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Near-miss in early pregnancy at Chris Hani Baragwanath Academic Hospital

Kholofelo Raisibe Madiba

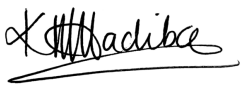


A research report submitted to the University of Witwatersrand, Johannesburg in partial fulfillment for the requirement of the degree of Master of Medicine, 2018.

30 November 2018

DECLARATION

I, Kholofelo Raisibe Madiba hereby declare that this research is my own work. I am submitting this research report for the degree Master of Medicine (Obstetrics and Gynaecology) at the University of the Witwatersrand, Johannesburg. This research report has not been submitted before for any degree or examination at this or any other university.



30 November 2018

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To my Heavenly Father, thank you for always being faithful. I am so humbled. To my daddy in heaven, I feel your love and support daily. To my family and friends (especially my best friend Camelia Coopen and the A.N.G's), I don't see how I could have done this without your prayers. My heart is filled with gratitude. To my supervisor, Dr. Salome Maswime, you have inspired me (and continuously do so) in so many ways. Thank you for your encouragement throughout this journey. To everyone who contributed to this cause, directly and indirectly, thank you.

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ABSTRACT

Introduction

The concept of maternal near-miss is well documented in South Africa and worldwide, however causes of near-miss in early pregnancy (<24 weeks gestation) need further exploration. A near-miss is a woman who had a life-threatening complication due to pregnancy or childbirth up to 42 days after delivery.

Objectives

To determine the frequency and severity of maternal near-miss occurring at less than 24 weeks gestation as a consequence of ectopic pregnancies, termination of pregnancies, miscarriages and molar pregnancies at the Chris Hani Baragwanath Academic Hospital.

Methods

This was a retrospective audit of near-miss in early pregnancy cases occurring between 1 January 2015 and 31 December 2016. Case records were reviewed and data was collected by the researcher.

Results

Thirty-nine cases of near-miss and 1 maternal death from early pregnancy were found over a 2 year period. Of these, 18 women had a near-miss as a result of ectopic pregnancies (46.1%), 13 from miscarriages (33.3%), 7 as a consequence of termination of pregnancy (18.0%) and one from a molar pregnancy (2.6%). HIV status and antenatal care booking status were amongst the most recognized risk factors. Twenty (51.3%) of the women were HIV positive and 36 (92.3%) of them had not had any antenatal care visits prior to hospital admission. All the women who had a termination of pregnancy had done so illegally and all women with an

ectopic pregnancy were found to have already ruptured at the time of presenting to the hospital. Septic shock occurred in 3 (42.9%) of the 7 women with an illegal termination of pregnancy. The majority (60%) of the women required a blood transfusion of ≥4 units. Five (13.5%) women had a hysterectomy as a consequence of haemorrhage or sepsis and 19 women (51.4%) required high care or intensive care admission. Patient related avoidable factors included unsafe termination of pregnancy (18.9%) and delay in seeking medical attention in 27% of the cases.

Conclusion

Ectopic pregnancies and unsafe termination of pregnancies were the most frequent causes of near-miss in early pregnancy resulting in severe haemorrhage and sepsis. This suggests that early ultrasound to diagnose ectopic pregnancy, access to contraception to prevent unwanted pregnancies and access to safe TOP services can prevent severe morbidity and mortality. Improving access to antenatal care services, coupled with patient education can improve maternal outcomes in women early in pregnancy.

PRESENTATIONS AND PUBLICATIONS

1. Madiba K, Maswime S. An audit of near-miss in early pregnancy in South Africa Poster presentation at the Royal College of Obstetrics and Gynaecology World Congress. Suntec City, Singapore- 23 March 2018.

2. Madiba K, Maswime S. An audit of near-miss in early pregnancy in South Africa. BJOG suppl: BEP6778 (limited time online version)

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ABBREVIATIONS

BHCG: Beta- Human Chorionic Gonadotropin

CHBAH: Chris Hani Baragwanath Academic Hospital

CTOP: Choice of Termination of Pregnancy

GOPD: Gynaecology Out-Patient Department

GTD: Gestational Trophoblastic Disease

HIV: Human Immunodeficiency Virus

ICU: Intensive Care Unit

MI: Mortality Index

MMR: Maternal Mortality Ratio

MVA: Manual Vaccum Aspiration

PID: Pelvic Inflammatory Disease

PMTCT: Prevention of Mother To Child Transmission

TOP: Termination of Pregnancy

TVU: Transvaginal Ultrasound

WHO: World Health Organisation

CHAPTER 1

PROTOCOL AND EXTENDED LITERATURE REVIEW

1.1 Introduction and background

The World Health Organisation (WHO) defines maternal near-miss as a severe maternal complication, where a woman could have died but survived due to medical or surgical intervention. Near-miss are potentially life-threatening conditions during pregnancy and after termination of pregnancy. The WHO have formulated a near miss-approach tool as a form of evaluating the quality of care for pregnancy related complications [(1)].

Early pregnancy is a pregnancy at less than 24 completed weeks of gestation [(2)].

1) ***Ectopic pregnancy***: Any pregnancy implanted outside of the endometrial cavity [(3)]. The most common complication of which is rupture, with internal bleeding which may lead to hypovolaemia. It is the leading cause of pregnancy-related death in the first trimester [(4).]
2) ***Termination of Pregnancy***: The spontaneous or artificially induced (medically or illegally) expulsion of an embryo or fetus prior to viability [(5)]. Possible complications include retained products of conception, persistent bleeding and sepsis [(6)].
3) ***Miscarriage:*** The spontaneous loss of a pregnancy before 12 weeks' gestation (early) or from 12 to 24 weeks gestation (late). Complications include haemorrhage and sepsis [(7)].
4) ***Molar pregnancy:*** Gestational Trophoblastic Disease. An abnormal pregnancy state in which a non-viable fertilized ovum implants in the uterus. The chorionic villi grow in clusters/ cystic masses and this pregnancy does not reach viability [(8)]. Acute complications include haemorrhage, with vaginal bleeding remaining the most common presenting symptom [(9)].

Data on maternal near-miss is well documented in South Africa and worldwide, however does not adequately describe the frequency and causes of near-miss in early pregnancy (<24 weeks gestation).

Table 1: WHO Maternal Near Miss Criteria [(10)].

Clinical criteria	
Acute cyanosis	Loss of consciousness lasting ≥ 12 hours
Gasping	Loss of consciousness AND absence of pulse/ heart beat
Respiratory rate >40 or <6/min	Stroke
Shock	Uncontrollable fit/total paralysis
Oliguria non-responsive to fluids or diuretics	Jaundice in the presence of pre-eclampsia
Clotting failure	
Laboratory-based criteria	
Oxygen saturation <90% for ≥60min	Ph <7.1
PaO2/FiO2 <200mmHg	Lactate > 5
Creatinine ≥300µmol/l or ≥3,5mg/dl	Acute thrombocytopenia (Platelets <50 000 /µL of blood)
Bilirubin > 100µmol/l or >6,0mg/dl	Loss of consciousness AND the presence of glucose and ketoacids in urine
Management-based criteria	
Use of continuous vasoactive drugs	Intubation and ventilation for ≥ 60 minutes not related to anaesthesia
Hysterectomy following infection or haemorrhage	Dialysis for acute renal failure
Transfusion of ≥5 units red cell transfusion	Cardio-pulmonary resuscitation (CPR)

1.2. Extended Literature Review

1.2.1. Maternal death and near-miss in early pregnancy

Extensive research has been done globally on maternal deaths: the causes, risk factors, and avoidable factors. The incidence of maternal death varies greatly between geographical areas. Studies in Europe have shown that the risk of a woman dying as a result of pregnancy or childbirth during their lifetime is 1:30 000 compared to 1:6 in the poorest countries in the world. The global estimate of the life-time risk for maternal death is 1:74 (i.e. 1 in 74 women will die from a pregnancy related cause) [(11)].

In recent years, great efforts have been made worldwide to reduce the number of maternal deaths and improve overall maternal health. In accordance with this, the 5th Millennium Development Goals was developed in order to promote efforts to reduce maternal mortality in every country by 75% between 1990 and 2015 [(11)].

The burden of maternal mortality is greatest in Sub-Saharan Africa and South Asia where a substantial proportion of maternal deaths occur in healthcare facilities [(11)]. The majority of maternal deaths occur in the third trimester (from 28 weeks onwards), up until the first week postpartum. Obstetric haemorrhage has been the main direct cause of maternal death in many countries, with 166 000 estimated deaths occurring worldwide each year as a result of haemorrhage, and 50% of the deaths occurring in Sub Saharan Africa [(11)].

According to the South African Saving Mothers Report, non-pregnancy related infection was the leading cause of maternal death between 2011 and 2013, accounting for 34% of maternal deaths. This figure is mostly related to the high prevalence of HIV in the antenatal population in South Africa. Obstetric haemorrhage was the second highest cause accounting for 16% of the deaths, followed by hypertensive disease in pregnancy at 14% [(12)].

The World Health Organisation (WHO) defines a maternal near-miss as a severe maternal complication, where a woman could have died but survived due to medical or surgical interventions. These potentially life-threatening conditions are found during pregnancy and up to 42 days after termination thereof . The WHO formulated a near miss approach tool to evaluate the quality of care for pregnancy related complications [1].

Early pregnancy is a pregnancy at less than 24 completed weeks of gestation [2] . Ectopic pregnancy is a pregnancy in which the fetus develops outside of the uterine cavity [3] . The rate of ectopic pregnancy is 11 per 1000 pregnancies, with a maternal mortality of 0.2 per 1000 estimated ectopic pregnancies. Improving the diagnosis and management of early pregnancy loss is important, in order to reduce the incidence of the associated psychological morbidity and avoid the unnecessary deaths of women with ectopic pregnancies [13].

