

Reducing maternal morbidity and mortality from caesarean section-related haemorrhage in Southern Gauteng

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Declaration

I, Tumishang Mmamalatsi Salome Maswime declare that this thesis is my own, unaided work. It is being submitted for the Degree of Doctor of Philosophy at the University of the Witwatersrand, Johannesburg. It has not been submitted for any degree or examination in any other university.



20th day of April 2017 in Johannesburg

Dedication

For my sons Farai and Taurai

Presentations

1. **Maswime S**, Buchmann E. Severe maternal outcome from caesarean section related haemorrhage in Southern Gauteng. Priorities in Perinatal Care Conference. Oral presentation, and conference paper, Drakensburg, South Africa, March 2015.
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Abstract

Introduction

The number of maternal deaths from bleeding during and after caesarean section (BDACS) has increased dramatically in South Africa in recent years. Four studies were conducted to gain insight on measures to reduce maternal deaths from BDACS. The aim was to identify clinical and health system factors associated with near-miss and maternal death from BDACS.

Methods

A systematic review was done on near-miss from postpartum haemorrhage, with a sub-analysis on BDACS. The field research, done in southern Gauteng, included: 1) a six-month prospective near-miss audit of women with BDACS in 13 hospitals; 2) a two-year retrospective maternal death audit in seven hospitals; and 3) a health systems audit in 15 hospitals.

Results

The systematic review on near-miss from PPH found two studies that described near-miss from BDACS, with a mortality index of 0-11%. In the near-miss and maternal death audits, the main risk factors for BDACS were pre-operative anaemia and previous caesarean section. Atonic uterus was the main cause of haemorrhage, with associated failure to use second line uterotonic drugs. Failure to diagnose and treat shock was the main reason why women died. Most maternal deaths from BDACS occurred in regional hospitals. The hospital systems audit identified shortages of second line uterotonic drugs and surgical skills availability as contributors to near-miss and maternal death from BDACS.

Conclusion

Although bleeding may be arrested through obstetric surgical techniques and easily available drugs, severe BDACS is a complex disease that requires a multi-disciplinary approach in a functional health system, especially regarding the detection and management of hypovolaemic shock. Measures to reduce maternal morbidity and mortality from BDACS include health system strengthening, with high care and critical care facilities, and improving the availability of drugs and surgical skills at district and regional hospitals.

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Natalspruit Hospital

Tambo Memorial Hospital

Far East Rand Hospital

Pholosong Hospital

Leratong Hospital

Edenvale Hospital

Southrand Hospital

Bheki Mlangeni Hospital

Heidelberg Hospital

Yusuf Dadoo Hospital

Carletonville Hospital

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Chapter 1

Literature Review

1.1. Introduction

Death as a consequence of pregnancy is an important cause of premature mortality globally (1). Obstetric haemorrhage is the leading cause of maternal deaths, and it accounts for 25% of maternal deaths internationally (2). Obstetric haemorrhage was the leading direct cause of maternal deaths in South Africa from 2011-2013, according to the Saving Mothers report, and accounted for 15.8% of all maternal deaths. Over 89% of deaths from obstetric haemorrhage were deemed possibly and probably avoidable (3). The leading cause of obstetric haemorrhage deaths in South Africa was 'bleeding during and after caesarean section' (BDACS) (3). The number of maternal deaths from BDACS has increased in South Africa in the last decade, (Figure 1.1.) (4).

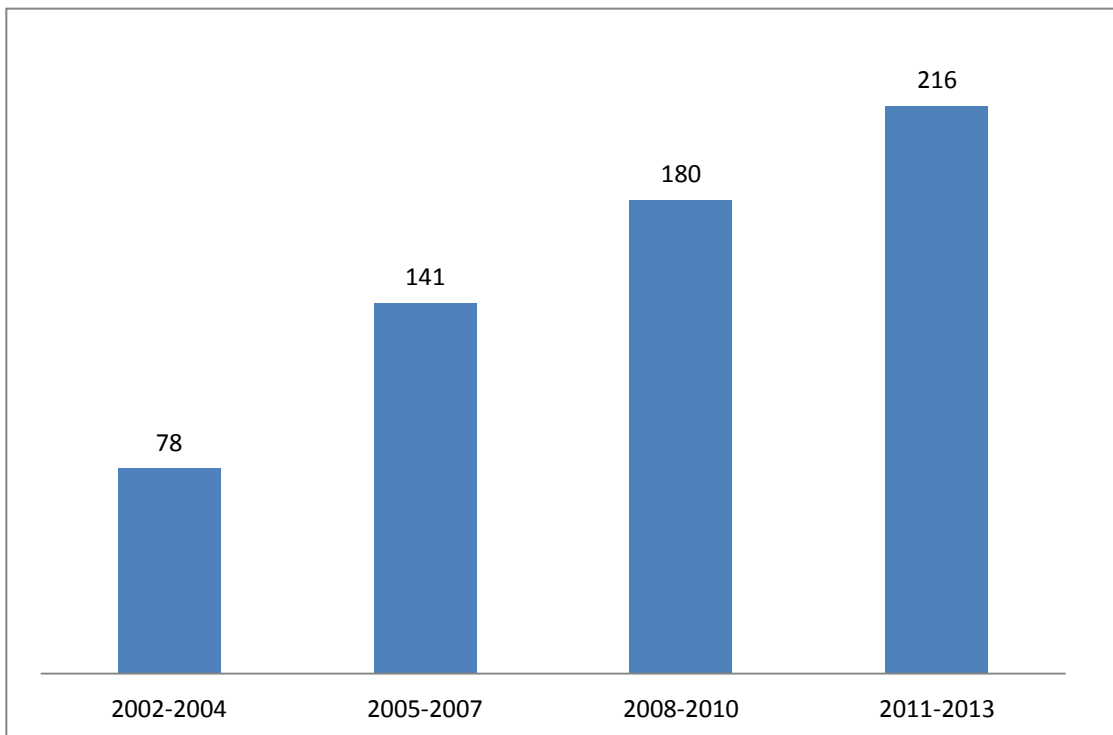


Figure 1.1: Maternal deaths from caesarean section related haemorrhage in South Africa

Figure plotted using data from Gebhardt (7)

The national caesarean section rate in South Africa of 23.1% (2011-2013) is believed to be inappropriately high when measured against the World Health Organization (WHO) recommended rate of 10 - 15%, and this is considered to be the main contributing factor to the increasing number of maternal deaths from BDACS (3,5,6,7). Substandard care, including inadequate initial assessment of patients, poor recognition of the problems, misdiagnosis, failure to follow management protocols and substandard resuscitation, are possible causes for the increase in avoidable maternal deaths (8).

Caesarean section is associated with a higher risk of endometritis, the need for blood transfusions, postpartum haemorrhage (PPH) and longer hospital stay than vaginal deliveries (9,10). Caesarean delivery is by itself associated with increased maternal morbidity and mortality, and delay in performing caesarean section in poorly resourced settings increases

maternal and newborn risks even more (11,12). Caesarean sections have recently been associated with a higher risk of near-miss morbidity, compared to vaginal deliveries (13).

This literature review will examine severe maternal outcomes from BDACS, the burden of disease from BDACS, clinical audits, healthcare system deficiencies, mechanisms of haemorrhage, risk factors for BDACS, and interventions to reduce morbidity and mortality from BDACS.

1.2. Severe maternal outcome from BDACS

Maternal morbidity is defined by the WHO as, ‘any health condition attributed to and/or aggravated by pregnancy and childbirth that has a negative impact on the woman’s wellbeing’ (14). The most severe morbidity is one that comes close to resulting in a woman’s death (a near-miss). In recent years, the concept of maternal near-miss has been widely adopted by the scientific community. With maternal deaths being rare events, near-miss has become the main audit tool for severe maternal outcomes in high-income countries (15). A near-miss is defined as a woman who experienced and survived a severe health condition during pregnancy, childbirth or postpartum. Maternal death is the most extreme indicator of deficiencies in obstetric care, while near-misses include women who came close to death, but survived owing to good fortune or appropriate medical intervention. The study of near-misses provides valuable information on how obstacles are overcome after the onset of an acute complication (15). Near-misses share similar characteristics with maternal deaths, but are not as rare as maternal deaths (16). Together, near-misses and maternal deaths can be grouped together as having ‘severe maternal outcome’ (15).

The maternal near-miss concept was described by Mantel et al. in South Africa in 1998, in a pilot study for a definition of a near-miss. Their rationale was that, with the decline in the number of maternal deaths, recommendations to improve maternal healthcare based on reports of rare events, such as maternal deaths, had little relevance (17). Applied to the woman who escapes death because of appropriate medical care, the concept of the ‘great save’ was borne out of this, with the advantage of providing a bigger picture of maternal disease and clinical responses (17). Mantel et al defined near-miss criteria based on organ system dysfunction or need for certain extreme interventions, for example admission to intensive care unit. Following on, other near-miss criteria were proposed separately by Fillipi et al., Geller et al. and Waterstone et al. (17-20). Until 2009, there was no international consensus on the definition or criteria for near-miss, also

described as severe acute maternal mortality (SAMM). The WHO initiated a process to develop a uniform definition, classification, and identification system for near-miss, using similar principles as those for classifying maternal deaths, with near-miss criteria based on those of Mantel et al. This resulted in the WHO maternal near-miss criteria, which have been adopted globally. These are divided into clinical criteria, defining disease end points such as shock and gasping; laboratory based criteria, including markers of multi-organ dysfunction; and management criteria, including life-saving interventions, such as intensive care unit admission, hysterectomy or massive blood transfusion (Table 1.1.) (15).

Table 1.1: The WHO criteria for near-miss

Clinical criteria	Laboratory criteria	Management based/ Intervention based
▪ Acute cyanosis ▪ Respiratory rate >40 or <6/min ▪ Shock ▪ Oliguria not responsive ▪ Clotting failure ▪ Jaundice with preeclampsia ▪ Loss of consciousness > 12hrs/no pulse/heart rate ▪ Stroke/paralysis/uncontrollable fit	▪ Oxygen saturation <90% for >60 min ▪ PaO₂/FIO₂ <200 mmHg ▪ Creatinine >300 mg/dL ▪ Bilirubin >100 mg/dL ▪ pH <7.1; lactate >5 mmol/L ▪ Platelets <50 000 /μL of blood ▪ Loss of consciousness with glycosuria/ketonuria	▪ Use of vasoactive drugs ▪ Hysterectomy: infection/hemorrhage ▪ Transfusion ≥5 units of packed cells ▪ Intubation >60 minutes not related to anesthesia ▪ Dialysis for acute renal failure ▪ Cardio-pulmonary resuscitation

Table drawn using data extracted from Say (15)

Various indicators based on near-miss can be calculated, such as the maternal near-miss ratio, the severe maternal outcome ratio and the mortality index, the latter expressing the number of women who die from life-threatening conditions (severe maternal outcome) in an institution. The indicators can be used to evaluate quality of care over a period of time, and across different

settings (Table 1.2) (15). Clinicians and managers will strive to reduce the mortality index in their institution. Even though near-misses can at times be regarded as obstetric successes (great saves), the consequences of near-miss related complications can be overwhelming (21). A near-miss from BDACs may have a hysterectomy, multiple surgical procedures, renal dialysis, and prolonged ventilation. These may result in chronic complications, post-partum depression, and even death after an extended period of suffering. The study of near-misses has revealed the extent of maternal ill health beyond the acute intrapartum and postpartum period. A study in Burkina Faso found that women with a life-threatening complication suffered from depression, anxiety and suicidal ideation. They also had financial difficulties due to costs incurred during and after childbirth (22). While most women make a full recovery, the sequelae of near-miss may be chronic maternal illness, disability and infertility.

Table 1.2: Near-miss indicators

Indicator	Equation	Definition
Severe maternal outcome	$SMO = MNM + MD$	The sum of maternal deaths and near-misses
Maternal near-miss ratio (MNR)	$MNR = MNM / 1000 \text{ live births}$	Number of maternal near miss cases per 1,000 live births
Severe maternal outcome ratio (SMOR)	$SMOR = MNM + MD / 1000 \text{ live births}$	Number of maternal near miss and maternal deaths cases per 1,000 live births
Mortality Index (MI)	$MI = MD / (MNM + MD)$	The risk of dying from a life-threatening condition, expressed as a percentage.

MD* is maternal death

MNM* is maternal near-miss

Table drawn using data extracted from Say (15)

The leading causes of maternal near-misses worldwide were believed to be obstetric haemorrhage and pregnancy related hypertension (23). Near-misses occurred in 1% of pregnant women in the

USA, but in low resource settings this proportion ranged from 3 - 9% (21). The proportion of deaths among women with severe maternal outcome (mortality index), varies per setting. High mortality indices are the rule in low resource settings. This may also be expressed inversely as a ratio of near-misses to maternal deaths, with low ratios found in low resource settings. Mantel et al. found that there were five times as many near-misses as maternal deaths in South Africa (17). In a similar study in a high-income setting in Canada, Baskett et al. reported a ratio of 27:1 (54 near-misses and two deaths). However, despite the diverse settings, both studies found that their near-misses mirrored their maternal deaths in terms of cause (24).

Caesarean delivery is known to be associated with high-risk pregnancy and maternal death, and, similarly, to near-miss. A finding from the WHO Global Survey in 2005 was that caesarean sections are associated with near-miss morbidity as well as an increased mortality index (25). Litorp et al. described the proportion of near-miss from BDACS in Tanzania, and stated that caesarean section complications accounted for a large proportion of near-misses and maternal deaths. Caesarean delivery was not only associated with, but also causal in, severe maternal outcome (13). The advantage of studies on near-miss is that they present a broader picture of the burden of severe maternal disease than simple descriptions of maternal mortality. For every maternal death, there are usually more women with a near-miss event. The mortality index allows us to calculate the percentage of women that died from a specific condition with severe morbidity. No studies have been found that evaluate the mortality index for BDACS. However, mortality indices can be extrapolated from data that describe the cause of near-miss, number of maternal deaths, and maternal near-miss. The mortality index from Litorp et al. study was calculated to be 11% (13). A mortality index for BDACS could not be calculated from data in any of the South African near-miss studies.

