)
 7. Senior Doctor (Senior Registrar, Consultant)
 8. Other (specify)

13. Mode of delivery

1. Normal (vaginal)
2. Ventouse/Forceps
3. Breech (vaginal)
4. Emergency caesarean section
5. Elective caesarean section
6. Laparotomy
7. (Abortion)
8. Not recorded

14. Fetal outcome in index pregnancy:

1. Live Birth
2. Still Birth
3. Abortion

Clinical state on admission

15. Pulse

1. Rate if recorded / min
2. Not recorded

16. Blood Pressure

1. Systolic..... mmHg
2. Diastolic..... mmHg
3. Not recorded

17. Temperature recorded?

1. Yes
2. No

Quality of Care

18. Time taken to be seen on arrival at UTH:

1. Less than 30 minutes
2. 30 – 60 minutes
3. >60 minutes

19. Time taken for initiation of emergency treatment (Inc blood transfusion, magnesium sulphate, hysterectomy etc as appropriate):

1. Less than 30 minutes
2. 30 -60 minutes
3. >60 minutes

20. Drugs and necessary equipment (including blood) available

1. Yes
2. No

21. Number of days in hospital days