The termination of a pregnancy is the spontaneous or artificially induced expulsion of an embryo or fetus prior to viability. Possible complications include retained products of conception, persistent bleeding and sepsis [5,6]. Nearly one-half of TOPs occurring worldwide are considered unsafe. These can result in maternal morbidity and mortality. Despite this, an estimated 21.6 million TOPs continue to be performed unsafely each year, resulting in the death of an estimated 47 000 women and disabilities in 5 million women [14]. Prevention of unsafe termination of pregnancies is important and requires a multi-disciplinary approach, including the provision of contraception and expanded access to safe termination of pregnancy [14].

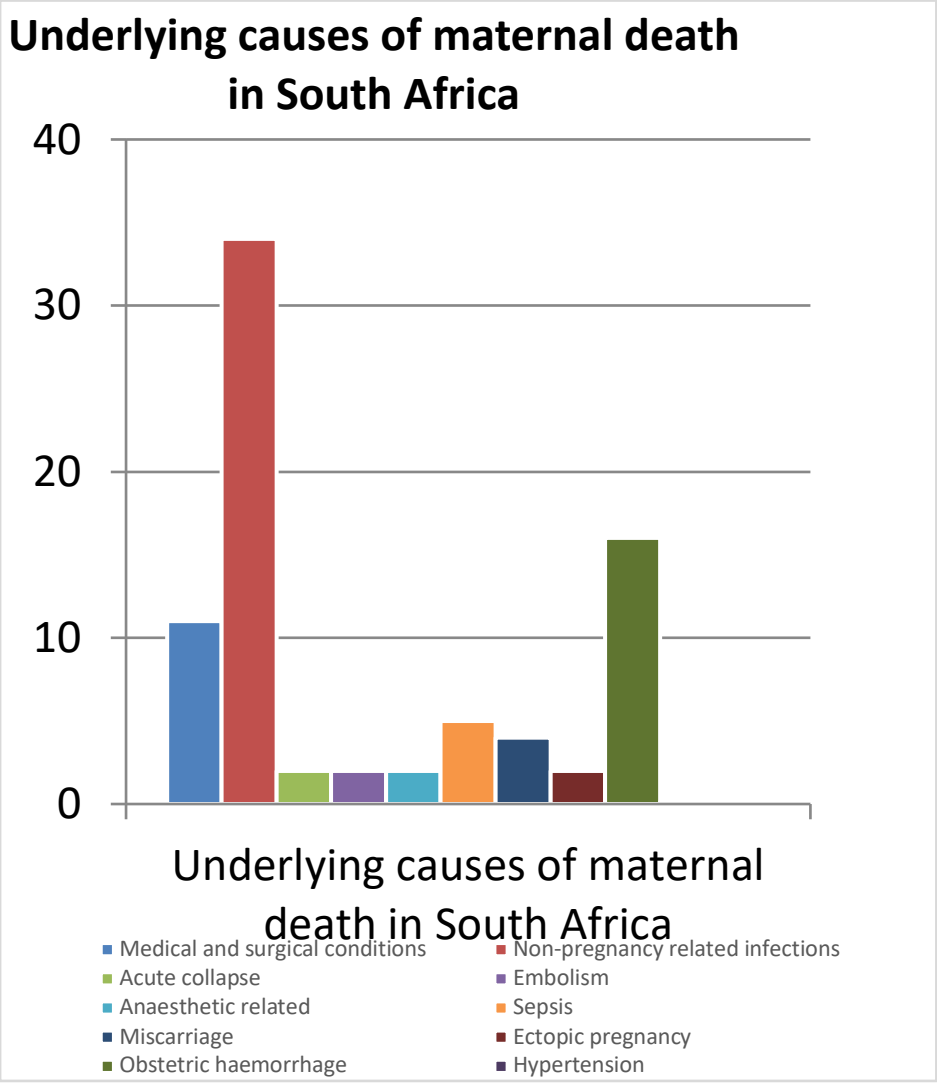
A miscarriage is the spontaneous loss of a pregnancy before 12 weeks (early miscarriage) or from 12 to 24 weeks (late miscarriage) of gestation [7] . In an incomplete miscarriage, the products of conception are passed but some remain retained in-utero. Complications include

haemorrhage and sepsis. A septic miscarriage occurs when the tissue from a miscarriage (frequently incomplete) becomes infected, carrying the risk of septicaemia [7].

Gestational Trophoblastic Disease is an abnormal pregnancy state in which a non-viable fertilised embryo implants in the uterus. The chorionic villi grow in clusters/cystic masses and this pregnancy does not reach viability [8].

As per The Saving Mothers Report, non-pregnancy related infections accounted for 36% of maternal deaths between 2011 and 2013 [12]. Obstetric haemorrhage accounted for 16% of the deaths while miscarriage (4%) and ectopic pregnancies (2%) were also shown to be significant contributors to maternal mortalities [12]. These are illustrated in the graph below:

Figure 1: Underlying causes of maternal death in South Africa 2011- 2013. Reproduced from Saving Mothers Report 2011-2013, National Committee for Confidential Enquiry [12].



In the South African Annual report and detailed analysis of maternal deaths due to non-pregnancy related infections in 2014, ectopic pregnancy and spontaneous miscarriage in early pregnancy were found to be a cause of death in 1.8% and 3.5% of all the maternal deaths respectively. Gestational Trophoblastic Disease related death was found in two cases (4.7%) [15].

Seventy-five percent of the women who died due to ectopic pregnancy and 72% of women who died following miscarriage were HIV positive. However, there were still a considerable number of deaths due to ectopic pregnancy and miscarriage where the HIV status was unknown or where testing had been declined. HIV positive women may often have additional chronic illnesses or risk factors that contributed to the adverse pregnancy outcome [15].

Unsafe termination of pregnancy still remains a cause of maternal deaths in South Africa accounting for 3.4% of deaths [15]. Legal termination of pregnancy was not a major cause of death as only two women had died. This is most likely due to the Choice of Termination of Pregnancy Act in South Africa which allows for safe termination upon request up to 12 weeks of gestation. The act also allows for termination up to 20 weeks' gestation in certain circumstances including undesirable socio-economic conditions of the mother [16] . There were, however, a few deaths as a consequence of sepsis. These deaths are possibly as a consequence of inequities in the coverage of termination of pregnancy services and deficiencies in contraceptive programs [15].

Souza JP et al conducted a cross-sectional study between 2010 and 2011 describing women attending health care facilities across 29 countries in Asia, Latin America, Africa and the Middle East. During this period, 2 538 (0.8%) out of 314 623 women were classified as near-misses with 486 (0.15%) maternal deaths [17]. Of the 2 538 potentially life-threatening events associated with early pregnancy, 4% were related to ectopic pregnancy and 11.6% due to TOP (9.3% TOP related haemorrhage and 2.3% TOP related infection). It was concluded that universal coverage of life-saving interventions need to be coupled with comprehensive emergency care and efforts to improve the quality of maternal health care, if reduction in maternal mortality is to be achieved [17].

During a one-year prospective descriptive multi-center study at the Kalafong and Pretoria Academic hospitals in South Africa, there were 13 429 deliveries, 147 (1.1%) of them were classified as near-miss. Forty-four (29%) of the near-misses were due to a gynaecological emergency in early pregnancy [18]. Pattinson et al conducted a prospective, descriptive study in both rural and urban settings of South Africa (Orange Free State, Pretoria and Greater Soweto). The objective of the study was to assess whether near-miss cases can be used as a surrogate measure for analysis of maternal deaths to describe the pattern of severe maternal disease and avoidable factors. A total of 551 women were studied over a two year period. Four hundred and twenty-three (77%) of the women had a near-miss and 128 (23%) of the cases were maternal deaths [19]. A higher proportion of women in the maternal death group (42.2%) had not sought any antenatal care in comparison to the near-miss group . The greatest number of near-misses and deaths occurred at more than 28 weeks' gestation. The four most common causes of near-miss were complications of hypertension (27.2%), postpartum haemorrhage (18.0%), antepartum haemorrhage (12.8%) and TOP (11.3%). Thirty (7.1%) of the near-misses and four (3.1%) deaths occurred due to ectopic pregnancy. This study concluded that review of near-misses gives information that compliments the findings of confidential maternal death enquiries. Because the leading causes of maternal death are different to the leading causes of near-miss, measuring the mortality index for each cause estimates the likelihood of a condition to lead to death. [19].

O'Herlihy conducted a study between 2006 and 2008 for the Centre for Maternal and Child Enquiries in Ireland [20]. The aim of the study was to identify women who had died due to a pregnancy-related complication before 24 weeks gestation and to look at the contributing factors. A total of 14 women were identified, six of the deaths (43%) occurred as a consequence of a ruptured ectopic pregnancy and five (36%) as a result of haemorrhagic complications following spontaneous miscarriage. Two (14%) died of sepsis associated with a spontaneous

miscarriage (9 to 16 weeks' gestation) and one as a result of haemorrhage from a molar pregnancy. Substandard care was recognised in 54% of the cases. In these women, earlier diagnosis and better treatment may have possibly prevented death. The number of deaths could have been less if medical personnel were aware of the importance of identifying the early symptoms of an ectopic pregnancy as well as the complications associated with a second trimester miscarriage [(20)].

In South America, a study by Madeiro et al in the northern part of Brazil focused on maternal death and near miss over a six-month period. In total ten (0.2% of all deliveries) maternal deaths and 56 (0.95% of all deliveries) cases of near miss were identified out of a total of 5841 live births. Of the near miss cases, only two (3.6%) were due to early pregnancy complications (one ectopic pregnancy and one septic termination of pregnancy). Three out of the ten maternal deaths were due to septic TOP. It was not possible to distinguish between spontaneous and induced TOP but infection- related complications are a known and common cause of morbidity and mortality in unsafe TOPs. Women who were unmarried and had TOPs after 14 weeks of pregnancy were found to be at the greatest risk of near miss or death [(21)].