1.2.1. Severe morbidity from PPH

The definitions of PPH, severe PPH and massive obstetric haemorrhage are determined by blood loss volumes, which are often inadequate descriptions of the clinical effect of blood loss on a patient. Discriminating severe from mild PPH according to near-miss criteria, provides a better description of adverse effects and patient outcomes, by adjusting for the individual patient's clinical profile in response to blood loss. It also eliminates misclassification caused by underestimation of blood loss. Near-miss criteria, such as those of the WHO, also have limitations. In settings where certain investigations cannot be done, and in facilities where staff are not well equipped to provide certain interventions, the number of near-misses may be underestimated. If a clearly indicated hysterectomy cannot be performed by a surgeon in a district hospital, the woman may not be counted as a near-miss if she survives by good fortune. If a blood bank is not available on site, or five units cannot be given because of a shortage, the number of near-misses recorded will be fewer. The near-miss criteria have limited application in district hospitals, because women with near-miss morbidity generally need referral to higher levels of care where the near-miss criteria can be applied.

1.2.2. Severe morbidity and mortality from BDACS

According to the latest South African Saving Mothers report, 363 maternal deaths resulted from BDACS from 2011-2013, the most yet recorded in a triennium since 1999-2001, when the triennial Saving Mothers Reports were instituted; 216 of the deaths were directly related to the procedure, 54 to placental abruption, and 26 to placenta praevia/accreta. The risk of dying from BDACS in South Africa was 1 in 3035 pregnancies. Many of the deaths took place in district and regional hospitals (81%). About one-third of the women (36%) had a repeat caesarean section (3). A recent study from Nigeria described complications of caesarean section surgery in a low-resource setting. Haemorrhage was the most frequently seen complication. Caesarean section

complications, defined as haemorrhage, wound dehiscence, anaemia, sepsis and others were experienced by 67 women, in a cohort of 504 who had a caesarean section. The major indications for caesarean section were prolonged labour and previous caesarean section. Haemorrhage accounted for 59.7% of complications, followed by wound dehiscence in 17.9%, and sepsis in 7.5%. The authors explained their findings from the fact that many women in that community delivered in their homes under the care of traditional birth attendants, and presented to hospital only if there were labour complications. Regarding in-hospital care, there was an inverse correlation between blood loss and the cadre of surgeons, i.e. the more junior the surgeon, the higher the blood loss. Ten maternal deaths were reported, of which six were caused by puerperal sepsis following prolonged obstructed labour, and only one was due to PPH. All the puerperal sepsis cases were referrals and their high mortality was believed to be due to the high number of patients referred with prolonged labour for emergency caesarean section. This was not a near-miss study, because near-miss definitions were not used; it only described known caesarean section complications (26). It is important to note that fewer women died from PPH, even though haemorrhage was the most frequently seen complication. This was not explained by the authors; however, the study was done in a tertiary hospital which receives referrals from four states and a neighbouring country. It may be that the tertiary hospital had sufficient skills, facilities, and supplies to manage severe blood loss.

Very few studies have been done on formally defined near-misses from BDACS, and no studies have been found specifically describing risk factors associated with near-miss and BDACS. There is also a wide disparity between the prevalence of near-miss from BDACS in the few studies done. Two large multicentre studies considered near-misses and included BDACS as one of the clinical causes. The World Health Organization Multi-Country Survey on Maternal and

Perinatal Outcomes examined severe maternal outcome from PPH. Among 3102 women with PPH, there were 484 maternal near-misses and 105 deaths. BDACS accounted for 34% of maternal near-miss and deaths from PPH (27). The strength of this study was the large sample size and inclusion of 28 countries from different regions, including low income and high income countries. The study, however, focused on interventions to prevent PPH and did not describe clinical factors pertaining to the population with BDACS. A study in the Netherlands done in 98 hospitals with 371 021 deliveries included 1606 women with major obstetric haemorrhage (88% with PPH). In this high-income setting, BDACS contributed to 11.4% of severe maternal morbidity from massive obstetric haemorrhage (28).

Two near-miss studies from low-resource settings have examined near-miss related to caesarean section. The study by Litorp et al. in Tanzania, briefly mentioned earlier, appears to have been the first to describe near-miss from caesarean section in a low-income country. The study was done in Dar es Salaam in two hospitals, one was a regional hospital and the other a university hospital. The university hospital manages about 9000 births, and the regional hospital about 20 000 births each year. The regional hospital was described as having a shortage of equipment including gloves and syringes, oxytocin, and blood, as well as frequent electricity failures. It only had one operating theatre shared by all surgical disciplines, and often had to refer patients to the university hospital for caesarean sections, since it could not meet the demand for caesarean sections. In a sample of women with 13 121 live births, the authors found 49 near-misses and 10 deaths associated with caesarean section; 12 near-misses and three deaths (a mortality index of 20%) were directly related to haemorrhage (BDACS). The caesarean section rate was 53% in the university hospital versus 6.5% in the regional hospital, and 87% of maternal near-misses were referred to higher levels of care alluding to health system deficiencies in the country (13).

The other study, done at Kathmandu Medical College Teaching Hospital in Nepal, with 1562 births in 24 months, found 36 near-misses associated with caesarean section, with only two near-misses and no maternal deaths from BDACS (mortality index of zero) (29). These studies, besides their own data, highlight the paucity of information on near-miss from BDACS. Both studies included near-miss from other causes besides haemorrhage, and data pertaining to caesarean section needs to be extrapolated from the results. While mortality indices could be calculated, risk factors and avoidable factors for severe morbidity were not adequately described.

The diverse findings in the different settings, together with the high BDACS mortality in South Africa, present a significant gap in knowledge on the burden of BDACS in terms of numbers and mortality index, as well as risk factors and avoidable factors. The local South African setting would therefore be suitable for studying near-miss and maternal death from BDACS.

1.3. Clinical Audit (Quality of care)

Clinical audit is defined as a range of methods used for monitoring and reporting on health outcomes and process of care. Audits permit review of adverse events and quality of care.

Clinical audits are based on a commitment to improve the healthcare system, and the concept of ‘best practice’ and evidence-based practice (30). Audit of maternal deaths and adverse events is considered essential in all health care environments. The review process creates an opportunity to lead interventions to prevent recurrence of these events (8). Auditing maternal deaths and near-misses from BDACS may allow clearer understanding of the causes and associated factors, and therefore prevention of future deaths.

In 2004, the WHO published *Beyond the Numbers*, which was a global examination of maternal mortality. It described an approach beyond simply counting numbers and maternal mortality ratios. It appreciated the fact that all maternal deaths and near-misses had a story to tell that could influence change in standard practice. This is the purpose of audits. More specifically, audits aim to address and improve technical accuracy of diagnosis and treatment, timeliness of interventions, service organisation, and staff roles and responsibilities (31). Related to audits, it is also necessary to study health system barriers to improved maternal outcomes, implying in the context of this review an evaluation of institutional preparedness for severe caesarean section related haemorrhage.

1.3.1. Donabedian model

The Donabedian model is well known as an approach to assess quality of health care. The model considers three standards, based on the belief that: the clinical outcome of a patient is influenced by the structure (facility and resources where the outcome took place), and the process (diagnosis and treatment by the healthcare workers) (32). Avedis Donabedian was concerned with methods,

and not just findings. The theory emphasised that the clinical outcome for a patient was the ultimate validation of the effectiveness and quality of a medical system. The process of care needs to be assessed to rule out mediocrity poor practice. The setting in which the care takes place adds valuable information about whether the setting influenced the outcome. Questions arise such as: is the facility adequate; is the equipment sufficient; what are the qualifications of the medical staff; what are the administrative structures; what teaching programs occur in the institution; and what operations are performed? Such questions need to be answered to eliminate structural deficiencies as causes of the outcome being audited (32). There is a clear distinction between actual care provided, and the capacity to provide care. The Donabedian model can be applied to measure resources and quality, and improve care across hospitals, group practices and health systems. Maternal deaths and near-misses are frequently due to healthcare process and structural deficiencies, and health system strengthening may improve maternal outcomes. And in auditing BDACS, the surgery and the audit are both done in hospitals, in settings with clear structures and processes with potential deficiencies. The Donabedian model is therefore ideally suited to audit of BDACS.

1.3.2. Saving Mothers reports

South Africa introduced confidential enquiries into maternal deaths in October 1997, when maternal deaths were made a notifiable event by law. The National Committee for Confidential Enquiries into Maternal Deaths was appointed by the Minister of Health, to count maternal deaths, determine their causes and evaluate the medical care received. Every three years, since 1999, the committee has released triennial Saving Mothers reports, making this data accessible in the public domain. The committee has made periodic recommendations which can be used to draw up clinical guidelines on how to manage various conditions, and how to prevent maternal life-threatening events (3). The committee uses avoidable factor audits to measure quality of

care. The factors are subdivided into: 1) patient related factors; 2) health-care worker related factors, and 3) health-care system related factors. The latter two factors relate to structure and process audits as suggested by Donabedian. According to the maternal death assessors who provided the audit data in the most recent Saving Mothers report, over 70% of the 216 deaths due to BDACS from 2011-2013 were clearly avoidable. Only 1.8% of the deaths had no suboptimal care. Common themes in the reviews of these deaths were: no attempt to take bleeding patients back to the operating theatre; clinically unstable patients referred to higher levels of care; and failure to follow PPH protocols. A common finding was failure to adhere to the guidelines as suggested in the Department of Health's caesarean section monograph (3).

1.3.3. Three delays method

The three delays method is another tool used to evaluate quality of care. The three delays model was formally described by Thaddeus and Maine, and has been applied especially in low-resource health care settings. The model has three components: 1) first delay, in deciding to seek care by the individual and/or family; 2) second delay, in reaching an adequate healthcare facility; and 3) third delay, in receiving adequate care at the health facility (33). The difficulty in using the model for auditing BDACS is the fact that only the third delay is directly applicable to this type of event. If a patient starts bleeding severely in hospital during or after a caesarean section, the patient and her family are not involved in determining the nature or extent of bleeding. This method is therefore not suitable for the evaluation of intra-operative and post-operative care.

1.3.4. Robson criteria

Use of the Robson criteria is a frequently recommended tool to audit caesarean sections, mainly to determine if the caesarean section rate in an institution is appropriate. The Robson score identifies contributors to caesarean section, such as previous caesarean section, breech

delivery and prematurity (34). The estimated caesarean section rate in South African district hospitals is 12-18%, in regional hospitals 25-32%, and in tertiary hospitals 32-38% (35). The use of the Robson criteria is simple, robust and reproducible, providing ten categories of mutually exclusive caesarean sections. However, they do not include clinical reasons for doing caesarean sections (34), and do not provide insight into the quality of care before, during and after the surgery. Nevertheless, in the case of BDACS, the use of the Robson criteria has potential in terms of reducing the caesarean section rate, which is an important determinant of the frequency of BDACS. The higher the caesarean section rate, the greater the numbers of cases of BDACS. The criteria may also be useful for determining risk factors as applied in the Robson criteria (parity, previous caesarean delivery and so on) and their role in BDACS.

In conclusion, health system factors have been highlighted as possible contributors to maternal deaths from BDACS. No studies have been done evaluating health system factors associated with BDACS. The Donabedian method appears to be the most appropriate measure of quality of care related to caesarean section related morbidity. The model correctly supposes that if structures and processes were different, a different outcome could have been expected.

1.4. Health system

1.4.1. Global surgery

The ability to provide access to safe surgery is a function of the structures and processes of a health system. Five billion people lack access to safe surgical and anaesthetic care. The Lancet commission on global surgery was launched in January 2014, to address inequities, knowledge gaps and policy regarding global surgery, particularly in low and low middle income countries. Case fatality rates rise in absence of surgical care for easily treatable conditions such as appendicitis, obstructed labour, congenital abnormalities, breast and cervical cancer. Related to obstructed labour, caesarean section and maternal health are a key priority in the global surgery agenda (36). The commission used the three delays model to depict an analogy about lack of access to surgery and anaesthesia. ‘A woman who lives hours away from the nearest hospital probably does not have access to timely surgery and anaesthesia. A woman who lives just minutes away from a hospital that does not have enough surgeons and anaesthetists available to offer care also does not have access to surgery and anaesthesia’. The three delays model is well applied here, including the issue of access to caesarean section. With BDACS, the concern is that even with access, there is still an appreciable and preventable risk to the patient. Caesarean section and its complications are part of the global surgery agenda. Furthermore, women with postoperative complications may require interventions from skilled surgeons, as well as high risk resources and facilities at accessible referral centres (36).

1.4.2. Structure

Access to safe motherhood remains a key problem, particularly in Sub-Saharan Africa and South Asia, the regions with the highest maternal mortality burden. Women face deprivation in access to skilled attendants at birth, and to timely referral for emergency care (37).

A review on maternity care in India reported that in some areas, one to two obstetricians serve populations of up to 2-million people (38). In India, government policy encourages specialists to perform all caesarean sections, unlike in South Africa, where a medical officer who has completed the two-year internship can perform a caesarean section (38). This creates a challenge in India as women in rural areas requiring caesarean section must travel long distances. Many women referred to higher levels of care do not follow through; they arrive too late, die at home, or die on the way to a higher level of care. Lack of medicines and supplies is a further challenge in Indian government hospitals. The country also faces a shortage of anaesthetists. In response to this challenge, a specialist obstetrician may administer anaesthesia before operating, while a medical officer or nurse maintains anaesthesia during the operation. For reasons of patient safety, some obstetricians are forced to perform caesarean sections under local anaesthesia infiltration (38). District hospitals in South Africa are similarly affected by staff challenges. In South African rural hospitals, it has not been uncommon to find one doctor doing a caesarean section alone, in the simultaneous roles of surgeon, anaesthetist, and paediatrician. This would often be a junior doctor without the expertise to manage the surgical, anaesthetic or even the neonatal complications (39).

Strategies to improve access to caesarean section, particularly in countries with shortages of doctors, midwives and middle level practitioners, remain a priority. However, even with these deficiencies corrected and with increased access, the health system must upscale other areas of service to prepare for emergencies arising from intra- and postoperative complications.

Anaesthetists, emergency patient transport, blood banks, and intensive care units or high dependency units are all pivotal in managing severe post-operative haemorrhage. System-wide improvements are therefore needed to offer accessible and safe surgical services.

In South Africa, access to caesarean section is not a major problem, but the ability to manage complications from caesarean section related haemorrhage remains a challenge. A recent South African study of 12 health districts evaluated staffing norms and access to care. The highest number of births and deaths occurred in district hospitals. Based on WHO staffing norms, the 12 districts had more than the total number of professional nurses required per district. Furthermore, there was also an excess of maternity units for the population served. Therefore, the safety of maternity units, rather than a shortage of staff or facilities, was the main concern, and the recommendations were to realign maternity services to maximise patient safety (40).

Litorp et al. reporting on the Tanzanian study on near-miss, blamed the high near-miss rate at caesarean section on the uneven distribution of staff and material resources between different health care facilities. The lack of drugs, sterile packs, post-operative beds, blood transfusion and trained staff were thought to be the reason for the elevated risk of caesarean section complications in regional hospitals. Post-operative surveillance was also a concern regarding BDACS (13).

In South Africa, 38% of the deaths from BDACS occurred at district hospitals, 43% at regional hospitals, and 16% at tertiary hospitals (2011-2013). The average caesarean section rate in district hospitals in 2014/15 was 22.7%. The proportion of caesarean sections was highest in regional hospitals. Thirty-five percent took place in district hospitals, 40% in regional hospitals and 25% in tertiary hospitals (41).

Gauteng province, which includes the cities of Johannesburg and Pretoria, has the highest number of births in the country, but had the second lowest case fatality rate per 10 000 caesarean

sections performed, after the Western Cape province (3). The caesarean section rate was highest in KwaZulu-Natal (28.8%) and lowest in Limpopo province (15.2%) (Table 2). The number of deaths from BDACS did not correlate with the caesarean section rate provincially. KwaZulu-Natal had the highest number of deaths from BDACS and the highest caesarean section rate. Limpopo and Mpumalanga provinces had the lowest caesarean section rates, and the highest case fatality rates for BDACS (Figure 1.2) (3). However, in the absence of possibly confounding variables, the apparent ecological association between low caesarean rates and high case fatality rates cannot be assumed to be causal.

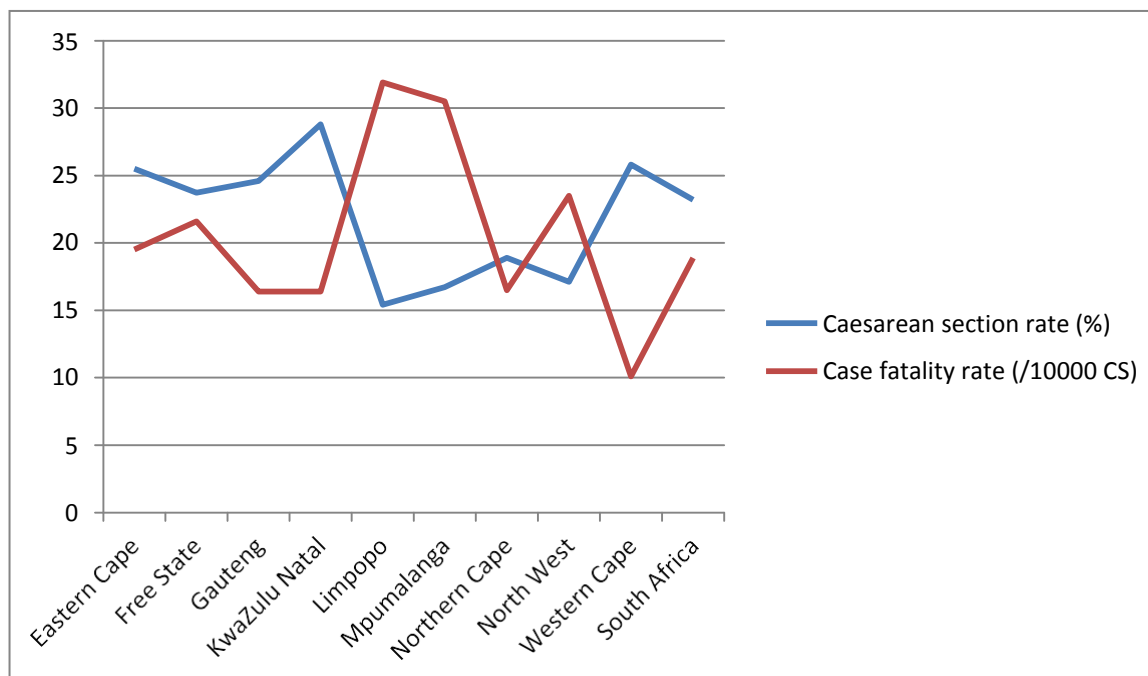


Figure 1.2: Caesarean section rate and case fatality rates for each province.

Graph drawn using data extracted from the Saving Mothers Report (3).

CS*: Caesarean section

The Saving Mothers report states that private hospitals in South Africa reported a total of 344 611 live births, and 118 deaths in the last triennium, and an institution-based maternal mortality ratio of 34/100 000 live births. The caesarean section rate in private hospitals was 67% in 2011 - 2013. Obstetric haemorrhage was the second most common cause of death. BDACS accounted for 4 out of 23 (17%) deaths from obstetric haemorrhage in the private hospitals. Private hospitals have a much higher caesarean section rate, but a much lower number of deaths from BDACS than public hospitals (3). There was also a difference in the distribution of deaths between public hospitals and private hospitals. Overall, there are wide variations between health systems between private and public care in South Africa. BDACS appears to be a problem affecting mainly the public healthcare system.

Some deaths from BDACS in South Africa occurred during and after transfer of women from lower to higher levels of care (3). Improved access to emergency obstetric care and reduced transport time reduces maternal mortality. An intervention to increase the number of ambulances and to reduce dispatch times was implemented in the Free State province. Thus, the maternal mortality rate was reduced from 129 to 61/100 000. Out of 45 new ambulances in the province, 18 were dedicated to obstetric use (42). Other provinces have attempted to follow this example. The North-West province bought 10 obstetric ambulances in 2014, and instituted 16 maternity waiting homes, to bring pregnant women closer to birthing units (43). Gauteng introduced 92 new general ambulances in 2015, bringing the ambulance fleet closer to 800 ambulances needed. However, the number of ambulances still falls short, according to the national norm, of one ambulance per population of 10 000 people. Gauteng would be required to have a minimum of 1200 ambulances (44). The main concern in the Free State was the number of women giving birth before reaching a healthcare facility (42). These adjustments in ambulance allocations were not intended for women with BDACS.

Amidst the shortage of ambulances, there is a growing concern with regards to ambulance personnel in South Africa. There is a dire shortage of Advanced Life Support (ALS) paramedics (45). This results in ambulances serving as a means of rapid transportation instead of a service providing advanced life support. There are three levels of training. The lowest is Basic Life Support which requires one month's training in first aid, cardio-pulmonary resuscitation, vehicle extrication and ambulance equipment. Intermediate life support includes insertion of intravenous lines and the use of manual defibrillation. Advanced life support provides critical care services such as advanced airway management and cardio-version (45). In 2014 South Africa had 8095 Basic Ambulance Assistants, 2603 Intermediate Life Support Practitioners and 360 Advanced Life Support Paramedics (46). An ambulance model for BDACS would require further up-scaling of inter-facility emergency transport, with a focus on obstetric ambulances staffed by personnel with skills to manage bleeding patients during transfer. Hospital care needs to be optimized to reduce the dependence on an already strained ambulance service.

1.4.3. Process

Caesarean sections are often performed by junior doctors who are not able to deal with life-threatening intraoperative haemorrhage. Recognition of postpartum haemorrhage and shock is often delayed, and the response inadequate. A common theme in South Africa is the reluctance to perform relook surgery at a district hospital, because of the lack of blood products, and lack of surgical confidence and competence (3).

Another important issue pertinent to the management of women with BDACS is the ability to provide comprehensive care for the women with complications from caesarean section haemorrhage. The Canadian near-miss audit conducted by Baskett and Sternadel noted that the most common obstetric complications requiring ICU admission were

hypertension, haemorrhage and sepsis. They highlighted the need for critical care units for obstetric complications. They recommended that in addition to protocols managing emergencies such as PPH, an obstetric unit should be skilled in the initial cardiopulmonary support of a critically ill patient (24). Regarding BDACS, the diagnosis and management of hypovolaemic shock and its complications has been listed as a common avoidable factor, yet none of the South African protocols/guidelines discuss the use of inotropes or ventilation in the early care of a shocked obstetric patient. The recently introduced use of colour coded charts to assist in the diagnosis of shock are helpful, but healthcare workers need to be trained on how to manage a shocked patient, or when to call for help from anaesthetists and intensivists.

In view of the problem of BDACS in South Africa, the question arises: how prepared are our hospitals to manage complications that arise from caesarean sections? Is the rising number of maternal deaths due to health system deficiencies, due to the rising caesarean section rate, due to the skills of doctors performing caesarean sections, or due to a population with a new risk profile? A health systems audit has not been done on preparedness for complications arising from caesarean section. Such an audit may enable us to determine the immediate and underlying causes for this epidemic of maternal deaths from BDACS. An important consideration with global surgery is that once surgery is accessible everywhere, more surgical complications will appear. The situation in South Africa may provide early warning of what is to come as obstetric services develop. As more low and low-middle income countries improve access to caesarean section, similar trends may appear, especially in Sub-Saharan Africa, as shown in the Tanzanian experience.

1.5. Mechanisms of haemorrhage

1.5.1. Causes of PPH

Immediately after delivery of the baby, myometrial contraction enables separation of the placenta and haemostasis. Control of postpartum placental site bleeding results from uterine contractility. This depends on hormonal and neuromuscular processes. Oxytocin acts on the myometrial oxytocin receptors, increasing the contractions. Prostaglandins are potent stimulators of myometrial activity, and participate in producing these contractions (47). In addition, the physiological increase in clotting factors helps to prevent blood loss after separation of the placenta (48). The causes of PPH can be subdivided using a mnemonic called the Four Ts. Tone is the commonest cause, followed by trauma, tissue and thrombin (Figure 1.3). Tone refers to atonic uterus. Trauma includes laceration, haematoma, inversion and rupture. Tissue refers to placental abnormalities (praevia and accreta) and retained products of conception. Thrombin refers to coagulopathies (49).

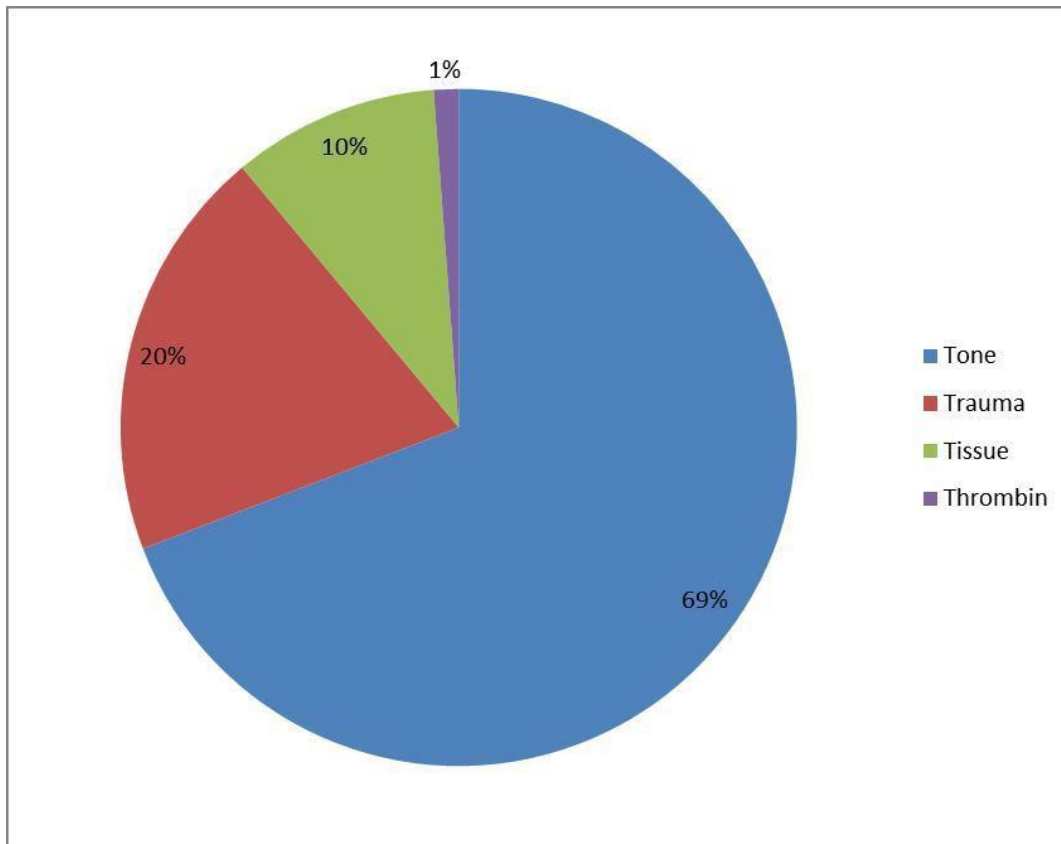


Figure 1.3: Causes of postpartum haemorrhage

Graph drawn using data extracted from Anderson (49)

An American study that included a total of 23 390 births assessed women who had atonic uterus following primary caesarean section. The authors reported a 6% rate of atonic uterus. Positive associations were multiple gestation, augmentation and induction of labour, and birthweight over 4500 g. More than half of the women did not have a risk factor for uterine atony (50). In general, PPH guidelines do not differentiate between caesarean section related haemorrhage and vaginal delivery related haemorrhage. This may be because atony may occur at both types of delivery, and some of the principles of management are similar. Yet, there is more blood loss expected at caesarean section, and caesarean section is associated with more severe maternal morbidity than vaginal delivery (51). In terms of PPH, caesarean section differs most obviously from vaginal birth in the incisions made, as well as the potential for non-incisional trauma related to opening

the abdomen and extracting the baby from the uterus.

1.5.2. Iatrogenic injuries from caesarean section

Iatrogenic injuries sustained at caesarean section are associated with increased morbidity and increased need for blood transfusion (52). Injuries may involve the urinary tract, the genital tract or the abdominal cavity. Well-known injuries include vascular trauma, accidental extension of the uterine incision, damage to the bladder, and damage to other organs, notably the intestine (53). A study done in the United Kingdom (UK) over an eight-year period evaluated urinary tract injuries in obstetric patients in a hospital that performed about 5500 births per year. Eighteen injuries were documented, and 15 were associated with caesarean section, 14 with emergency cases and 1 with an elective caesarean section. The bladder injury rate was 1.4/1000 caesarean deliveries, and the ureteral injury rate was 0.27/1000 caesarean sections. All the injuries took place in the early hours of the morning, associated with the duty hours of inexperienced, unsupervised junior staff. Perhaps surprisingly, most caesarean sections were done in women who had never had a caesarean section before. It was postulated that caesarean sections in women with previous caesarean sections were done by more senior staff, with more vigilance (54). Bowel injury is not common at caesarean section, but the risk increases with the number of previous caesarean sections (55). Abdominal adhesions are fibrous band-like structures that form between abdominal organs when surgical trauma induces inflammation and disrupts normal tissue. Adhesions develop following 46-55% of primary caesarean sections. Some adhesions are easily separable at repeat operation, but others are thick and dense, resulting in considerable surgical difficulties that may include trauma and haemorrhage. The risk of adhesions increases with each caesarean section. Surgical techniques to reduce the formation of adhesions involve careful tissue handling, good haemostasis, removal of free blood, and maintenance of tissue

moisture (55). Trauma to bowel and urinary tract is not classified as BDACS. Trauma in BDACS refers to injuries that involve failed haemostasis in the uterine incision, lateral extension (tearing) of the uterine incision, or injury to other tissues.