Bashour et al conducted a cross sectional study of maternal near miss cases amongst major public hospitals in four middle-eastern countries. The overall maternal near miss ratio was 7.8 per 1000 live births. A total of 6 maternal deaths and 71 near miss cases were identified out of 9 063 deliveries across the four regions. Only 11 (14.5%) of the near miss cases were due to early pregnancy conditions including eight ectopic pregnancies and three TOP related complications. Haemorrhage-related complications were the most frequently found conditions among maternal near-miss cases across the hospitals. Women who experienced near miss were found to be older and less educated. Coagulation dysfunction followed by cardiovascular dysfunction were the most prevalent type of organ dysfunction in the population. Use of the

WHO tool showed improvement in the overall quality of care in women presenting with complications in pregnancy [22].

The mortality index was introduced by Vandecruys et al in 2002; it is calculated by dividing the number of maternal deaths by the combined number of maternal deaths and near miss events, expressed as a percentage [23] .The ratio shows the proportion of women with near-miss who subsequently demise and provides a measure of the quality of the healthcare service with regard to managing certain disease processes. The lower the mortality index the better the care provided [23]. The ratio was initially used by Vandecruys et al in order to compare near-miss and maternal mortality in the Pretoria Academic Hospital Complex, South Africa, for the year 2000 and the years 1997-1999 [23]. A subsequent study was performed in the Pretoria Academic Hospital Complex by Cochet et al [24]. Maternal deaths and near-miss were identified between 1 January 2000 and 31 December 2001. In 2000, the combined number of women with near-miss and maternal deaths was 94 (76 with near-miss and 18 maternal deaths) with a rate of 649/100 000 live births. In 2001 there were 147 in total (131 with near-miss and 16 maternal deaths) and the rate was 889/100 000 live births. Despite a significant increase in the number of women with near-miss events during 2001, the mortality index decreased from 19.1% in 2000 to 10.9% in 2001. This implies that the care of severely ill pregnant women improved in the Pretoria Academic Complex during 2001. Despite the increase in actual numbers, the quality of care provided remained consistent or even improved [24].

1.2.2. Massive haemorrhage in early pregnancy

The use of blood products is a critical life-saving intervention [25]. A massive blood transfusion is defined as the use of four or more units of blood products following maternal haemorrhage.

Massive haemorrhage in early pregnancy is rare but can be life threatening. Spontaneous miscarriage is the most common cause of vaginal bleeding in early pregnancy. Molar pregnancy should always be considered as a differential diagnosis if there is unusually heavy vaginal bleeding [25].

In the United Kingdom (UK) the Centre for Maternal and Child Enquiries (CMACE) reported, six deaths that resulted from haemorrhage in early pregnancy between 2006 and 2008 [26]. Five deaths due to haemorrhage following a spontaneous miscarriage occurred in the same time period. Seven deaths occurred secondary to sepsis in early pregnancy and were categorized separately. Two out of the seven deaths were associated with miscarriages between 9 and 16 weeks' gestation and a further two following termination of pregnancy (one surgically induced and the other medically induced). The ages of the women who died ranged between 21 and 41 years (median 36 years). Substandard care was considered to be a significant contributor. The study concluded that the number of women dying before 24 weeks gestation due to haemorrhage was less than in any previous studies in the UK. However, the numbers could have been lower if health-care workers were aware of the importance of timeously diagnosing early symptoms of ectopic pregnancy. Use of the WHO near-miss criteria helps in identification and adequate management of women at risk of death from massive haemorrhage in early pregnancy [26].

1.2.3. Ectopic pregnancy

Ectopic pregnancy is a recurrent medical condition that is an important cause of maternal mortality and morbidity in low-income and middle-income countries. The incidence is 1-2% (10 – 20/1000 live births) in low and middle-income countries. The overall incidence is increasing worldwide, possibly due to an increase in Pelvic Inflammatory Disease [27].

In South Africa, 1.8% of maternal deaths occurred following ectopic pregnancy between 2011 and 2013[12]. The large majority of the women (91%) presented at less than 20 weeks' gestation with only 9% at more than 20 weeks [12]. Anaemia was found to be a considerable risk factor for death due to ectopic pregnancy, 33.3% of the women with ectopic pregnancy were found to be anaemic [12]. According to the South African Saving Mothers Report 2011-2013, the highest number of deaths as a consequence of ectopic pregnancy and miscarriage occurred in Gauteng. They accounted for 2% and 3.6% of the statistics respectively. This may be due to the fact that Gauteng province has the highest population concentration in the country [12].

A case-control study conducted in 2012, in the Netherlands, aimed to determine the association between patient-related risk factors and severe maternal morbidity in women with tubal ectopic pregnancy [28]. They compared 29 women with severe abdominal haemorrhage requiring transfusion to 99 control women who were haemo-dynamically stable. The study did not identify any patient related factors for the risk of severe haemorrhage. Findings showed that in 43% of women, substandard care (particularly misdiagnosis) was involved [28].

In Brazil, a multi-centre cross sectional study was conducted, with prospective surveillance in order to assess the occurrence of severe maternal complications associated with ectopic pregnancy. Over a period of 12 months (between June 2009 and May 2010), three hundred and twelve (3.3%) out of the 9 555 women identified with severe complications associated with pregnancy, delivery, or postpartum period, had complications secondary to an ectopic pregnancy. There was one maternal death attributed to ectopic pregnancy. She was a woman who presented to one of the participating centres already in severe haemorrhagic shock after a laparotomy had been performed in another hospital. She subsequently demised [27]. Haemorrhage was the most widely used diagnostic criteria for near-miss in the identification of complicated cases of ectopic pregnancy. Infection was not identified as statistically significant ($p= 0.195$) for morbidity due to ectopic pregnancy. In this study, the near-miss

incidence ratio was 0.3 out of 1000 live births and 0.7% (1/140) for deaths related to ectopic pregnancy, a proportion lower than that observed in all developed countries. No important risk factors for increased severity were identified but there seemed to be deficient or substandard care associated with complicated ectopic pregnancy cases. Despite laboratory and imaging advances that enable early diagnosis and treatment, ectopic pregnancy is still an important cause of maternal death. Improving clinical guidelines and interventions for the prevention of severe morbidity from ectopic pregnancy may reduce near-miss events in women with an ectopic pregnancy [27].

In Nigeria, a retrospective study over a ten year period was done to determine the incidence, pattern of presentation and management of ectopic pregnancies at Usmanu Danfodiya University Teaching Hospital, Sokoto [29]. There were a total of 20 095 deliveries and 7 254 gynaecological admissions in that time period with 298 women (1.5%) presenting with ectopic pregnancy. A total of 163 women (77.3%) were married and 21.3% were single. Almost a third of the women were nulliparous. This was thought to account for the delay in health-seeking behaviour, evidenced by the large proportion (70.1%) of women presenting with a ruptured ectopic pregnancy and 34.1% with haemorrhagic shock. There were no other risk factors identified. The age of the women ranged between 16-40years (mean 26.8 SD ±5.0 years) and the peak age group was 26-30 years. Only 4.3% of the women had a history of a previous ectopic pregnancy, 4.3% had previous pelvic surgery and 9% had a previous termination of pregnancy [29].

Ectopic pregnancy still remains a major gynaecological problem associated with considerable morbidity and mortality. A high index of suspicion and the use of modern diagnostic techniques will assist in early diagnosis obviating the need for radical treatment. In addition, promotion of family planning and prompt diagnosis and adequate treatment of pelvic infections will help to reduce the ectopic pregnancy rate worldwide [29].

1.2.4. Miscarriage

In South Africa, during the period 2011 to 2013, a total of 43 maternal deaths occurred due to miscarriage-related complications. Almost 70% (n=30) of these were due to sepsis. Non-traumatic haemorrhage accounted for 14% of these deaths (n=6) and three cases (7%) had uterine trauma (perforation at evacuation) as a contributory factor towards the final cause of death [12]. Anaemia contributed to maternal death in 25% of the women with miscarriage[12].

Lombaard et al. conducted a retrospective audit on all women that presented to Steve Biko Academic Hospital with a septic incomplete miscarriage from January 2008 to December 2010. The severity of disease and the mode of resuscitation was investigated for each case and women were classified according to the WHO near miss criteria. Nine percent of the 417 cases with near-miss and 30% of the 30 maternal deaths in that period were attributed to septic incomplete miscarriages [30].

1.2.5. Termination of pregnancy

Unsafe TOPs are defined as termination of pregnancy procedures performed by unskilled individuals or conducted in inadequate, ill-equipped environments that do not conform to minimal medical standards [31]. The worldwide burden of unsafe TOP is high [32]. Worldwide, 1 in 10 pregnancies end in an unsafe TOP [32]. It is estimated that they account for 13% of maternal mortalities worldwide [33]. In developing countries, five million women are admitted to hospital every year for treatment due to unsafe TOPs. Limited access to safe TOP services results in a much higher rate of near-miss [33]. A systematic review of 15 studies describing complications of TOPs in an unsafe setting in Africa, Asia and Latin America, was performed by Adler et al [34]. It aimed to determine the near-miss incidence attributed to unsafe TOPs over

a ten year period. Most of the studies were published before the WHO near-miss criteria were developed. The near-miss criteria in the study was based on clinical diagnoses representing organ failure or dysfunction (including hypovolemic shock, sepsis, gangrenous uterus and uterine perforation). The results showed that across three continents, 237 women experienced a near-miss from TOP for every 100 000 live births annually. The use of the WHO near-miss criteria in such cases can greatly enhance our understanding of the factors related to near-miss associated with safe/unsafe TOP [34].