The source of bleeding in the maternal deaths from BDACS was poorly classified in the Saving Mothers Report. A secondary analysis of the Saving Mothers data by Gebhart et al revealed that the source of the bleeding was not always recorded in the patient folder, e.g. uterine incisional trauma versus bleeding from uterine tears. Delay in recognition of internal bleeding after caesarean section was also a recurring theme (7). Knowledge about the mechanism of bleeding enables the surgeon to decide on the optimal management plan for each patient. Although guidelines and protocols are readily available in the South African setting on the management of PPH, the clinician's understanding of the origin and seriousness of the condition will determine whether they follow the correct steps on the protocol. The relative contributions of atony versus trauma versus retained products in BDACS have not been determined in the literature.

1.6. Contributors to BDACS

The increase in BDACS in South Africa is believed to be due to the increase in the caesarean section rate, and due to the change in the risk profile of patients, especially a larger proportion of women with previous caesarean section (56).

1.6.1. Risk factors for PPH

Risk factors for PPH, irrespective of mode of delivery, include maternal age ≥ 35 years, multiple pregnancy, uterine leiomyomata, pre-eclampsia, antepartum haemorrhage and uterine rupture. Caesarean section itself is a risk factor, as is instrumental vaginal delivery (57). Recent studies have separated risk factors for PPH in elective and emergency caesarean sections. A study done in the USA found that risks associated with elective caesarean sections were uterine leiomyomata, blood clotting disorders, antepartum haemorrhage and preterm birth. Risk factors specifically associated with caesarean section include general anaesthesia as opposed to regional anaesthesia, pre-eclampsia, chorioamnionitis, prolonged labour, macrosomia, increased body mass index (BMI), previous uterine scar, placenta praevia and placental abruption (57,58). PPH frequently occurs in women without risk factors. The importance of identifying risk factors early in pregnancy is that it allows women to be managed and delivered at the appropriate level of care. However, PPH is unpredictable in most cases, and therefore requires adequate systems to be in place to manage patients effectively at any level of care.

A study at Johannesburg's Chris Hani Baragwanath Hospital (CHBAH) by Hassim described profiles of women undergoing emergency obstetric hysterectomy for severe haemorrhage. Previous caesarean section and placenta praevia were the main risk factors. Of 27 women who had hysterectomy for obstetric haemorrhage over a one- year period, 63% had

uterine atony, and 17% had uterine lacerations. Thirteen women (48%) delivered by caesarean section. There was no correlation with increasing parity. Prolonged labour was a risk factor in 5/27 and prolonged second stage of labour in 8/27 women. Two women died, one intra-operatively because of haemorrhage that could not be controlled, and the other in ICU from a ruptured subcapsular liver haematoma (59). The limitation of this study was the small number of patients, defined by the time period. The study also did not look at other consequences of intractable haemorrhage. The study however gave insight into the risk factors associated with PPH in a South African hospital.

A study by Ayob, also at CHBAH, described the caesarean section rate, the Robson criteria, and near-miss related to caesarean section over a two-month period. The caesarean section rate was 39% among 3898 births (60). The most frequent Robson categories were those that included previous caesarean section. There were four near-misses from BDACS (1 per 1000 operations), and no maternal deaths. Given the relative rarity of BDACS-related near-miss and death, the sample size was small.

A large study in the UK, as part of the UK Obstetric Surveillance System, considered peripartum hysterectomy (61). The study included 315 women who underwent peripartum hysterectomy for management of postpartum haemorrhage. By definition, peripartum hysterectomy is a near-miss event, although the study was not of near-misses, and did not consider other near-miss inclusion criteria. The causes of bleeding were uterine atony in 53% of the cases, placenta accreta in 38%, extension of the uterine incision at delivery in 6%, and genital tract laceration in 3%. Eighty percent of the women were delivered by caesarean section; 38% had placenta praevia and 38% had morbidly adherent placenta. Two women died, resulting in a case fatality rate of 0.6%. Eighty-four percent required ICU care, 20% required a second look laparotomy, and 21% had other organ system

damage. The proportion of women requiring ventilation and dialysis was low. The most important finding of the study was that severe morbidity from BDACS is associated with uterine atony and placental pathology (61). The study provided useful information on underlying pathology of BDACS, but necessarily excluded women who did not need hysterectomy. Studies are needed that specifically focus on the full spectrum of severe morbidity (all near-miss criteria and death) associated with BDACS. Extrapolations made from similar studies reporting isolated near-miss events such as hysterectomy or ICU admission may not provide a representative picture of the nature and effects of BDACS.

1.6.2. Caesarean section rate

Caesarean section has become one of the most widely performed surgical operations in the world, with higher caesarean section rates in high-income countries. The caesarean section rate varies worldwide (62). The South African caesarean section rate in public service institutions in 2011-2013 was 23.1% (3). Factors that may contribute to increased caesarean section rates globally are improvement in anaesthetic and surgical techniques, reduced risk of operative complications, decreased training for clinicians in instrumental vaginal deliveries, litigation against obstetric care providers, increased use of electronic fetal heart rate monitoring, changes in health systems, and patient demands for caesarean section without medical indication (25,51). Patient demands are sometimes based on the belief that caesarean section may protect against urinary and faecal incontinence, and genital prolapse. Changes in societal norms have also led to the notion that a woman has a right to choose her method of delivery (25). Although these factors are known to be associated with increases in caesarean section rates, these reasons have not been explored in the South African context, particularly in the public hospitals.

Institutional studies may give insight into the caesarean section indications. In Ayob's study at CHBAH, indications for caesarean section included fetal distress (44.8%), dystocia (12.7%) breech presentation (5.1%), planned repeat caesarean section (17.2%), failed induction of labour (0.9%) and failed vaginal birth after caesarean section (VBAC) (6.1%) (60). As access to caesarean section increases, especially in sub-Saharan Africa, caesarean section rates will rise globally. Reasons for increases in the caesarean section rate need to be explored. The clinical indications for caesarean section in women with BDACS need to be determined. And the number of women who die as result of BDACS, who had an unnecessary caesarean section, needs to be quantified.

1.6.3. Complicated caesarean sections

Repeat caesarean section is a leading indication for caesarean sections today. They account for a third of caesarean sections in the USA (51). They are not without technical challenges, and the surgical difficulties are widely documented. The South African caesarean section monograph states the difficulties associated with a repeat caesarean section. Fibrosis from the previous operation leads to poor exposure, and difficulties delivering the baby. Adhesions may result in bowel and bladder injuries. The surgeon must be cautious throughout the caesarean section (35).

Vaginal birth after caesarean section (VBAC) refers to a woman who had a prior caesarean section who plans to deliver vaginally, rather than by an elective repeat caesarean section (63). The term 'once a caesarean, always a caesarean' was adopted by the New York Association of Obstetricians and Gynecologists from 1916. At the time, all women who previously had a caesarean section, were advised to have a repeat caesarean section. VBAC emerged in 1980, from the National institutes of Health Consensus Conference as a safe measure to reduce the caesarean section rate (64). Globally, VBAC became accepted practice. A study in Nigeria found a VBAC success rate of 55%, less than

the 70% success rate in the USA. This was associated with the fact that over 30% of the Nigerian women had no antenatal care prior to hospital admission and 70% presented in advanced labour (65). A South African study done at CHBAH between 2003 and 2005 reported a VBAC success rate of 52% (66). Along with the global increase in caesarean section rate, there has been a decline in the rate of trial of labour after caesarean section (attempted VBAC). With repeat caesarean section increasing the risk for BDACS, a decline in VBAC attempts can reasonably be associated with a surge in caesarean section related haemorrhage.

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Understanding predictors for BDACS is an essential step in the prevention and management of PPH. A woman who has had a previous caesarean section, and ultrasound findings suggestive of a placental abnormality, is more likely to bleed. Knowledge about the causes of PPH, and the likelihood for bleeding, allows the clinicians to predict the transfusion requirements. This knowledge allows the surgeon and the multidisciplinary team to anticipate BDACS, and to implement measures to prevent BDACS (67). Risk factors directly related to severe BDACS need to be studied further.

1.7. Interventions to reduce morbidity and mortality from BDACS

Various recommendations have been made, particularly in the South African context, where deaths from BDACS have been headlined as a national emergency. Key recommendations suggested by Hofmeyr are:

1. preventing unintended pregnancies,
2. reducing unnecessary caesarean sections, and
3. providing adequate prophylactic uterotonics (68).

The reasons for the rise in deaths from BDACS appear to be multifactorial, and the problem highlights various health system gaps, such as the unmet need for contraception, the rise in the number of unnecessary caesarean sections, and deficits in skills and knowledge in managing women with post-operative complications. Furthermore, studies on obstetric haemorrhage have shown that, even with antepartum diagnosis of conditions such as placenta praevia, and optimal pre-operative preparation, a patient may still have an unfavourable outcome because of massive bleeding (69).

The burden of unwanted pregnancies and unnecessary caesarean sections has direct implications on absolute numbers of maternal poor outcomes, but two further questions that need to be asked are: are women dying because more women are bleeding during and after caesarean section, or are they dying because of inadequate systems to manage complications associated with BDACS? And, should interventions be focused on the pre-conception stage, the antenatal stage or the intrapartum and postoperative stage?

1.7.1. Health systems: safe caesarean section

There are minimum standards in South Africa that a hospital should have to perform caesarean sections. If these standards are not met, caesarean sections should not be performed in the

hospital. The hospital may need to temporarily cease services until all the standards are met. These are requirements from the Department of Health, published in a caesarean section monograph written in 2013 (35). There should be sufficient medical personnel (nurses and doctors) to provide comprehensive preoperative, intraoperative and postoperative care. Anaesthesia needs to be performed by an experienced doctor, with the sole task of providing anaesthesia. A surgeon may be assisted by a nurse if there are only 2 doctors available for the caesarean section (35). Equipment needs to comply with the South African ESMOE (Essential Steps in Managing Obstetric Emergencies) guidelines, which includes equipment for maternal intubation, manual ventilation, and other equipment in case of cardiopulmonary resuscitation. A refrigerator with a store of emergency blood is required in every hospital that performs caesarean sections. Oxytocin must be available in theatre prior to caesarean section. If postoperative recovery facilities do not exist, it is the responsibility of the operating theatre team to fully recover the patients (35). Vital postoperative assessments need to be made at a recommended frequency of: half hourly for two hours, hourly for a further four hours, two hourly for a further six hours, and four hourly for a further 12 hours. Patients who may require high care or ICU after caesarean section, and babies who may require neonatal unit admission, must ideally be triaged to the appropriate hospital prior to caesarean section (35).

The critical question is whether these standards are being met by South African hospitals, particularly in district hospitals where many caesarean sections take place. Secondly, do these standards also apply to intractable bleeding because of caesarean section? Is oxytocin enough to manage a woman who has intractable bleeding post-operatively, and if not, are there other pharmaceutical means to manage the bleeding, and are there functional ambulance services properly equipped to transfer patients to a higher level of care, in the shortest time possible? In the Saving Mothers report of 2011-2013, deaths related to BDACS were reported in

ambulances on the way to higher levels of care (3). It may be that the monograph standards have been set only for management of uncomplicated caesarean sections.

1.7.2. Methods of training

An outstanding review by Masden et al of advances in surgical training for caesarean section was published in 2013. Based on studies which evaluated the learning curve in caesarean section, the authors concluded that trainees should perform approximately 10-40 caesarean sections under supervision before mastering the procedure independently (70). This requires a formal training programme with theoretical instruction, video tutorials, practical experience, supervision, and, importantly, formal assessment. Locally, the Health Professions Council of South Africa expects medical interns to perform at least 10 caesarean sections under supervision before they can register as independent medical practitioners. There are no formal guidelines on teaching methods for caesarean section. There is no assessment, and there is no recommendation on the minimum experience or qualifications required by the supervising surgeon. Training methods for caesarean section have not been evaluated in South Africa. Unfortunately, caesarean section training in South Africa is not standardised. Doing 10 caesarean sections under supervision does not guarantee acquisition of the necessary skill, but at least it ensures a degree of exposure to the operation and surgical skills in general.

The Objective Structured Assessment of Technical Skills (OSATS), developed in Canada, was described by Martin et al in the British Journal of Surgery, as an evaluation model for surgical residents. This was introduced as an alternative to the Objective Structured Clinical Examination (OSCE). The type of scoring system that was initially proposed used a checklist with the following components:

- respect for tissue,
- knowledge of instruments,
- use of assistants,
- flow of operation, and
- knowledge of the specific procedure (71)

This method of evaluation promised to be a valid one in testing technical skills for surgical procedures. The trainee medical officer or registrar completes a logbook with a certain number of caesarean sections completed, prior to assessment. The OSATS assessment for caesarean section was found to be an important tool in demonstrating and documenting the successful attainment of mandatory skills. The assessment provides evidence of training, confirmation of competence, and confirmation of continued competence (68). The Royal College of Obstetricians and Gynaecologists now uses the OSATS model for summative and formative assessments for caesarean sections. The OSATS model for caesarean section has been described as useful when assessing competence in uncomplicated caesarean sections, but is not as easily applied during difficult or complicated caesarean sections (68).

Intraoperative video enhanced surgical training allows trainees to perform the task, instead of a supervisor. The use of simulators for training enhances learning efficacy and patient safety. It allows for repeated practice in a safe environment. The trainees can further use live animal models until they are comfortable to operate on human patients. The role of videos in caesarean section training still needs further investigation (68).

ESMOE, referred to earlier, is the South African programme for obstetric emergency training. The programme was first recommended in the 2005-2007 Saving Mothers report, after

knowledge and skills deficits were found to be a major contributor to avoidable maternal deaths. A 12-module programme was developed nationally, initially for medical interns. ESMOE was evaluated in 2008 during a pilot phase. Frank et al compared 68 interns in their obstetrics and gynaecology rotations, using a pre-test and a post-test. The study showed a clear improvement in knowledge and skills in interns who had been trained, compared to those who had not been trained (72). Moran et al later evaluated the effect of ESMOE on maternal mortality. When the number of maternal deaths increased in South Africa in 2008 - 2010, a decision was taken to upscale ESMOE, which included training for all obstetric doctors and midwives, and not just interns. This was intended to reduce the number of healthcare worker associated factors in maternal deaths. The subsequent Saving Mothers report, from 2011-2013, showed an 11% decrease in mortality, but this was largely due to the decline in non-pregnancy related infections (mostly deaths from HIV/AIDS), probably a direct result of antiretroviral treatment rollout after 2008. Deaths from obstetric haemorrhage and ectopic pregnancy did not decrease. Moran et al concluded that it may have been too early to expect an impact on the number of maternal deaths. The authors also suggested that having knowledgeable and skilled staff may have only a limited impact on reducing maternal mortality if the health system is not functional (8). ESMOE focuses on acute management of obstetric emergencies, and is likely to be most useful in settings where clinicians need to improve skills in a properly functioning healthcare system. In the South African setting this may not be sufficient to save lives. For example, ESMOE will train a doctor on how to arrest haemorrhage, but the facility in which the doctor works may not have supplies of the required uterotonic drugs. A further possible limitation with ESMOE training is that it focuses on short-term lifesaving skills, but does not assist in management of the patient with multi-organ dysfunction because of haemorrhagic shock. Such patients need organ system support as part of pre-ICU care, often in anticipation of and during an ambulance road trip to a referral hospital. The number of hospitals that can provide a multi-disciplinary approach or

critical care services in this country is limited, and the number of specialist obstetric intensivists is even smaller. Perhaps integrating ESMOE with some basic critical care training will equip the district medical officer to manage the patient with BDACS while waiting for the patient's transfer to a higher level of care. Healthcare worker factors are a recurring theme in the evaluation of maternal deaths from BDACS. Questions will continue to arise about the adequacy of the training provided in performing caesarean sections, and managing associated bleeding. Modules such as ESMOE are aimed at improving obstetric emergency skills, but the direct effect on BDACS has not been evaluated.

1.7.3. Monitoring

Intraoperative and postoperative monitoring are essential components in the management of women with BDACS. According to Gebhardt et al.'s overview of South African maternal deaths from BDACS (2011 – 2013), responses from nurses and doctors to deteriorations in vital signs were poor. Doctors often gave telephonic advice instead of assessing patients with deteriorating vital signs. Colour-coded early warning charts were not found in folders, and often there was a delay in recognition of internal bleeding (7). According to Thaddeus and Maine, phase III delays occur at the treatment facility. An example of phase III delay in a woman that died as a result of bleeding after giving birth is given: '...the time spent struggling to get an admission card, the time spent getting admitted, the time the midwife was called, the time the midwife finished eating, the time the bleeding started, the time the doctor couldn't be found, the time the haematologist came, the time the night nurse changed, by the time the doctor signed the consent, the woman had died...' (33). Late and incorrect diagnosis, and delay in appropriate management, leads to avoidable maternal deaths. The recognition and the means to diagnosis of BDACS and haemorrhagic shock are vital to the management of these conditions.

1.7.3.1. Visual estimation of blood loss

While commonly used in the labour ward and operating theatre, visual estimation of blood loss is compromised by the element of underestimation, potentially leading to delay in diagnosing and treating ongoing massive PPH (73). The concept of ‘too little being done too late’ relates to the fact that a healthy pregnant woman can lose up to 30% of her blood volume without a change in systolic blood pressure. Also, women with BDACS often bleed internally with no visible blood loss. This results in a false sense of security, with consequent delayed management (67). Visual estimation nevertheless gives an indication of a minimum blood loss, has no costs and ensures close attendance of health care workers. Blood loss can also be estimated through measurement of the content of drainage bottles, and by weighing blood-soaked swabs or drapes. Obstetric blood loss is more complex because of the added amniotic fluid and loss onto floors and flat surfaces. Few studies have been done looking at the validity of visual estimation, and have reported underestimation (73). Blood loss can also be overestimated, contrary to the findings of most studies. Larson et al compared the inter-individual agreement on estimated blood loss compared with actual measurement of blood in 29 women with a caesarean section and 26 women with a vaginal delivery. A tendency to exaggerate was found, especially at caesarean section. However, these women did not have postpartum haemorrhage and underestimation would not have been a problem in them (73). Close postoperative monitoring is essential after caesarean section, and should involve more than just documenting the heart rate and blood pressure. No studies have looked critically at measurement of postoperative blood loss. Bodur et al compared pre-operative and post-operative haemoglobin levels in 100 women with an uneventful caesarean section. There was a consistent decline in haemoglobin levels, but none of the women needed blood transfusion (74). Post-operative care also involves looking under sheets for vaginal bleeding, something that patients may find annoying if done too frequently. Patients

after caesarean section may be found lying in a pool of blood when it is too late.

1.7.3.2. Shock index

The shock index measures the maternal heart rate divided by the systolic blood pressure. It is a reliable predictor of the need of blood transfusion (67). The shock index has been used by general surgeons and trauma surgeons for decades to assess hypovolaemic shock and the severity of non-hypovolaemic shock (67). A systematic review on the relationship between blood loss and clinical signs included 10 articles that calculated the shock index. The findings suggested that the shock index may identify hypovolaemia in women without hypotension, and that it is a better predictor of bleeding than either heart rate or systolic blood pressure alone. The normal range for the shock index in a non-pregnant patient is 0.5-0.7. An emergency department in the UK compared the shock index with conventional vital signs to diagnose acute critical illness in non-pregnant adults. An elevated shock index was associated with patients who needed immediate treatment, admission and ICU transfer. Heart rate and blood pressure did not independently identify shocked patients as well as the shock index (75). A study in New York city examined the ability to identify women with a ruptured ectopic pregnancy using the shock index, compared with traditional vital signs. A shock index >0.70 was a better predictor of tubal rupture than the heart rate or systolic blood pressure alone (76). However, due to the physiological changes of pregnancy, a shock index in advanced pregnancy of greater than 0.9 is a more accurate indicator of compensatory changes, and therefore early diagnosis of haemorrhage (68, 77). This may be a useful test in our setting. The advantage is that the shock index is an easy arithmetic calculation that can be done mentally or using a calculator. It does not require special additional devices. An awareness of the shock index needs to be created amongst anaesthetists, obstetricians, midwives and medical officers in central and peripheral hospitals. The South African Department of Health recently introduced colour coded early warning chart in all hospitals, to identify abnormal vital

signs early in postnatal women (78). The limitation with these charts is that the routine vital signs have a low sensitivity to haemorrhage including that from PPH and BDACS. There is no place on the chart where the shock index can be entered.

1.7.3.3. Point of care monitoring

Point of care testing is increasingly finding favour for detecting haemostatic changes in bleeding patients intraoperatively and postoperatively. Visco-elastic devices are used in combination with standard laboratory tests. The advantages of the tests are quicker results, with the ability to detect clotting process disruption, and disorders of clot formation and fibrinolysis (79). ROTEM® is a point of care analyser which uses thromboelastometry to test for haemostasis in whole blood. ROTEM® can detect clotting time, clot formation time, maximum clot firmness and maximum lysis. Thromboelastography provides graphical representation of the clotting process, and assesses fibrin polymerisation and clot strength. Coagulation and platelet function analysers assess haemostasis, coagulation, fibrin gel formation, fibrinolysis and platelet formation (79). A systematic review on PPH described the accuracy of ROTEM® to predict outcomes. ROTEM® was accurate at predicting blood transfusion, invasive procedures, Fresh Frozen Plasma transfusion and platelet transfusion (79). The use of ROTEM® has not been described in South African hospitals. District hospitals without laboratory facilities may benefit from such devices, as may regional and tertiary hospitals with blood banks and the facilities to respond to the requirements of women with coagulopathies and haemostatic instability. The availability of blood gas monitors and ward haemoglobin measurement devices also assist in the management of patients with BDACS.

1.7.4. Medical interventions

The key to managing caesarean section related haemorrhage is in recognising excessive bleeding,

before it becomes catastrophic. Various interventions are effective for the management of severe caesarean section related haemorrhage, and many of these interventions depend on the availability of drugs, resources and surgical skills.

1.7.4.1 Uterotonics

There is consensus on the use of a single dose of oxytocin as the first line agent for prevention and treatment of PPH, at vaginal or caesarean delivery. Side-effects are uncommon, but include hypotension, myocardial infarction, arrhythmia, nausea, vomiting and flushing. The dose of intravenous oxytocin for prevention of PPH at caesarean section remains a controversial issue, and there is no clear evidence for a definitive optimal rate of infusion following bolus (80). Following two maternal deaths in South Africa, reported in the Saving Mothers report for 2005-2007, which were considered directly related to oxytocin, the consensus was to give the lowest possible effective dose. This often causes disputes between anaesthetists and surgeons as the dose appears to be suboptimal. For treatment of PPH, The Royal College of Obstetrics and Gynaecology (RCOG) recommends a rapid infusion of 40 IU/1500 mL crystalloids at 125 mL/hr in women with uterine atony (80). Consensus has not been found in South Africa on the most appropriate dose for prevention of BDACS and anaesthetic related complications.

Carbetocin is a long acting oxytocin analogue. It may prove to be a more effective and safer agent than oxytocin. A Cochrane systematic review comparing oxytocin and carbetocin at caesarean section for prevention of PPH found that carbetocin was associated with a reduced need for other uterotonics (81). Carbetocin is currently not available in South African hospitals, and is expected to be considerably more expensive than oxytocin.

Misoprostol is a prostaglandin E1 analogue. Misoprostol is inexpensive and stable at room temperature, factors which make it appropriate for use in low resource settings (82). It has proved to be effective in the prevention and treatment of PPH despite the side effects of hyperpyrexia, shivering and diarrhoea. Misoprostol, however, has been shown to be inferior to oxytocin as a prophylaxis and treatment for PPH (82). The WHO has recommended that misoprostol should only be used in the absence of oxytocin as a first line drug for treatment of PPH, and in the absence of ergometrine, and other prostaglandins as a second line agent (82). The South African caesarean section monograph recommends 400 µg of misoprostol in addition to oxytocin and other uterotonics for medical management of BDACS despite evidence from Cochrane systematic reviews that misoprostol should be reserved for settings where no other uterotonics are available (35). The use of misoprostol routinely after caesarean section in centres where oxytocin is available should be avoided.

Ergometrine is a naturally occurring ergot alkaloid which has been widely accepted as second line agent in the management of PPH in the absence of contra-indications. The adverse effects include a rise in the mean arterial pressure, renal artery spasm and coronary artery spasm. Its use has been associated with myocardial infarctions and it should always be used cautiously.

Ergometrine is widely available in South Africa, and recommended for use in the management of BDACS. There is some evidence of failure to use second line drugs in the treatment of BDACS in the South African setting (3). The reason for failure to use these drugs has not been determined. The availability of all uterotonic drugs in lower levels of care (regional and district hospitals) needs to be explored, as well as the knowledge about the drugs among clinicians.

1.7.4.2. *Tranexamic acid*

The efficacy of tranexamic acid in reducing intraoperative blood loss in surgical patients is proven (83). Such conclusive evidence is not yet available for treatment of PPH. A systematic review included three trials which were conducted in women with PPH. The three studies included 461 patients, 235 who received tranexamic acid, and 226 controls. All the trials favoured the use of tranexamic acid, suggesting an associated reduction in blood loss. However, the numbers of patients were few, and, according to the authors of the review, the scientific methodologies were poor (84). The World Maternal Antifibrinolytic (WOMAN) Trial is currently in progress, started in 2009, and has recruited over 20 000 women to date. The trial is scheduled to close recruitment in 2016 (85). It is a randomised, placebo-controlled trial, with the aim to determine the effect of early administration of tranexamic acid to women with postpartum haemorrhage on mortality, hysterectomy, and other morbidities (86). Most of the existing data does not provide evidence specifically for women with BDACS, and evidence for BDACS cannot necessarily be extrapolated from surgical trials. However, data is available from a meta-analysis on randomised controlled trials including 11 studies on the effect of tranexamic acid on blood loss during and after caesarean section. A total of 2531 women were included in the final analysis; 1276 received intravenous tranexamic acid and 1255 received nothing or placebos as control, in six countries. Tranexamic acid given before caesarean section significantly reduced blood loss during and after the operation, and was associated with a lower incidence of PPH and less need for blood transfusion (87). The studies used three different dosages (1g; 10mg/kg; 15mg/kg). The outcome measures varied from intra-operative blood loss (9 trials), to haemoglobin (6 trials), to incidence of PPH (5 trials). The WOMAN trial promises to provide stronger evidence because of the large sample size, the diversity of regions, and the standardisation of dosages and outcome measures (85). Current guidelines recommend the use

of tranexamic acid in the bleeding patient. In our setting, we may not be able to give tranexamic acid routinely as prophylaxis, but it should be considered in all women with PPH.

1.7.4.3. Recombinant factor VIIa

The use of recombinant Factor VIIa has been reported in case reports and case series of PPH. A case series in Finland included 12 women with intractable PPH, who received recombinant factor VIIa. Eleven women responded to the Recombinant Factor VIIA, and one woman did not respond. Prior to administration the women had received between 10 and 42 units of packed red cells, and four women did not require any further transfusion afterwards. Recombinant Factor VIIa was found to be beneficial in addition to the required surgical and conservative medical interventions. It is licensed for treatment of bleeding episodes in patients with congenital haemophilia A or B, and patients with Factor VII deficiency. It leads to greater thrombin generation, well above physiological levels (88). It is expensive, and the association with thromboembolic events does not make it an ideal treatment modality (52). Some case reports have been reported apparently successful use of Recombinant Factor VIIa in patients with caesarean section. Some of the patients already had evidence of disseminated intravascular coagulation. (89,90). A randomised controlled trial was done in France, comparing the use of Recombinant FVIIa for woman with PPH in whom oxytocin and sulprostone infusion had failed. The study had 84 women with 42 women in the intervention group and 42 women in the control group. There was a reduced need for second line therapy (compression suture, vascular ligation and hysterectomy) in the intervention group, regardless of the mode of delivery (91). Recombinant Factor VIIa is not readily available in South Africa. Use should be limited to cases where first and second line treatment have failed.

1.7.5. Non-surgical non-pharmacological interventions

Such interventions include expulsion of clots, uterine massage, intravenous fluids, uterine tourniquets and uterine tamponade. Uterine massage has now been included by the International Federation of Gynaecology and Obstetrics (FIGO) in routine third stage of labour care as a measure to prevent PPH (92).