Souza et al. conducted a secondary analysis of data from the WHO Multi-country Survey on Maternal and Newborn Health between May 2010 and December 2011[35]. The objective of the study was to summarise the individual and institutional characteristics of termination of pregnancy related near-miss reported at health care facilities worldwide. Women from a total of 23 countries were involved in the study. Three hundred and twenty-two women with miscarriage/termination of pregnancy-related near-miss and 27 maternal deaths were identified. Haemorrhage was found to be the most common cause for near-miss. Infection, (alone and in combination with haemorrhage), was the most common cause of death. Unintended pregnancy, unsafe TOP and limited health resources were common in the study population and may have influenced how frequently termination of pregnancy-related adverse outcomes occurred [35].

In South Africa, in 2006, Mbele et al. published a study that showed that the mortality index (MI) and maternal mortality ratio (MMR) due to TOPs had declined significantly over the 10 years following the implementation of The Choice of Termination of Pregnancy Act in 1996 [36]. However, it was also found that the prevalence of critically ill women due to complications of TOP remained the same. They concluded that further reduction in morbidity and mortality could be achieved by increasing the number of healthcare facilities offering second-trimester TOPs and by addressing the barriers associated with access to the services. These will further

reduce the morbidity and mortality of unsafe TOPs and the number of critically ill women presenting as a consequence thereof [36].

In 2015, Doran F. and Nancarrow S. conducted a systematic review of literature published between 1993 and 2014 on the barriers and facilitators of access to first-trimester TOP services for women in the developed world. Included papers were from the United States of America, Canada, Australia, New Zealand, Sweden, Northern Ireland/Norway and the United Kingdom. From the perspective of TOP service providers, barriers included moral opposition to TOP, lack of training, too few physicians, staff harassment and insufficient hospital resources [37]. The women expressed barriers to include the lack of access to TOP services (distance and lack of service availability), negative attitudes of the staff and the associated costs of the procedure. The conclusion from the review was that access to termination of pregnancy services can be enhanced by increasing training, increasing the range of service options (e.g. the use of telehealth, which is the provision of the access to termination of pregnancy services telephonically to reduce travel costs and waiting times) and increasing the availability of clear referral guidelines of women to alternative providers in the case where staff members have moral opposition to TOP. The evidence suggested that despite the fewer legal barriers to accessing TOP services, women in developed countries still face inequities when considering the level of quality and access to the services [37].

Between 2006 and 2007, Harris J. et al. conducted 34 interviews and one focus group discussion with health care providers who were involved in a range of TOP service provision in the Western Cape Province in South Africa [38]. They aimed to explore the personal and professional attitudes of the individuals working in the TOP service sector. Conscientious objection was recognised in the form of refusal to open files for the women, refusal to provide the requesting women with basic nursing care, refusal to prescribe or administer the necessary medication and refusal to assist in the operating room. Rape, incest, foetal abnormalities and

poor socio-economic circumstances were considered as legitimate reasons for seeking a safe TOP among both providers and non-providers. Providers who were "pro-choice" maintained that a lack of objectivity regarding a woman's right to choose arose from pre-judgment of women as irresponsible without considering the long term consequences of an unplanned pregnancy. Providers also expressed feeling stigmatized and isolated, coupled with the struggle to endure the comments and attitudes of their fellow colleagues. Areas of conflict included staff members feeling that there was a possibility that women were using termination of pregnancy as a means of contraception. Women requesting TOP were also perceived as sexually irresponsible. Recommendations from the study were the strengthening of contraceptive counselling and its integration into post TOP care. Psychosocial needs of providers need to be acknowledged and addressed. Support programs for providers may improve utilization of TOP services [38].

1.2.6. Gestational trophoblastic disease

Sun et al published a report which described the frequency of potentially life-threatening conditions and maternal near-misses amongst women with hydatidiform mole [39]. Data was collected from the New England Trophoblastic Disease Centre between 1994 and 2013. Only six women (1.6%) developed complications such as severe haemorrhage, severe pre-eclampsia or respiratory distress which may have necessitated blood transfusion or ICU admission. When using the WHO near-miss criteria, none of the 375 women with molar pregnancy suffered a near-miss event and there were no maternal deaths. It seems that there is a low rate of potentially life threatening conditions occurring with molar pregnancy, however this study was done in a well-resourced setting. There is a scarcity of data from low and middle income studies on death or near-miss from gestational trophoblastic disease [39]. A review of the management

outcomes of hydatidiform mole in south east Nigeria by Igwegbe and Elejed showed a case fatality rate of almost ten percent [40]. This was much higher than the study by Sun et al [39]. All of the maternal deaths in the Nigerian study were in women who had presented with irreversible shock suggesting that GTD is associated with massive haemorrhage [40].

1.2.7. Avoidable factors

With the introduction of antiretroviral therapy, the maternal mortality rate in South Africa has decreased significantly since 2011. However, of all the maternal deaths reviewed by the Confidential Enquiries in maternal death committee, 57.3% were found to be potentially preventable. Lack of appropriately trained doctors was recognised as an avoidable factor in 16.9% of the maternal deaths and lack of appropriately trained nurses in 10% of the cases. This resulted in an overall contribution of 41.2% and 24.3% respectively towards avoidable factors in preventable deaths. The majority of the avoidable factors were identified at district hospital level. Common areas of substandard care included problems with recognition of the diagnosis (24.1%) and failure to follow standard protocols in 25.7% of the maternal deaths [12].

In the descriptive study by Pattinson et al. medical personnel were identified as a large contributor to maternal morbidity and mortality. Over 50% of near-misses and almost 55% of maternal deaths were due to health care worker related factors. Issues identified included errors in the initial assessment of the women, problems in making a diagnosis and poor or inadequate patient monitoring. The most important factor was the implementation of a poor management plan which contributed to 25.8% of the near misses and 22.7% of the deaths [41].

1.2.8. Near-miss: An effective diagnostic tool

Near-miss events occur approximately five times more frequently than maternal deaths. By including women with near-miss in maternal death audits, the number of cases increases five-fold [24]. With the increase in numbers of cases identified, data can be collected more quickly allowing faster identification and correction of problems in health care systems [24]. It provides researchers with an end point that is clinically meaningful and occurs more frequently than maternal death [18].

With the introduction of confidential enquires into maternal death programs in numerous countries around the world, the general causes of maternal deaths in many regions have been identified and steps taken to prevent them. The near-miss audit has the added benefit of identifying commonly occurring regional disease patterns and progression, therefore helping to focus development of skills and health care resources in certain areas to manage cases effectively. The near-miss audit also provides greater benefit to clinicians and managers as it provides a clearer view of morbidity in their local communities. This more detailed and specific information can be used to create preventative programs and guide the allocation of heath care resources [18].

1.3. Aims and objectives

Aim of the study

The aim of the study is to determine the frequency, risk factors and severity of near-miss and maternal mortality in early pregnancy.

Objectives

- To determine the frequency of maternal near-miss occurring at less than 24 weeks gestation as a consequence of ectopic pregnancies, termination of pregnancies, miscarriages and molar pregnancies at Chris Hani Baragwanath Academic Hospital Obstetrics and Gynaecology Complex.
- To determine the mortality index in early pregnancy
- To determine the causes of and risk factors associated with near-miss and maternal deaths in early pregnancy

Methodology

Setting

The study will take place at Chris Hani Baragwanath Academic Hospital (CHBAH), a tertiary hospital in Soweto. CHBAH has over 20000 deliveries a year. The Gynaecology department has a Gynaecology Outpatient Department, a Cold-case clinic, a Follow up clinic, a Colposcopy unit, a Termination of pregnancy unit, a HIFU unit and 2 gynaecology theatres. The department has a monthly maternal mortality meeting, and a weekly near-miss meeting. All near-miss cases are recorded in a near-miss book and are reported to the Head of Department daily.

Study population

Case records of all women at <24 weeks gestation meeting the near miss criteria who presented at CHBAH over the period 1 January 2015 to 31 December 2016 will be used to collect data. All-near-miss and maternal deaths occurring at less than 24 weeks gestation will be included. Women meeting the management-based criteria as per the WHO Near-Miss will be included.

Cases that do not meet the criteria will be excluded. Women who are under the age of 18 years and those who did not give consent will be excluded from the study.

Inclusion criteria

Women over the age of 18 years with a gestational age of less than 24 weeks or within 42 days after the end of a pregnancy of less than 24 weeks with one or more of the following events:

- Hysterectomy
- Relook laparotomy
- Intensive care unit admission
- Cardio-pulmonary resuscitation
- Use of inotropes
- Ventilation for more than 60 minutes
- Renal Dialysis
- Transfusion of 4 or more units of red packed cells
- Death

Sample Size

A period sample will be used with no sampling strategy. According to the departmental statistics there are approximately 20 women classified as near-miss in early pregnancy a year.

Study design

This will be a retrospective cross-sectional study. Data will be collected from case records. The interventional near-miss criteria will be used to identify patients. Patient demographics, the nature of the pregnancy and near-miss event will be described. Clinical, laboratory and interventional near-miss criteria as well as associated avoidable factors will also be described.

Data source

A record of near-miss cases is kept in the department. Case reports of identified women will be acquired from the Records Department and data collected from them. Records from Main ICU, Main High Care, Maternity High Care and Gynaecology Theatre records will also be utilized. National Health Laboratory Service reports will be viewed. The information will be used to complete a data collection sheet. No patient interviews will take place as part of the study.

Data analysis

Descriptive data analysis will be used, using means ± standard deviations for normally distributed data; medians and ranges for non-normally continuous data; proportions and percentages for categorical data. Precision will be managed using 95% confidence intervals. Hypothesis testing will explore Chii-squared, Mann-Whitney or Fischer's exact to explore associations.