1.7.5.1. Uterine tourniquets

Uterine tourniquets are well established for controlling bleeding at myomectomy and other pelvic haemorrhage. In the case of bleeding during caesarean section, an elastic urinary catheter is tied tightly around the uterus, to occlude arteries in the broad ligament. It is then secured with a clamp. This can be done as a temporary measure while completing other parts of the operation, while waiting for a more senior surgeon, or for a patient who will be transferred to a higher level of care. Other temporary measures which have been used successfully are clamping of the utero-ovarian ligaments, aortic compression, and abdominal packing (93). The tourniquet method was first described in a quasi-experimental study by Ikeda et al in 2005, in 4 women with placenta accreta. The group with a tourniquet required 0-4 units of blood, and blood loss was 1280-1800 mL, while a group without tourniquets had a blood loss of 4300-5350 mL, requiring 12-32 units of blood (94). Deng et al, from China, described using a tourniquet device in women with placenta praevia during elective caesarean section. The study had a case group with 14 patients and a control group with 20 patients, in a population with 10 209 births. The rubber tourniquet was placed in the lower segment before extracting the baby, with the aim of reducing blood flow to the uterus. The frequency of PPH was significantly reduced and the proportion of transfused patients was also reduced in the case group (93). Breen reported a case series in Zambia with 13 patients in whom a tourniquet was placed at laparotomy or caesarean section as a temporary measure before transferring the patient for specialist care. All the patients had a hysterectomy

done within 24 - 43 hours after the tourniquet technique. Other medical and surgical methods were attempted in addition to the tourniquet technique, which provided time for blood transfusion, and correction of shock, anaemia and coagulopathy. All of the patients survived (95). This study shows how a simple technique can improve maternal outcomes in a low resource setting. The advantage of the tourniquet is the simplicity of application, and the fact that it gives the surgeon time while waiting for blood or deciding on the next intervention.

1.7.5.2. Interventional radiology

Interventional radiology is frequently used to arrest uterine bleeding, including PPH, in well-resourced settings. It is a highly specialised and technology-dependent procedure, and cannot be done in a setting that does not have skilled radiologists. Different methods have been described, including balloon occlusion and embolization, and prophylactic catheter placement and embolization prior to peripartum hysterectomy. Selective arterial embolization can also be done, limited to the uterine arteries. A recent study by Niola et al described uterine artery embolization in 50 women before caesarean section where placental abnormalities had been confirmed. Only six women required hysterectomy, and 34% required ICU (96). This method was effective, but would not be feasible in our resource-limited setting. In South Africa, detailed ultrasound scanning is not routinely offered to pregnant women, and the diagnosis of placenta praevia and accreta is often incidental. The service with radiologists trained in uterine artery embolization is limited to a few tertiary hospitals.

1.7.5.3. Anti-shock garment

The use of the non-pneumatic (Velcro) anti shock garment has been described for postpartum haemorrhage. It is used as a first aid device for obstetric haemorrhage. It provides lower body circumferential counter-pressure which shunts blood from the lower extremities and abdominal

area to the essential core organs, and thus retains the blood pressure. Its use is associated with decreased morbidity, decreased bleeding by up to 50%, and improved survival. Within minutes, women have been reported to have regained consciousness, and normalised vital signs (97). This is particularly recommended for women who may have a delay in accessing comprehensive emergency obstetric care (42). This device is not available in South Africa. It may be a useful temporary measure in women who are waiting for referral to a higher level of care, or where there are operating theatre delays (Figure 1.4). In a systematic review of five observational studies and one cluster randomised trial of, the non-pneumatic shock garment following severe PPH, Pillegi-Castro et al found a significant reduction in the number of maternal deaths compared to the standard of care. The garment is recommended as a temporising measure in settings where delays in PPH management are common. The hospital settings varied, and included tertiary hospitals (98). This would be useful in our setting, particularly because of the evidence we have of delays. The studies done described management of PPH and were not specific to BDACS, but the efficacy should be similar in both situations.



Figure 1.4: Non-pneumatic anti-shock garment. Reproduced from Miller (99)

1.7.5.4. Uterine Tamponade

The earliest method of tamponade to achieve haemostasis was uterine packing. There has been a reluctance to use this method because of the increased risk of trauma, infection and concealed bleeding. More recently methods involving the insertion of a rubber or silicone balloon in the uterine cavity have been used. The balloons are inflated with normal saline and act by exerting inward-to-outward pressure greater than the systemic arterial pressure, preventing continual bleeding. The hydrostatic pressure effect of the balloon on the uterine arteries is also thought to be the mechanism to achieve haemostasis. Balloons have been used in other anatomical sites such as the bladder, oesophagus and vagina (100). There are five types of balloons that have been used for PPH (Figure 1.5 and 1.6):

1. Bakri balloon (Uterine balloon),
2. Sengstaken-Blakemore tube (Oesophageal balloon),
3. Rusch balloon (Urological balloon),
4. Foley catheter, and
5. Condom catheter.

The inflation capacity varies from 80mL in a Foley catheter, to up to 1500mL in Rusch balloon. The Bakri balloon was the first intra-uterine balloon (100). The Bakri balloon is available in South Africa, but not in all public hospitals. The condom catheter is a cost-effective method that is used in South Africa. A systematic review on uterine balloon tamponade for the treatment of post-partum haemorrhage in resource-poor settings, included 13 observational studies. There were no controls. The studies were conducted in seven countries mainly in Asia and Sub-Saharan Africa; 241 women had a uterine balloon inserted to arrest post-partum haemorrhage. The modes of delivery were vaginal, assisted and caesarean section. Most women had a condom catheter inserted (193/241), the Foley catheter was used in five women and the Sengstaken-Blakemore catheter in one woman, some studies did not specify the type of catheter that was used. The condom catheter was successful in 186/193 women (96%) (101). The condom catheter is safe, easy and quick to insert. In some instances, a glove has been successfully used instead of the condom (102). Balloon tamponade is an effective way of achieving haemostasis in women with BDACS and should always be considered, especially in lower levels of care. The condom catheter is preferable if the Bakri is not available.

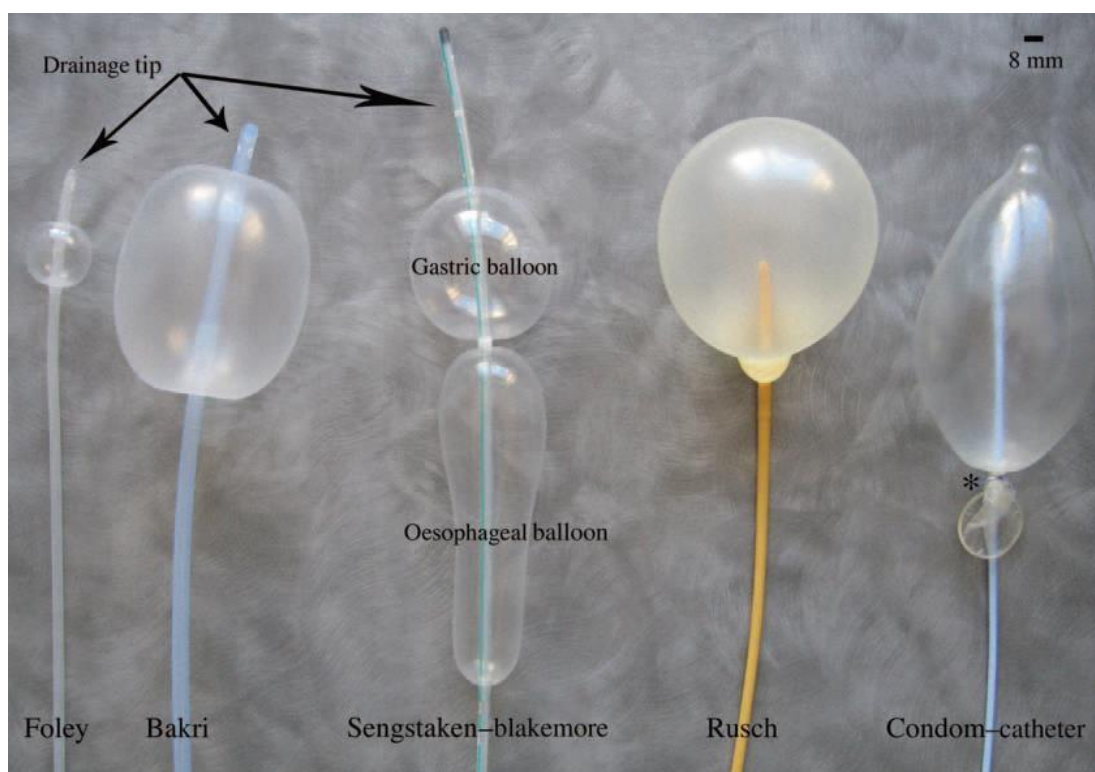


Figure 1.5: Distal aspect of tamponade balloons. Reproduced from Georgiou (100)

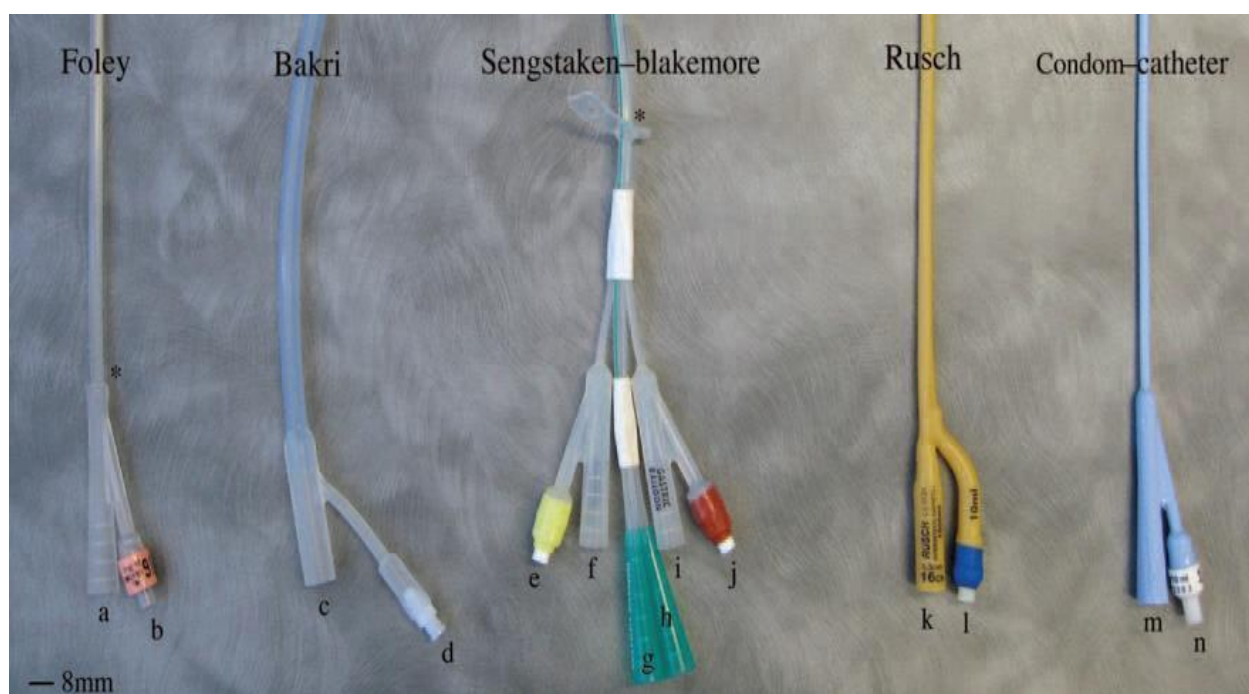


Figure 1.6: Proximal aspect of tamponade balloons Reproduced from Georgiou (100)

1.7.6. Surgical interventions

Various surgical interventions for BDACS have been described. Surgical measures are either conservative (sparing the uterus) or definitive (hysterectomy). Basic surgical principles are followed, the most important of which is to find the source of bleeding. The surgeon needs first to explore the uterus for lateral tears extending from the uterine incision, tears into the broad ligament, and tears involving the uterine arteries. Methods such as internal iliac ligation and hysterectomy are specialised skills which require an experienced surgeon.

More recently, simpler measures such as the B-Lynch brace suture or other compression suture techniques have been introduced and may be more useful and feasible in the management of BDACS. Compression sutures have been shown to be effective in arresting life-threatening haemorrhage in women with atonic uterus (103). The practice of uterine compression sutures is growing, and has generally been found easier than stepwise devascularisation and hysterectomy. Compared to hysterectomy, compression suture procedures preserve fertility and avoid the complications of hysterectomy, especially in the hands of inexperienced surgeons. (103). The B-Lynch brace suture was first described in 1997 as a simple, life-saving, fertility sparing suturing technique (104) (Figure 1.5). B-Lynch reported a case series of 11 patients who had a brace suture between 2001 and 2004 in Scotland. In a population of 25500 deliveries, 11 B-Lynch operations were done and only three women required a subsequent hysterectomy (28%), with minimal intraoperative and postoperative complications (103). A study by Tadakawa followed up woman after B-lynch procedures, including subsequent pregnancies and menstrual complications, and concluded that the B-Lynch did not jeopardise fertility (105). Modifications of the B-lynch technique have been described. The common modifications are the Cho and the Hayman suture. Other suture techniques include the Pereira and the Hackethal suture. Matsubara et al describes 11 different suture techniques. There have been no reported maternal deaths from uterine

compression sutures, however uterine necrosis, pyometra and uterine synechiae have been reported (106).

Hysterectomy remains the definitive procedure for arresting uterine bleeding. A systematic review published by Rossi et al, on emergency postpartum bleeding, included 981 women who had undergone emergency hysterectomy after delivery; 73% of the women had delivered by caesarean section. Maternal deaths occurred in 2.6% of the women, and were caused mainly by haemorrhagic shock and consumptive coagulopathy (107). Morbidity associated with caesarean hysterectomy is high and the procedure should be reserved for life-threatening haemorrhage, where other measures have failed, or if attempts to perform other measures may further compromise the condition of the patient. A 27-year retrospective review of obstetric hysterectomies in Dublin described morbidity associated with hysterectomy. There were 37 caesarean sections associated with hysterectomy, and 15 vaginal deliveries. Morbidity included urinary tract infections, wound infections, bladder injuries and paralytic ileus. Less frequent adverse outcomes were pneumonia, thrombo-embolism, septicaemia, and vesicovaginal fistulae. Subtotal hysterectomy is considered as a potentially safer option, because it is less time-consuming, safer with inexperienced surgeons, requires less pelvic dissection, and patients require less blood transfusion than those who have a total hysterectomy (108). The subtotal operation may however not be effective for bleeding that extends to the lower uterine segment and the cervix (108). The availability of skilled surgeons who can perform hysterectomies is a problem in district hospitals, as reflected in the Saving Mothers report of 2011-2013, by the number of deaths related to BDACS where doctors in district hospitals did not take the patients for second-look laparotomy, but opted to transfer patients to a higher level of care (3).

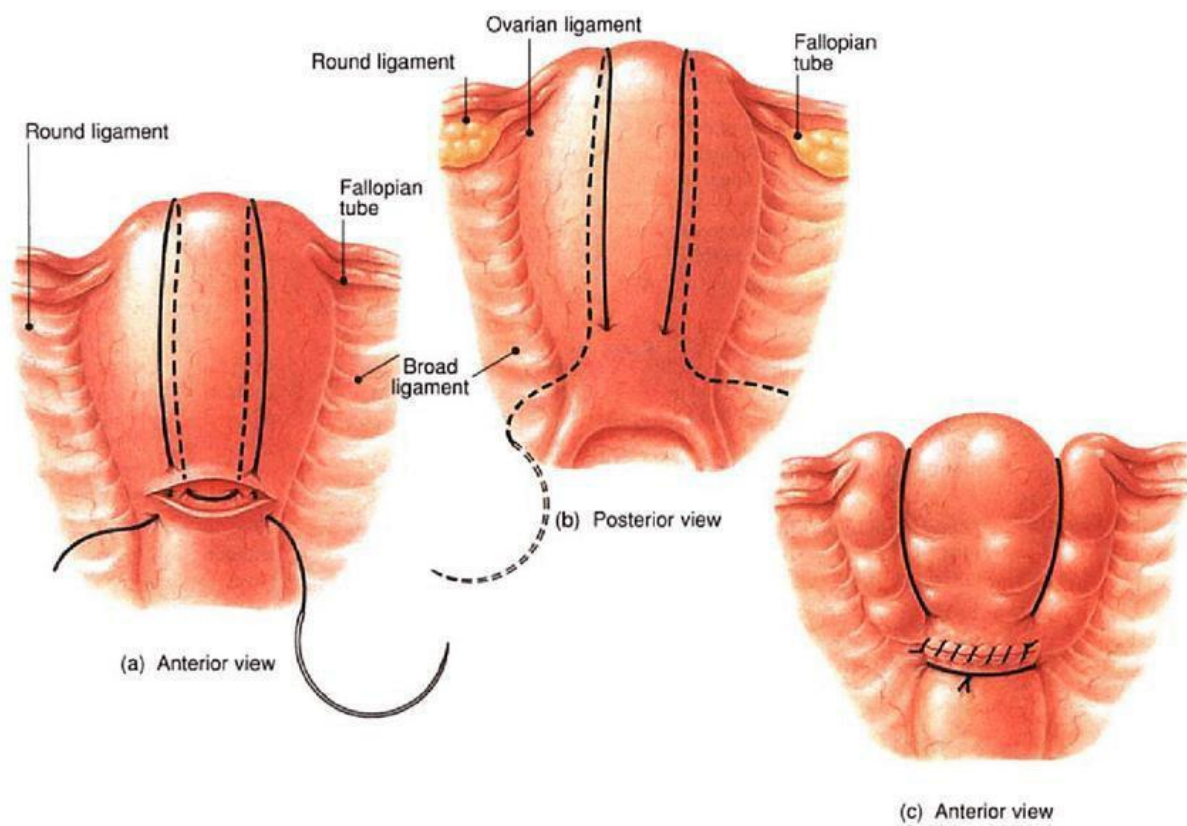


Figure 1.5: B-Lynch surgical technique. Reproduced from B-Lynch (104)

1.8. Summary of literature review

Obstetric haemorrhage is a leading cause of maternal mortality globally. Deaths from BDACS have increased in South Africa since 2002 and have been headlined as a national emergency. The increasing caesarean section rate is believed to be the main contributing factor. In addition, substandard care, misdiagnosis and poor recognition of problems are major contributory reasons for maternal mortality in South Africa.

The study of maternal near-miss has become the main audit tool for quality of care in high income countries. Near-misses and maternal deaths share similar characteristics, but near-misses provide an opportunity to determine how obstacles were overcome after the onset of acute complications. Caesarean sections are associated with increased near-miss morbidity and maternal mortality. Studies on near-misses associated with BDACS are few, highlighting the paucity of information on severe morbidity from BDACS. The Donabedian model is able to distinguish between actual care provided and the capacity to provide care, and thus appears to be the most suitable audit tool to evaluate quality of care in women with BDACS.

Access to timely caesarean section is a key priority in the Global Surgery Commission. The ability to manage complications from caesarean section related haemorrhage is a challenge. The majority of women with BDACS die in district and regional hospitals, or en-route to higher levels of care. Lack of resources and essential drugs, and the uneven distribution of drugs contribute to near-miss and maternal deaths at the lower levels of care. The shortage of ambulances and Advanced Life Support paramedics further compromise the hospital referral system. The recognition and management of shock is often delayed. This is compounded by the lack of comprehensive obstetric guidelines on critical care aspects, and the absence of multi-disciplinary teams in lower levels of care.

The question: ‘are more women dying because more women are bleeding during and after caesarean section, or are they dying because of inadequate health systems to manage BDACS’ has not been answered. Methods of caesarean section training have not been standardised and there is no formal method to assess competence in South Africa. Post-operative monitoring is important and should include more than blood pressure and heart rate readings. The shock index and point of care devices have been suggested as measures to improve post-operative monitoring.

Consensus has not been found on the most appropriate dose of oxytocin for prevention and treatment of BDACS. Carbetocin may prove to be more effective than oxytocin, but is not available in South Africa and may be more expensive. The availability of second line drugs in South Africa across different levels of care should be explored. Ergometrine is the main second line agent for atonic uterus. Tranexamic acid is recommended in women with BDACS.

Recombinant Factor VIIa is expensive and not readily available and should be limited to cases where first and second line treatments have failed. Effective non-surgical modalities are the uterine tourniquet and the non-pneumatic anti-shock garment, the latter of which is not available in South Africa. The glove and condom catheter are simple, cost-effective devices to achieve haemostasis in women with BDACS. Surgical techniques are more definitive, but may be difficult or have complications.

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Chapter 2

Methods

2.1. Problem statement

The number of maternal deaths from BDACS has increased in South Africa. Current evidence comes from the Saving Mothers reports, which highlight healthcare worker and healthcare system deficiencies, but lack detail on risk factors and causes.

The problem appears to be multi-factorial. Recommendations do not seem to have a direct bearing on BDACS, but are mostly aimed at reducing the caesarean section rate and improving pre-conception and antenatal care.

The following research gaps have been identified: the near-miss rate for BDACS globally; a near-miss audit on BDACS in South Africa; risk factors and causes of death from BDACS; quality of care in the management of BDACS; and health system barriers to the management of BDACS.

2.2. Research Objectives

1. To undertake a systematic review of near-miss resulting from postpartum haemorrhage, with a focus on BDACS.
2. To evaluate preparedness for complications of caesarean section, and to determine constraints to safe caesarean section in southern Gauteng.
3. To determine risk factors and causes of near-miss related to BDACS, and to evaluate quality of care in women who had a life-threatening complication from BDACS in

southern Gauteng over a six-month period.

4. To determine risk factors, clinical events and potentially avoidable factors in maternal deaths from BDACS.

2.3. Setting and hospitals eligible for inclusion in the study

Gauteng is the province with the largest population and the highest number of births in South Africa, even though it is the smallest province in terms of land surface area. Gauteng province has 25 public hospitals with maternity units, 18 in southern Gauteng and seven in northern Gauteng. The hospitals in northern Gauteng are part of the University of Pretoria and the Sefako Makgatho University clusters. Seventeen of the 18 hospitals in southern Gauteng are part of the University of the Witwatersrand cluster. Southern Gauteng is geographically divided into four districts, namely Johannesburg Metro, Sedibeng District, Ekurhuleni Metro and West Rand District. The 17 hospitals from the University of the Witwatersrand cluster were included in this study (Table 2.1). Seven of the hospitals are district hospitals, seven are regional hospitals and three are teaching (tertiary) hospitals attached to the university. In southern Gauteng, over 100 000 births occur in the 17 hospitals each year, including about 25 000 caesarean sections.

Table 2.1: University of the Witwatersrand cluster of hospitals

District	Hospital	Level of care
Ekurhuleni	Bertha Gxowa Hospital	District
	Far East Rand Hospital	Regional
	Natalspruit Hospital	Regional
	Pholosong Hospital	Regional
	Tambo Memorial Hospital	Regional
Johannesburg	Bheki Mlangeni Hospital	District
	Charlotte Maxeke Johannesburg Academic Hospital	Tertiary (teaching)
	Chris Hani Baragwanath Academic Hospital	Tertiary (teaching)
	Edenvale Hospital	Regional
	Rahima Moosa Mother and Child Hospital*	Tertiary (teaching)
	South Rand Hospital	District
Sedibeng	Heidelberg Hospital	District
	Kopanong Hospital	District
	Sebokeng Hospital	Regional
West Rand	Carletonville Hospital	District
	Leratong Hospital	Regional
	Yusuf Dadoo Hospital	District

Rahima Moosa Mother and Child Hospital* is a regional hospital, but functions as a tertiary hospital

2.4. Synopsis of the study design

The research was divided into four themes:

2.4.1. *Systematic review*

A prevalence systematic review was conducted with the aim of determining global near-miss rates and mortality indices for near-miss from PPH. A prevalence systematic review, is a systematic review used to accurately measure the prevalence of a disease, including the proportion of people who have the disease (prevalence) or how often the disease occurs (incidence) (1). A proposal was submitted to PROSPERO and published on 17/04/15 (2). PROSPERO is an international prospective register of systematic reviews. The methodology followed PRISMA guidelines. The inclusion criteria were near-miss audits published in English between 1995 and 2014. Four databases were screened for titles: Pubmed, Embase, Scopus and grey literature. Data extracted included the country, the year that the audit was done, and whether the study was community or hospital based. The total number of live births, near-miss, deaths, near-miss from PPH and deaths from PPH were required for the study to be included. Causes of PPH, the near-miss criteria used, and near-miss defining criteria for PPH were also extracted. More details on the methods are given in Chapter 3.

2.4.2. *Health systems audit*

A health systems audit was conducted in 15 hospitals in southern Gauteng. Consent was sought from 17 hospitals, but was denied in two hospitals, for reasons not clearly stated. This was a cross-sectional audit done between July 2014 and May 2015. Interviews were conducted by the researcher using a structured questionnaire. At each hospital, the researcher interviewed the obstetrics and gynaecology head of department (HOD), or a senior staff member that had been selected by the HOD for the interview. The interviews were set out to determine staffing, skills,

facilities, teaching and resources in each hospital. The number of nursing staff and doctors was calculated according to the number of staff on the monthly rosters. Skills to perform lifesaving procedures such as obstetric hysterectomy and B-Lynch brace suture were inquired about.

Facilities were evaluated by the availability of a blood bank, intensive care unit, high care area, 24-hour operating theatre and postoperative recovery area. Questions about the methods of teaching caesarean section and the requirements before a new surgeon could operate independently were asked. The availability of essential drugs to treat caesarean section related haemorrhage was assessed. More detail on the methods is presented in Chapter 4.

2.4.3. Maternal near-miss audit

This was a cross-sectional audit of BDACS done in 13 hospitals from July to December 2014. Consent was sought from 17 hospitals, two hospitals declined, and two hospitals were not able to allocate a staff member to report on the near-miss events that occurred in the hospitals. The 13 hospitals included three teaching hospitals, seven regional and three district hospitals. The World Health Organization intervention criteria were used to identify cases of near-miss, adapted to suit the population (3) (Table 2.2). Women with an extra-uterine pregnancy, and where another cause of haemorrhage was the primary reason for bleeding, were excluded. Women with a ruptured uterus were also excluded, because the trauma to the uterus was not related to the caesarean section, and if the fetus was in the abdominal cavity, it was no longer a caesarean section.

Table 2.2: Near-miss criteria used in this study

Inclusion criteria	Near miss markers
Any woman with a caesarean section with a combined intra-operative and post-operative blood loss of more than 1000 mL, with a gestational age of ≥ 24 weeks or who delivered a baby ≥ 500 g, with 1 or more of the following:	Admission to intensive care unit
	Post-operative ventilation
	Inotropic support
	Caesarean hysterectomy
	Relook laparotomy with or without hysterectomy
	Acute dialysis
	Referral to a higher level of care

The researcher trained staff at each hospital on how to identify a near-miss related to BDACS. When a staff member identified an eligible near-miss, they informed the researcher telephonically, who then travelled to the hospital to determine if the case matched the inclusion criteria. The researcher also travelled frequently to the hospitals to remind staff members about the study. Data was collected after informed consent was obtained from the near-miss patient prior to data collection. Data was collected from the antenatal record card, on the age and gestation of the patient, gestation at first visit, number of antenatal visits, and problems and management during the antenatal period. The inpatient folders were used to examine the caesarean section notes, post-operative notes, and details about the haemorrhage. To ensure inclusion of all eligible patients, the hospital admission book was screened for admissions during pregnancy, reason for admission at the time of delivery, diagnosis at the time of admission, reason for caesarean section and complications relating to the surgery. Further details on the study methods and data analysis are provided in Chapters 5.

2.4.4. Maternal death audit

This was a cross-sectional audit of maternal deaths from BDACS. The audit was conducted in seven hospitals for maternal deaths from January 2013 to December 2014. Consent was sought from 17 hospitals, two declined (where another maternal care audit was being done), and eight could not provide records of all the maternal deaths from BDACS. The data were collected from July 2014 to March 2015.

The case definition for maternal deaths from caesarean section related haemorrhage was intraoperative or postoperative death (≤ 42 days) resulting from acute haemorrhage of at least 1000 mL blood loss, at or after caesarean section at ≥ 24 weeks gestation. Women with significant antepartum haemorrhage that preceded the caesarean section, as well as those with

uterine rupture with a partially or completely extruded fetus, and women with an advanced extra-uterine pregnancy, were excluded. The age, parity, gravidity, weight and body mass index (BMI) were collected from the antenatal records. Antenatal visits and any pathology which occurred were evaluated. Risk factors were considered, such as previous caesarean section, HIV infection, anaemia, placental abruption, placenta praevia and multiple pregnancy. Events surrounding the caesarean section, including fetal outcome, details and findings during the caesarean section, and post-partum events and interventions, were documented. Details about the time of death, place and cause were documented. The Donabedian model was used to evaluate quality of care in each case (4). Further details on the study methods and data analysis are provided in Chapter 7.

2.5. Ethical and administrative approval

Ethics clearance was obtained from the University of the Witwatersrand Human Research Ethics Committee (M140137) (Appendix 2). All data sheets were anonymised in terms of the name, hospital number and birthdate of the patients. Permission to undertake research activities in the hospitals was granted by the Gauteng Department of Health research office. Permission was sought from each hospital's Chief Executive Officer, and the HOD (Appendix 2). Permissions for the near-miss audits were sought from the HODs and Nursing Managers. Consent to teach medical and nursing staff was sought in each hospital, from the HOD. Other research documentation including data sheets are attached as Appendices 3-13.