Ethics

Ethics approval has been obtained from the Human Research Ethics Committee (HREC) of the University of Witwatersrand (M170464). Permission to perform the study has been obtained from the CHBAH CEO.

Funding/budget

Printing and travel costs will be covered by the researcher. All running expenses will be covered by the researcher.

Timeline

- Ethics application- April 2017
- Data collection- June 2017 to August 2017

- Data analysis- September 2017
- Write up- October 2017 to December 2017

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CHAPTER 2: SUBMISSIBLE ARTICLE

TITLE: An audit of Near-miss in early pregnancy at Chris Hani Baragwanath Academic Hospital, Soweto, South Africa.

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Short Title: Near-miss in early pregnancy in South Africa

Conflict of Interest: None

Keywords: near-miss, maternal death, early pregnancy, ectopic pregnancy, miscarriage, termination of pregnancy, gestational trophoblastic disease

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ABSTRACT

Introduction

The concept of maternal near-miss is well documented in South Africa and worldwide, however causes of near-miss in early pregnancy (<24 weeks gestation) need further exploration. A near-miss is a woman who had a life-threatening complication due to pregnancy or childbirth up to 42 days after delivery.

Objectives

To determine the frequency and severity of maternal near-miss occurring at less than 24 weeks gestation as a consequence of ectopic pregnancies, termination of pregnancies, miscarriages and molar pregnancies at the Chris Hani Baragwanath Academic Hospital.

Methods

This was a retrospective audit of near-miss in early pregnancy cases occurring between 1 January 2015 and 31 December 2016. Case records were reviewed and data was collected by the researcher.

Results

Thirty-nine cases of near-miss and 1 maternal death from early pregnancy were found over a 2 year period. Of these, 18 women had a near-miss as a result of ectopic pregnancies (46.1%), 13 from miscarriages (33.3%), 7 as a consequence of termination of pregnancy (18.0%) and 1 from a molar pregnancy (2.6%). HIV status and antenatal care booking status were amongst the most recognized risk factors. Twenty (51.3%) of the women were HIV positive and 36 (92.3%) of them had not had any antenatal care visits prior to hospital admission. All the women who had a termination of pregnancy had done so illegally and all women with an

ectopic pregnancy were found to have already ruptured at the time of presenting to hospital. Septic shock occurred in 3 (42.9%) out of the 7 women with an unsafe termination of pregnancy. The majority (60%) of the women required a blood transfusion of ≥4 units. Five (13.5%) women had a hysterectomy as a consequence of haemorrhage or sepsis and 19 women (51.4%) required high care or intensive care admission. Patient related avoidable factors included unsafe termination of pregnancy (18.9%) and delay in seeking medical attention in 27% of the cases.

Conclusion

Ectopic pregnancies and unsafe termination of pregnancies were the most frequent causes of near-miss in early pregnancy, resulting in severe haemorrhage and sepsis. This suggests that early ultrasound to diagnose ectopic pregnancy, and access to safe TOP services and contraception can prevent severe morbidity and mortality. Improving access to antenatal care services, coupled with patient education can improve maternal outcomes in women early in pregnancy.

INTRODUCTION

Women play a crucial role in the social, economic, and cultural activities of their society. Preserving the health of women improves the economic and social well-being of communities. The majority of maternal deaths occur late in pregnancy with a small minority occurring at less than 24 weeks gestation[1]. There are comparatively few studies detailing the incidence and prevalence of near miss events due to early pregnancy complications such as ectopic pregnancy, miscarriage, termination of pregnancy and gestational trophoblastic disease.

According to the South African Saving Mothers Report 2011-2013, 1,8% (80 out of 4 425) of maternal deaths were as a consequence of ectopic pregnancy and 43 (1%) deaths occurred due to miscarriage [2]. The Choice of Termination of Pregnancy Act was introduced in South Africa in 1996 [3]. By 2006 studies showed a reduced mortality index (MI) and maternal mortality ratio (MMR) from termination of pregnancies, although the number of critically ill women presenting with complications due to TOP remained the same [4].While most women survive complications of pregnancy, a much smaller proportion develop life-threatening complications and some of the women die. Evaluating the cases of women who survive life threatening pregnancy complication can enlighten us about the processes in place, or lack thereof, for adequate care of pregnant women [5].

A near-miss occurs when a woman has a life-threatening complication due to pregnancy or childbirth up to 42 days after delivery or termination of pregnancy [6]. The benefit of a near-miss audit is that it provides a more inclusive view of disease patterns. It can guide clinicians and policy makers in determining the needs of a community, creating preventative programs and the allocation of health care resources. It provides researchers with an end point that is clinically meaningful and occurs more frequently than maternal death [7]. The aim of this study

was to determine the frequency, associated risk factors and the severity of near-miss in early pregnancy.

Methods

The study took place at Chris Hani Baragwanath Academic Hospital (CHBAH), a tertiary level hospital in Soweto, South Western Johannesburg. Ethics approval was obtained from the Human Research Ethics Committee (HREC) of the University of the Witwatersrand (M170464). Permission to perform the study was obtained from the CHBAH Chief Executive Officer (CEO).

CHBAH has over 20 000 deliveries a year. The Gynaecology department has an Outpatient Department, an emergency department and a Termination of pregnancy unit. There are two gynaecology theatres. All maternal deaths are notified, and near-miss cases are audited and recorded in a near-miss book.

Case records of all women at <24 weeks gestation or within 42 days after the end of an early pregnancy who met the modified management based Near-Miss criteria between the period 1 January 2015 to 31 December 2016 were used to collect data. All maternal deaths occurring at less than 24 weeks were also included. Inclusion criteria consisted of women over the age of 18 years with a gestational age of less than 24 weeks or within 42 days after the end of a pregnancy of less than 24 weeks with one or more of the following events: Hysterectomy, relook laparotomy, Intensive Care Unit admission, Cardio-Pulmonary Resuscitation, use of inotropes, ventilation for more than 60 minutes, renal dialysis, transfusion of 4 or more units of red packed cells or death. Cases that did not meet the above criteria were excluded. Women who were under the age of 18 years and those who did not give consent were also excluded from the study.

This was a retrospective cross-sectional study. Data was collected from case records and a modified management based near-miss criteria tool was used to identify women with adverse events at less than 24 weeks gestation. Patient demographics included age, parity, booking status, history of previous ectopic pregnancy or miscarriages and gestational age. The nature of the near-miss event of death was also described. Clinical, laboratory and management near-miss criteria were described as well as patient, healthcare worker and administrative avoidable factors explored.

Case records of women who met the near-miss criteria were acquired from records and data was collected. Records from Main ICU, Main High Care, Maternity High Care and Gynaecology Theatre were also utilised. The data was extracted onto a data collection tool. No patient interviews took place as part of the study.

A period sample was used with no sampling strategy. According to the departmental statistics there are approximately 20 women classified as near-miss in early pregnancy a year. Case records for 39 cases of near-miss and 1 maternal death in early pregnancy were identified.

Descriptive data analysis was used, using means ± standard deviations for normally distributed data; medians and ranges for non-normally continuous data; proportions and percentages for categorical data.

Results

There were 47 cases of near-miss from early pregnancy identified between 1 January 2015 and 31 December 2016. The women had all presented to the Gynaecology outpatients department at CHBAH as acute emergencies. There was one maternal death from a septic incomplete miscarriage after an unsafe TOP. Of the 47 near-misses recorded, case records were only found

for 39 maternal near-miss cases. One maternal death case record was obtained. It was not possible to ascertain whether the 8 women were correctly classified as near-misses.

The mean age in the study group was 30.6 SD 5.4 (range 23-46) and the mean parity amongst the women was 1.7 SD 0.95 (range 1-4). Thirty-six of the women (92.3%) had not sought any antenatal care prior to presentation. The Rhesus status was unknown in 20 (51.2%) of the women. Some women were tested and 18 of them (46.1%) were Rhesus positive. The Rhesus was negative in one woman. Twenty-three (59%) women tested negative for Syphillis and in 16 (41%) of the women the status remained unknown. None of the women tested positive. Twenty (51.3%) of the women were HIV positive on presentation and 13 (33.3%) were HIV negative. The HIV status was unknown in 6 (15.4%) of the women. Of the 20 HIV positive women, eight belonged to the ectopic group (40% of HIV positive group). This made up 44.5% of the entire ectopic pregnancy population. Patient characteristics are summarised in table 4.1 below.

	Frequency (percentage) **N=39**		
Mean Age	30.6 (SD 5.4)		
Mean Parity	1.7 (SD 0.95)		
Booking status: - Unbooked - Booked	 36 (92.3) 3 (7.7)		
Rh status: - Positive - Negative - Unknown	 18 (46.1) 1 (2.6) 20 (51.2)		
RPR: - Positive - Negative - Unknown	 0 23 (59) 16 (41)		
HIV status: - Positive - Negative - Unknown	 20 (51.3) 13 (33.3) 6 (15.4)		
HIV status according to index pregnancy: - Ectopic (n=18) - Miscarriage (n=13) - TOP (n=7) - GTD (n=1)	**Positive** 8 (44.5) 8 (61.5) 4 (57.2)	**Negative** 7 (38.8) 2 (15.4) 3 (42.8) 1(100%)	**Unknown** 3 (16.7) 3 (23.1) 0
Antiretroviral treatment: - Yes - No	**N=20** 12 (60) 8 (40)		

Table 2. Patient characteristics

Ectopic pregnancy was the leading cause of near-miss (18 women =46.1%), followed by miscarriages (33.3%). Seven women (18%) presented with complications due to termination of pregnancy and only one woman (2.6%) had gestational trophoblastic disease. Most of the women (92.3%) had not started antenatal care prior to admission. Over half (51.3%) were HIV positive. The majority (60%) of them were already on antiretroviral treatment. The percentages of HIV positive women were higher in the subgroups of TOPs (57.2%) and miscarriages (61.5%). Almost 45% of the women with an ectopic pregnancy were HIV positive.

Three out of the 39 near-misses (7.7%) had an ectopic pregnancy in a previous pregnancy. Two of them presented with a second ruptured ectopic pregnancy. Nine (23%) of the near-misses had a history of one or more miscarriages in a previous pregnancy. The woman diagnosed with gestational trophoblastic disease, had a total of seven previous miscarriages.

Only one woman with an ectopic pregnancy (5.6%) was unruptured at presentation. All of the women who presented following TOP had had an unsafe termination. This also applied to the maternal death following TOP. Of the 13 women who had a miscarriage, 12 (92.3%) presented with an incomplete miscarriage and one (7.7%) with a missed miscarriage.

The only woman with GTD (2%) presented with a recurrence of the disease at 16 weeks' gestation. The mean gestation in this study population was 11.7weeks (SD ±5.87). Over half of the population (53.8%) were between 4 and 12 weeks' gestation. Fifteen (83.3%) of the ectopic pregnancy women were between 4 and 12 weeks' gestation. In the miscarriage group, there was an equal distribution of women between 4 and 12 weeks' gestation and 13 to 20 weeks' gestation (46.5%). Five women (71.4%) in the TOP group were between 13 and 20

weeks' gestation with the remaining 2 (28.6%) between 21 and 24 weeks gestation. The maternal death case was at 23 weeks' gestation.

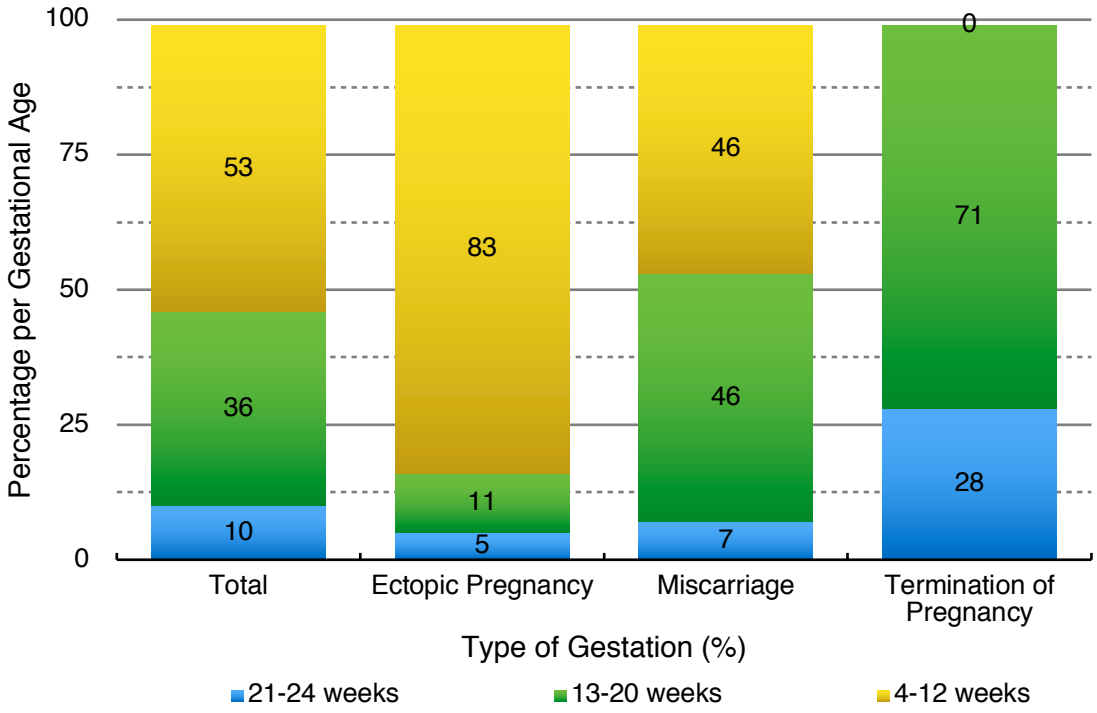

Figure 2: Gestational Age of Index Pregnancy

Diagnostic criteria for near-miss

Sixteen women (41%) had a lactate >5. The highest number of women with an increased lactate level was in the ectopic pregnancy group. They made up 7 (44%) of the 16 women in the entirety and 38.9% of the 18 total ectopic pregnancies. A pH of <7.1 was found in 20.5% (n=8) of the near-miss women. Two women (25%) were in the miscarriage group, four (50%) in the ectopic group and the remaining 25% in the TOP population. Thrombocytopenia, defined as platelets less than 50 000/µL of blood, was found in eight of the women (20.5%). There was an equal distribution in numbers between miscarriages and TOPs represented (3 each). A creatinine >300mg/dL was found in 5 women (12.8%) with 4 (80%) of them as a result of TOP. The other woman had an ectopic pregnancy. A decreased PaO2/FiO2 ratio was found in 3

women (7.7%). Increased bilirubin (>6) was found in 8 of the women (20.5%). More than 75% of all near-miss women presented with shock. The maternal death case also met this criteria. Fourteen out of the 39 women (47%) were in the ectopic pregnancy group. This made up 77.8% of the women with an ectopic pregnancy. Thirty-three percent (n=10) of the total near-misses with shock were in the miscarriage group, making up 76.9% of the miscarriage population. Six out of the seven TOP cases (85.7%) had hypovolemic shock. Oliguria not responding to fluids or diuresis was found in 5 (12.8%) of the near-misses and also in the maternal death case. Three of these (60%) were as a result of TOP and the remaining 40% (n=2) were in the ectopic group. Clotting failure was diagnosed in 4 of the near-misses (10.2%). TOP women made up 3 (75%) of these, therefore 43% of the total TOPs. One of the miscarriages had an increased respiratory rate.

	Miscarriage (n=13)	Ectopic (n=18)	TOP (n=7)	TOTAL (n=39)
MANAGEMENT BASED CRITERIA				
Vasoactive drugs	4 (0.8%)	1 (5.6%)	4 (57.4%)	9 (23%) *1 Maternal death
Hysterectomy	0 (0%)	1 (5.6%)	3 (42.9%)	4 (10.2%)
Transfusion	9 (69.2%)	8 (44.4%)	6 (85.7%)	23 (59%) *1 Maternal death
Dialysis	0 (0%)	1 (5.6%)	2 (28.6%)	3 (7.7%)
Prolonged intubation	11 (84.6%)	16 (88.9%)	6 (85.7%)	34 (87.2%) * 1 GTD *1 Maternal death
CPR	0 (0%)	0 (0%)	0 (0%) *1 Maternal death	0 (0%)
ICU admission	7 (53.8%)	7 (38.9%)	5 (71.4%)	19 (48.7%)

Table 3: Management Based Criteria

Management based criteria is indicated in Table 3 above. Almost a quarter of the women (23%) required vasoactive drugs. More than half of the women required transfusion of blood products.

Approximately 85% or more of women in each group required prolonged intubation however, less than 50% were admitted to ICU.

All of the three women requiring hysterectomy following TOP had developed complications secondary to unsafe termination of pregnancy. They all presented in septic shock with subsequent multi-organ failure. The woman with an ectopic pregnancy who required hysterectomy was found to have a left broad ligament ectopic pregnancy at eight weeks gestational age. A hysterectomy was performed following intraoperative complications and massive haemorrhage.

37 women required a blood transfusion (36 near-misses and 1 maternal death), although not all of them met the management-based criteria of a massive blood transfusion. Twenty-three (59%) of the near-miss cases and the maternal death case required 4 or more units of blood products. 9 (39%) were in the miscarriage group, 8 (35%) in the ectopic and the remaining 6 (26%) in the TOP group.

The most frequently occurring procedure was found to be a laparotomy (n=23, 59%). A relook laparotomy was done in 15.4% of the cases. All women with an ectopic pregnancy underwent laparotomy. One of the ruptured ectopic women required a relook on the same day due to suspected ongoing intra-abdominal haemorrhage. This was based on what was considered (retrospectively) as an erroneous blood gas result (Hb 3.5) due to a faulty blood gas machine. Intra-abdominal bleeding was excluded at the relook. The post relook Hb was 9.6. In a woman with a ruptured ectopic pregnancy, a total abdominal hysterectomy was done at the first laparotomy as a result of ongoing bleeding intra-operatively. A relook laparotomy was done 3 days later for suspected intra-abdominal sepsis but there were no significant findings at this operation. Another relook laparotomy in the ectopic pregnancy population was in a patient who was initially seen and assessed as an incomplete miscarriage and had a manual vacuum

aspiration done. She was discharged but returned 2 weeks later complaining of diarrhoea. Uterine perforation and ruptured ectopic pregnancy were suspected at this visit. Laparotomy revealed pus in the abdomen and she was considered a Pelvic Inflammatory Disease (PID) grade 4. After 2 days of no clinical improvement she had a relook laparotomy, as a ruptured ectopic pregnancy was still suspected. Her quantitative BHCG was 21. The final relook laparotomy was in a fourth ruptured ectopic pregnancy patient. Suspected intra-abdominal bleeding was the indication for the operation. It was noted that the ectopic pregnancy was only identified and surgically removed at the relook laparotomy. Unfortunately, no operative notes were made for the initial laparotomy. The 2 relook laparotomies in the TOP population were on the same patient. Intra-abdominal sepsis was suspected on both occasions. This patient had clotting failure, renal failure and meningitis following unsafe termination of pregnancy.

Of the women presenting with miscarriage or TOP, the majority (84.6% and 71.4% of their population group respectively) underwent evacuation of the uterus. The one maternal death case also an evacuation done in theatre. One of the women who were admitted for TOP-related complications had a manual-vacuum aspiration done five days prior to the index admission. This admission was for continuous vaginal bleeding, requiring an evacuation of her uterus in theatre. She had severe haemorrhage during the procedure, resulting in multi-organ dysfunction and metabolic acidosis. A life-saving hysterectomy was done. The woman with GTD had a suction and curettage.

Over 90% of the women had not received any antenatal care including the woman who died. A quarter (25.6%) of the women had delayed seeking medical care. This included the woman diagnosed with GTD, who had defaulted follow up after suction curettage for the same diagnosis one year prior to presentation. All of the women who had a TOP had used an unsafe service.

A total of three (7.7%) women were incorrectly diagnosed. The 3 women all had a ruptured ectopic pregnancy. Five (12.8%) of the women received substandard management after being correctly diagnosed. This occurred more frequently in the group of women with a miscarriage (15.4%) and TOP (28.6%). Delay in patient referral was found in 2 cases (5.1%) and initial management at inappropriate level in 5.1%. Inadequate or infrequent monitoring was found in 2 cases (5.1%). These were made up of 1 miscarriage and 1 ectopic pregnancy. No avoidable factors were identified in the majority of cases (61.5%). No healthcare worker- related avoidable factors were found in the maternal death.

A high proportion of women (41%) could not access an ICU bed despite their need for critical care services. This was also a challenge in the woman who died. There was a shortage of blood products (12.8%), particularly in women with miscarriage (23%). A delay in admission to the critical care unit (10.3%) was also found in women presenting with miscarriage (23%). Lack of an appropriately trained nurse or doctor was found in one case (2.6%) of ectopic pregnancy. A problem with transportation from one institution to another was found in one miscarriage case.

Discussion

This study described women who experienced life-threatening pregnancy complications associated with an early pregnancy loss. The majority of the women had not sought any antenatal care prior to their hospital presentation. Almost 50% of women in low- and middle-income countries (LMICs) did not receive adequate antenatal care [(8)]. Antenatal care presents opportunities to identify pregnancy risks and to monitor and support the general health care of pregnant women who may be susceptible to a range of potentially fatal conditions [(9)]. Studies from low and middle resource countries, especially in sub-Saharan Africa, have reported higher numbers of infrequent or no antenatal visits which have been shown to correlate with higher

maternal mortality rates [10]. The 2016 World Health Organisation Ante Natal Care model recommends that the first contact a pregnant woman should have with a health care worker is before 12 weeks' gestation [11]. In this near miss study, over half (53.8%) of the women had not sought antenatal care and presented at less than 12 weeks' gestation. The majority of them had a ruptured ectopic pregnancy. This supports evidence that early antenatal care booking, and early ultrasound for dating and determining the location of the pregnancy, can prevent complications that lead to near-miss in early pregnancy. Community education programs and ease of access to antenatal care services will aid in encouraging women to seek care early in pregnancy. It is desirable for all pregnant women to have an ultrasound as soon as pregnancy is confirmed, although this may not always be feasible in resource-limited settings. An early ultrasound assessment in the first trimester aims to visualise and confirm pregnancy viability, to determine the location of the pregnancy, to detect multiple pregnancies, to evaluate normal embryonic or fetal development and to observe adnexal structures[12]. Supplying local clinics which are usually the entry point of initiating antenatal care, with ultrasound machines; and training of staff on how to make the above assessments in the first trimester can further aid in the diagnosis and timeous referral of abnormal pregnancy states.

A quarter of the women required a relook laparotomy for suspected ongoing intra-abdominal bleeding or sepsis. In one woman, a ruptured ectopic was only diagnosed and successfully managed at the second laparotomy. This reflects that there was inadequate clinical assessment and management of the women by the healthcare workers in some of the cases.

Unsafe TOP still remains a cause of maternal death in South Africa, accounting for 3.4% of maternal deaths [13]. All 7 of the women who had a termination of pregnancy presented after an unsafe or illegal TOP. Five of the women (71.4%) were between 13 and 20 weeks pregnant, which, according to The South African Choice on Termination of Pregnancy Act (1996), is within the legal gestational age for safe termination if it is as a consequence of rape, incest, or

poses a health risk to the woman [3]. Two women were beyond the legal gestational age of 20 weeks with 1 unsafe TOP culminating in a maternal death. TOPs have been legal in South Africa for over 20 years. This raises questions about access to safe TOP, utilization and whether women requesting TOP are treated with dignity. One recommendation would be to explore why women still opt for an unsafe TOP despite access to SAFE TOP services. A high percentage of women who had a TOP presented in hypovolemic shock and multi-organ dysfunction. Three women required a life-saving hysterectomy as a consequence of septic and haemorrhagic shock. Similar results were found by Dragoman et al. between May 2010 and December 2011. Haemorrhage was found to be the most common cause for near-miss and infection . Haemorrhage alone was also found to be the most common cause of death after unsafe TOP [14]. Unsafe TOP still appears to be prevalent and is associated with maternal near-miss and mortality. Women's perceptions of barriers to TOP services include difficulties in accessing the service due to having to travel long distances, as well as the scarcity of the facilities, coupled with long waiting periods [15]. Health-care workers can also be a barrier to the safe TOP process as they may have different opinions on the provision of the service. This may lead to the refusal of providing the service. In South Africa, all health-care workers are expected either to provide TOP services or to refer a woman to a healthcare worker who will provide the service. Some workers fear stigmatisation and negative attitudes from their colleagues who are non-providers or are anti-TOP[16]. Addressing the barriers may improve utilization of TOP services and reduce life-threatening complications of TOP. Improving access to contraception services and encouraging women to utilize them effectively can lead to the prevention of unplanned/unwanted pregnancies and possibly decrease the number of unsafe TOPs.

Almost half (48.7%) of the women in the study required ICU admission with the majority of the women requiring prolonged intubation. In a similar study conducted in India in 2010,

Chawla et al. looked at the etiological factors leading to the need for ICU admission amongst obstetric patients [17]. Shock and respiratory dysfunction were common. Of the 35 women, 2 women were admitted during early pregnancy. Four women (5.7%) were admitted to ICU due to complications associated with TOP and ectopic pregnancy. Respiratory insufficiencies and haemodynamic instability, were the most common reasons for ICU admission. In their study, 2 women with an ectopic pregnancy, 1 woman with a TOP and 1 woman presenting with a miscarriage survived. Unconfirmed pregnancies, miscarriages and TOP in the first and second trimesters of pregnancy can lead to an increased near-miss incidence and maternal mortality. The availability of critical care services, early antenatal booking, and first trimester ultrasounds may prevent more avoidable deaths in low and middle income countries[17].

Massive haemorrhage requiring blood transfusion in early pregnancy can be life-threatening. This is evident in the number of women with haemorrhagic shock in this study. More than half the women (59%) who had a near-miss needed a massive blood transfusion. There were also a proportion of women who needed a blood transfusion but did not meet the criteria of a massive transfusion. This affirms that the availability of blood and blood products is critical in the management of women with massive haemorrhage. The availability of blood products and prompt access to the products is crucial in the resuscitation and stabilisation of women who have suffered severe haemorrhage as a consequence of ruptured ectopic pregnancy miscarriage and TOP. In Sub-Saharan Africa , where there is a critical shortage of blood products, severe haemorrhage is a leading cause of deaths related to pregnancy [18]. Half of the maternal deaths in the world from severe bleeding occur in sub-Saharan Africa. Lack of availability of blood products, lack of donors and logistic failures prove to be contributory factors [18]. Prompt access to adequate blood for transfusion is critical for the prevention of death. Evidence is required to find feasible and financially sustainable ways for providing quantities of safe blood in communities with shortages of blood donors [18].

Fifty-one percent of the women with near miss were HIV positive, however only 60% were on anti-retroviral therapy. Eight (44.5%) of the women with an ectopic pregnancy and eight (61.5%) of miscarriages were HIV positive. It is worrying that 40% of the HIV positive women were not on anti-retroviral therapy. Considering that most of the women were unbooked, it may be that some of the women were tested for HIV for the first time during the hospital admission. In the South African Annual report and detailed analysis of maternal deaths due to non-pregnancy related infections in 2014, 75% of the women who died following ectopic pregnancy and 72% who died following miscarriage were HIV positive [19]. HIV positive women may often have additional chronic illnesses or risk factors. Unbooked, undiagnosed HIV positive women with an early pregnancy loss may not be getting the opportunity to test or initiate anti-retroviral therapy (ART) hence depriving them of the benefits of the ART programme.

The findings of this study allude to the fact that patient education, early initiation of antenatal care, early ultrasound and pre-conception HIV testing may all lead to improved pregnancy outcomes in women with a risk of having an early pregnancy loss. The strength of this study is that it describes near-miss and the severity of complications in a population of women who have an early pregnancy loss. Only a few studies have described maternal outcomes associated with early pregnancy loss to this extent. Few women had initiated antenatal care prior to their index presentation. Whilst routine measures such as starting antenatal care and getting an ultrasound early in pregnancy may protect women from complications later in pregnancy, these measures may not necessarily be protective for women who have early pregnancy loss or the associated complications. This particularly applies to settings where there is limited access to ultrasound machines. The main limitation of this study was that not all case records were found. Patient demographic factors such as the level of education, level of income and marital status of the women were not included in the records. It would have been valuable to include more demographic data. The study provides new information about a subject that hasn't been well

studied and alludes to the reasons why women in low and middle income countries may have adverse outcomes in early pregnancy. Future prospective studies would be valuable in exploring patient demographics and healthcare worker and administrative factors associated with patients presenting with adverse outcomes. Suggestively, formulating questionnaires to be completed on admission will lead to the compulsory inclusion of information and possible explanations for the near-miss event. Clinical guidelines should emphasize the importance of early antenatal care and ultrasound even in poor countries, to save more lives.

Conclusion

Near-miss in early pregnancy is not very common but in this study was is associated with severe morbidity and mortality. Early ultrasound to diagnose ectopic pregnancy and access to safe, legal TOP services can prevent morbidity in early pregnancy. Improved access to contraception, antenatal care services and patient education can improve maternal outcomes in women with early pregnancy complications. Availability of critical care services and blood products is crucial in the management of adverse outcomes in early pregnancy. Continuous healthcare worker training and the implementation of strict adherence to protocols for the management of critically ill women presenting early in pregnancy is vital and will help decrease the morbidity and mortality due to complication occurring early in pregnancy.

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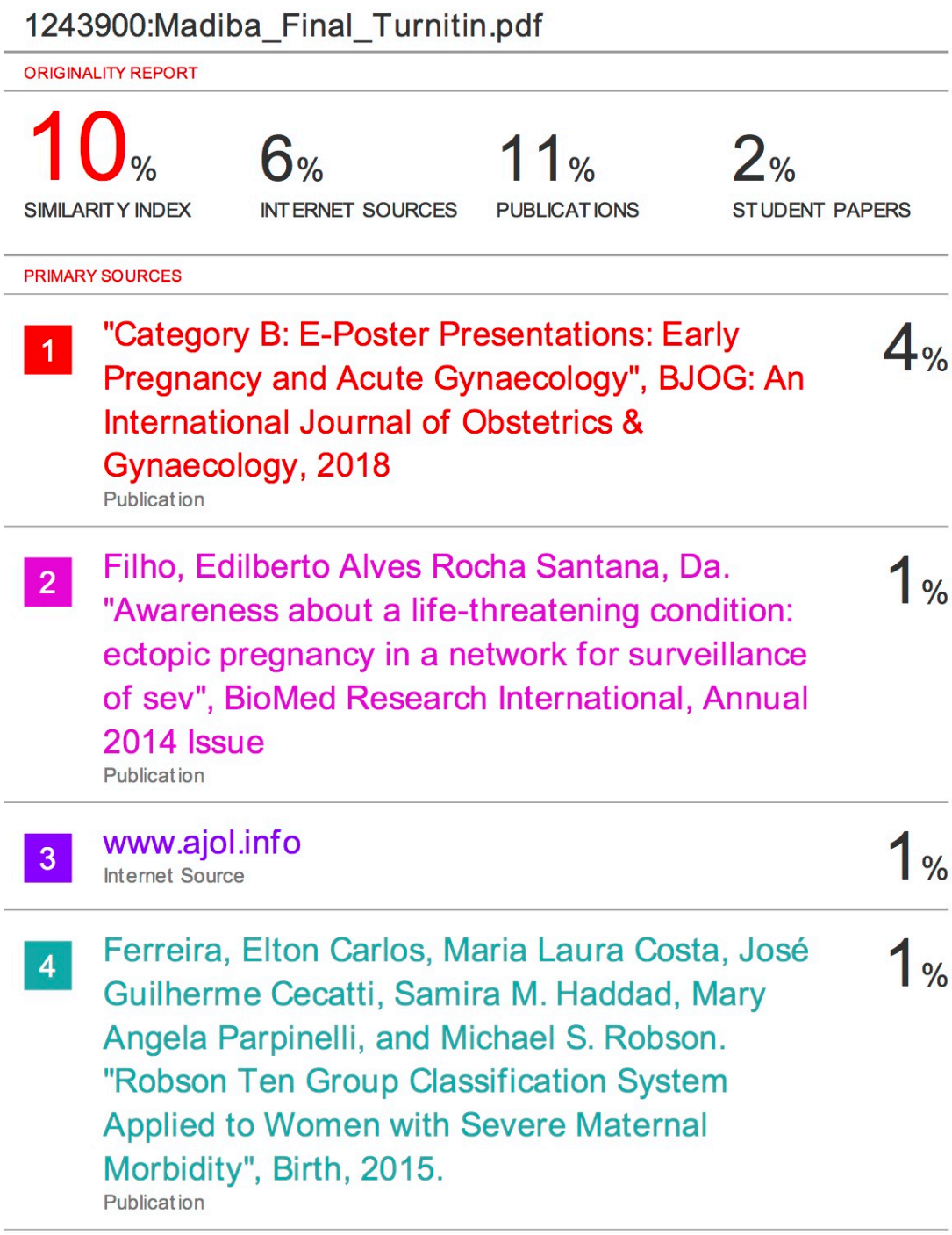
CHAPTER 3: APPENDICES

3.1. Turnitin Originality Report



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3.2. NEAR-MISS DATA COLLECTION TOOL

Age	
Parity	
Gestation	
Booked	☐Yes ☐No ☐Unknown
Rh	☐Positive ☐Negative ☐Unknown
RPR	☐Negative ☐Positive ☐Unknown If Positive, treatment completed ☐Yes ☐ No
RVD	☐Negative ☐Positive ☐Unknown If Positive, on treatment☐ Yes ☐No What treatment: CD4 count or ☐Unknown

	Viral load or ☐Unknown
Dates	Date of admission: Date of discharge: Date of near-miss event: Date of death: Time of death:

DIAGNOSIS	☐**Ectopic Pregnancy** ☐Rupture ☐Unruptured ☐**Termination of pregnancy** ☐Spontaneous ☐Artificial Induction ☐Legal ☐ Illegal ☐**Miscarriage** ☐Complete ☐Incomplete ☐Septic ☐Threatened ☐Missed ☐**Gestational Trophoblastic Disease** ☐Partial ☐Complete ☐Choriocarcinoma ☐Other

	Specify ☐**Other** Specify

ICU admission? Y/ N

Clinical criteria	
Acute cyanosis	
Gasping	
Respiratory rate >40 or <6/min	
Shock	
Oliguria non responsive to fluids or diuretics	
Clotting failure	
Jaundice in the presence of pre-eclampsia	
Shock	
Stroke	
Clotting failure	
Loss of consciousness lasting ≥ 12 hours	
Uncontrollable fit/total paralysis	
Laboratory-based criteria (List all relevant blood results with date and time)	
Oxygen saturation <90% for ≥60min	
PaO2/FiO2 <200mmHg	
Creatinine ≥300µmol/l or ≥3,5mg/dl	
Bilirubin > 100µmol/l or >6,0mg/dl	
Acute thrombocytopenia (<50 000 platelets)	

Lactate > 5	
Ph <7.1	
Loss of consciousness AND the presence of glucose and ketoacids in urine	
Management-based criteria	
Use of continuous vasoactive drugs	
Hysterectomy following infection or haemorrhage	
Transfusion of ≥5 units red cell transfusion	
Cardio-pulmonary resuscitation (CPR)	
Dialysis for acute renal failure	
Intubation and ventilation for ≥ 60 minutes not related to anaesthesia	

Describe Near-miss event:

Maternal Outcomes

- Near-miss
- Death
    - Specify cause of near-miss/death:

Fetal outcome

- TOP
- Spontaneous miscarriage
- Induced miscarriage
- Hysterotomy with live baby
- Hysterotomy with dead baby
- Continued with pregnancy

Surgical procedures

- MVA
- Evac
- Suction curettage
- Laparotomy
- Hysterotomy

- Hysterectomy
- Relook laparotomy
- Other, specify:

Blood transfusion: Number of units

Avoidable factors

Patient related:

- Lack of information
- No antenatal care
- Infrequent antenatal care
- Delay in accessing medical help
- Declined medication/surgery/advice
- Family problem
- Community problem
- Unsafe abortion
- No avoidable factors
- Other: Specify

Healthcare worker related:

- Problem with recognition of diagnosis
- Delay in referring patient
- Management at inappropriate level
- Incorrect diagnosis
- Substandard management of correct diagnosis
- Inadequate or infrequent monitoring
- No avoidable factors

Administration related:

- Transport problems: Home to institution
- Transport problem: institution to institution
- Lack of accessibility
- Delay in initial critical care (overburdened service)
- Lack of health care facilities: ICU
- Lack of health care facilities: Blood/ blood products
- Lack of health care facilities; Other
- Lack of appropriately trained staff: Doctors

- Lack of appropriately trained staff: Nurses
- Technical problems
- No avoidable factors
- Other: Specify

R14/49 Dr Kholofelo Madiba

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M170464

NAME: (Principal Investigator)	Dr Kholofelo Madiba
DEPARTMENT:	Obstetrics and Gynaecology Chris Hani Baragwanath Academic Hospital
PROJECT TITLE:	Near-Miss in Early Pregnancy
DATE CONSIDERED:	05/05/2017
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Dr Salome Maswime
APPROVED BY:	Professor P. Cleaton-Jones, Chairperson, HREC (Medical)
DATE OF APPROVAL:	21/06/2017

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary in Room 10004, 10th floor, Senate House/3rd floor, Philip Tobias Building, Parktown, University of the Witwatersrand. I/We fully understand the conditions under which I am/we are authorised to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit to the Committee. I agree to submit a yearly progress report. The date for annual re-certification will be one year after the date of convened meeting where the study was initially reviewed, in this case, the study was initially review April and will therefore be due in the month of April each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical).

Principal Investigator Signature

Date 27/06/17

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Obstetrical & Gynaecological Society of Singapore

Royal College of Obstetricians & Gynaecologists

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This is to certify that

Kholofelo Raisibe Madiba

presented a poster presentation titled

An audit of near-miss in early pregnancy in South Africa

at

RCOG World Congress 2018, Singapore

21 - 24 March 2018

Professor Janice Rymer FRCOG, London
Vice President Education; Chair of Congress Committee

A/Prof Timothy Yong Kuei Lim FRCOG, Singapore
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