2.6. Budget

The research was funded by Carnegie Corporation of New York for a two-year period, for full-time study by the researcher.

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2. South African Medical Research Council, Self-initiated research grant: R145 500

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A systematic review of maternal near miss and mortality due to postpartum hemorrhage

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Abstract

Background: Postpartum hemorrhage (PPH) is the principal direct cause of maternal mortality worldwide. Analysis of maternal near miss could increase understanding of survival among women with life-threatening PPH.

Objectives: To determine the near-miss ratio and maternal mortality index for PPH globally.

Search strategy: A prevalence systematic review was conducted of English-language articles published from 1995 to 2014. Suitable articles were identified from the Scopus, PubMed, Embase, and Grey Literature databases. The main search terms used were “maternal near-miss” and “severe acute maternal morbidity.”

Selection criteria: Near-miss studies and audits describing the severe maternal outcome rate for PPH were included.

Data collection and analysis: Data were extracted from eligible publications. Quantitative analysis and narrative synthesis were used.

Main results: For 26 included studies, the median near-miss ratio for PPH was 3 per 1000 live births. The mortality index for PPH was 6.6% (range 0.0%–40.7%). The mortality index was highest in low-income countries and lower middle-income countries. Overall, PPH was the most frequent contributor to obstetric hemorrhage, with atonic uterus identified as the main cause.

Conclusions: Women in low-income countries and lower middle-income countries have an increased likelihood of severe PPH and of dying from PPH-related consequences.

KEYWORDS

Near miss; Obstetric hemorrhage; Postpartum hemorrhage; Severe acute maternal morbidity

1 | INTRODUCTION

Postpartum hemorrhage (PPH) is the leading direct cause of maternal mortality worldwide, and one-third of all maternal deaths in Africa and Asia can be attributed to this condition.¹ The occurrence of PPH is not

limited by setting or geographic region: among high-income countries (HICs), an increase in maternal deaths from PPH has been recorded that is associated with rises in maternal age at delivery, cesarean delivery, multiple pregnancy, and induction of labor.² Nevertheless, most maternal deaths are recorded in low-income countries (LICs) and

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middle-income countries. The disparities in outcomes are believed to reflect differences in quality of care.¹

There has been a substantial decrease in the number of maternal deaths,³ leading to the study of near misses as a proxy for maternal mortality. Analysis of near misses provides both the opportunity to understand maternal survival in life-threatening clinical situations and a tool to measure quality of care.³ Furthermore, recording near misses can help to determine trends in conditions that lead to life-threatening complications; this approach also enforces awareness and advocacy for promoting policy action and improved quality of care. PPH accounted for the highest number of near misses and maternal deaths in the WHO multicountry survey on maternal and newborn health, which was the largest study conducted to date to assess the management of severe maternal complications.⁴

Since 2009, a growing global consensus on the measures used to identify near misses has led to the widespread adoption of WHO criteria,³ which are based on the original definition of Mantel et al.⁵ Definitions of PPH can vary but the markers of maternal near miss are easily characterized and include hysterectomy, blood transfusion, admission to the intensive care unit (ICU), and hypovolemic shock.² With these definitions in place, a standardized description of PPH outcomes became possible and studies from various regions and settings were subsequently conducted. Nonetheless, a preliminary search of the literature found that no systematic reviews had been published on the topic of near miss due to PPH.

The objectives of the present review were to determine the frequency, causes, near-miss ratio, and mortality index of PPH. Additionally, these outcomes were compared across various national-level income groups.

2 | MATERIALS AND METHODS

A prevalence systematic review was conducted among a population that included maternal deaths and near misses due to PPH, irrespective of the mode of delivery. The proposal for the present analysis was deposited in the PROSPERO international prospective register of systematic reviews.⁶

A maternal near miss is defined by survival of a life-threatening complication during pregnancy, delivery, or within 42 days of termination of pregnancy. Such complications could be due to any cause either related to, or aggravated by, the pregnancy or its management; however, accidental or incidental causes are excluded.³ Maternal mortality is defined as death during pregnancy or within 42 days after termination of pregnancy due to any cause aggravated by the pregnancy or its management (but not incidental or accidental causes).⁷ Maternal deaths and near misses together are severe maternal outcomes (SMOs).³ The mortality index (expressed as a percentage) is the number of maternal deaths divided by the number of women with SMO.³ The higher the mortality index, the greater the proportion of maternal deaths. The maternal near-miss ratio is the number of near misses per 1000 live births, whereas the SMO ratio is the number of women with SMO per 1000 live births.³ For the purposes of the present systematic

review, PPH was defined as reported by the authors in the source material, resulting in the near miss or death outcome.

Studies or audits published in English were eligible for inclusion in the present systematic review if they enabled calculation of near-miss prevalence numerators and denominators for PPH, enabled calculation of the mortality index for PPH, and used validated near-miss criteria.^{3,5,8-10} Articles or conference presentations published from 1995 to 2014 were included. The rationale for commencing in 1995 was that the first pilot study for obstetric near misses was published in 1998,⁵ so a start date of 1995 would ensure that no earlier articles might be missed.

The PubMed, Scopus, Embase, and Grey Literature databases were searched using the terms "near-miss," "obstetric near-miss," "maternal near-miss," "severe acute maternal morbidity," "severe acute obstetric morbidity," and "life-threatening obstetric complications." The final search was performed on January 20, 2016. A complementary search of reference lists from the articles identified was also performed.

Titles and abstracts were screened by one reviewer (SM); full articles were reviewed by two independent reviewers (SM and EB) for methodological validity and inclusion criteria. The data were critically evaluated by SM and EB using a tool for systematic reviews based on prevalence studies, which had been adapted from the Joanna Briggs Institute MASTARI Critical Appraisal tool for descriptive studies.¹¹ The inclusion criteria were clearly defined, with outcomes assessed using objective criteria and reliable measurements. Disagreements on inclusion were resolved by mutual agreement. Formal quality grading was not performed, meaning that studies were either included or excluded; however, the discussion gave appropriate emphasis to studies with the most robust methodologies and results.

Data of interest included the year of audit, the country where the audit had been conducted, WHO region, and the World Bank country income level per person. The country income level per person was used to create the following national classifications: LIC, lower-middle-income country (LMIC), higher-middle-income country (HMIC), and HIC.¹² Studies were classified as prospective or retrospective, and the near-miss criteria plus their individual elements noted. The setting for each study was described as follows: hospital or community based, rural or urban, private hospital or public hospital, teaching hospital, and the number of hospitals included. The number of live births, total births, deliveries, total near misses, total maternal deaths, near misses due to PPH, and maternal deaths due to PPH were noted. Near misses due to PPH were subdivided by cause, including atonic uterus, retained placenta, and cesarean delivery. To provide a clinical context, the numbers of near misses and maternal deaths due to non-PPH obstetric hemorrhage (prepartum hemorrhage and uterine rupture) were recorded. Authors of articles for possible inclusion were contacted electronically when important data were missing or unclear. Responses were received from two of the four authors contacted.

The present systematic review used quantitative analysis and narrative synthesis to describe the findings. Statistical analysis was conducted using Stata version 13 (StataCorp, College Station, TX, USA). Descriptive data were expressed as proportions and percentages, or as medians with ranges and interquartile ranges. Correlations were tested using the Spearman rank correlation test. Comparisons of

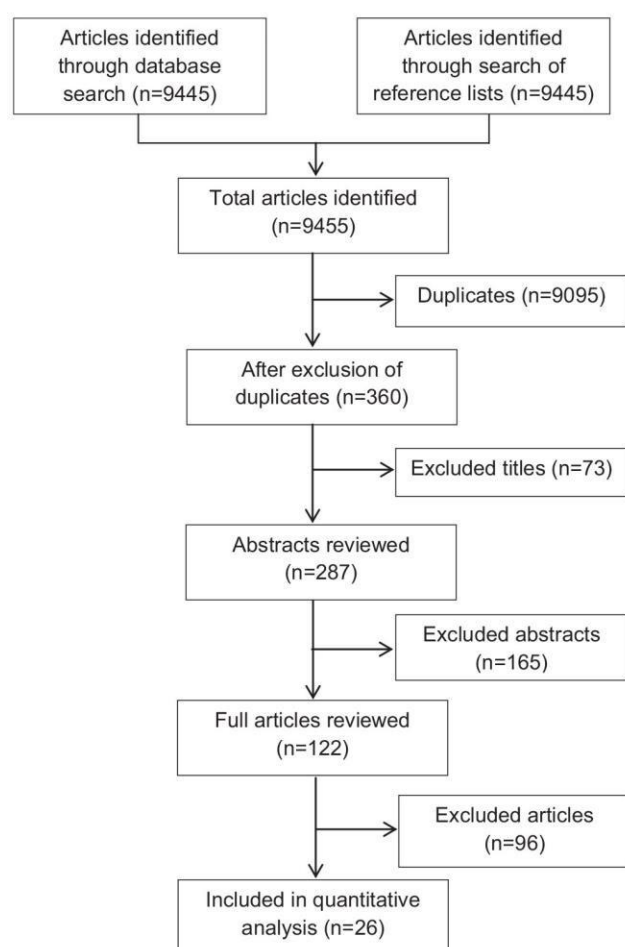


FIGURE 1 Flow diagram outlining selection of the 26 articles included in the systematic review.

continuous data were made using the Wilcoxon rank-sum test. $P < 0.05$ was considered statistically significant.

3 | RESULTS

The article selection process is outlined in Figure 1. In all, 122 full articles were appraised for inclusion in the present systematic review. Among the 73 articles excluded before abstract review, 71 did not meet the inclusion criteria and two could not be retrieved for screening. Suitable data were extracted from 25 studies published in peer-reviewed journals and one study that had been presented as a conference poster.^{3,12–37}

The 26 studies included in the present analysis are outlined in Table S1. These studies involved 17 countries and contained data collected between 1988 and 2013, with 560 479 live births. The median year of publication was 2007. All WHO regions were represented in the analysis, with three LICs, 13 LMICs, six HMICs, and four HICs. The duration of data collection ranged from 2 months to 15 years. The studies were conducted in public hospitals ($n=17$), private hospitals ($n=1$), or both public and private hospitals ($n=3$); five studies did not specify the

hospital level. Fourteen (54%) studies were conducted in urban hospitals and four (15%) in rural hospitals, with the remainder conducted in mixed or unspecified settings. The criteria used by the various studies to define near miss were WHO–Mantel ($n=18$),⁵ Fillipi ($n=3$),⁸ Geller ($n=2$),⁹ Waterstone ($n=1$),¹⁰ and valid modifications ($n=2$).^{32,34} All 26 studies used hysterectomy as a near-miss marker. Blood transfusion was used as a marker in 24 (92%) studies, ICU admission in 15 (58%), and hypovolemic shock in 20 studies (77%). The number of units used to define massive blood transfusion varied from study to study. Three studies^{16,24,32} used one or two units of blood transfusion as a near-miss cutoff; these were all conducted in LICs or LMICs. A negative correlation was found between the number of units of blood for the near-miss cutoff and the near-miss ratio ($r=-0.49$; $P=0.012$).

The median number of live births per study was 7197 (range 851–158 297). Data regarding live births were available for 14 studies, and were imputed for the remaining 12 studies by subtraction from total births to remove the expected stillbirth proportion (Table S1). This calculation involved estimating stillbirth rates of 10 per 1000 live births for HICs, 15 per 1000 live births for HMICs, and 20 per 1000 live births for LMICs, on the basis of a global review of stillbirth rates.³⁸ All three studies from LICs^{13,16,27} included live-birth data.

The median all-cause near-miss ratio was 20 per 1000 live births and the median mortality index was 12.5% (Table 1). The median near-miss ratio caused by PPH was 3 per 1000 live births and the median mortality index regarding PPH was 6.6% (Table 1).

The median near-miss ratio was significantly higher in LICs and LMICs than in HICs and HMICs ($P < 0.001$) (Table 2). Significant between-group differences were also observed for the maternal mortality ratio and the SMO ratio ($P < 0.001$ for both).

Seven studies reported on the clinical causes of near miss related to PPH. Atonic uterus was the most frequently reported cause: among 684 near misses in six studies with relevant data,^{19,24,27,29,30,35} 241 (35.2%) were due to atonic uterus (range 0–3 of 83–98 near misses). Retained placenta was reported in four studies.^{24,27,30,35} This complication was the most frequent cause of PPH-related near-miss in two Indonesian studies (65.9% and 29.7%),^{24,30} but was an infrequent finding in a Brazilian study (5.5%).³⁵ Other causes of PPH included placenta accreta, which was noted as the most frequent cause of PPH in a study from Argentina (51 of 128 cases [39.8%]).²⁹ Large numbers of women had unspecified causes of PPH in the seven studies that reported causes of PPH-related near-miss.^{13,19,23,27,29,30,35} One study from Tanzania¹³ and one study from Nepal²⁷ reported SMOs from bleeding during or after cesarean delivery. The Nepalese study found an SMO ratio for bleeding during and after cesarean delivery of 3.0 per 1543 live births (equivalent to 1.9 per 1000 live births), with a mortality index of 0%.²⁷ The SMO ratio in the Tanzanian study was 61.0 per 13 121 live births (equivalent to 4.6 per 1000 live births), with a mortality index of 11%.¹³

Usable data were available from 15 studies to compare prepartum hemorrhage and uterine rupture as additional categories of obstetric hemorrhage among LICs and LMICs versus HICs and HMICs. Obstetric hemorrhage as a whole had a higher median SMO ratio and mortality index among LICs and LMICs than among HICs and HMICs (Table 3).

**TABLE 1** Near miss and mortality indices among the 26 studies included in the systematic review.^a

Measure	Lowest	25th Centile	Median	75th Centile	Highest
All-cause SMO					
Near-miss ratio per 1000 live births	1	5	20	77	153
Maternal mortality ratio per 100 000 live births	2	52	256	617	2811
SMO ratio per 1000 live births	2	8	22	41	181
Mortality index	0.9	6.2	12.5	15.5	32.5
SMO caused by PPH					
Near-miss ratio per 1000 live births	1	2	3	7	35
Maternal mortality ratio per 100 000 live births	0	2	32	119	588
SMO ratio per 1000 live births	1	2	4	7	36
PPH as a proportion of all SMO	7.3	14.1	23.3	30.0	73.7
Mortality index	0.0	0.8	6.6	16.7	40.7

Abbreviations: SMO, severe maternal outcome; PPH, postpartum hemorrhage.

^aValues are given as percentage, unless otherwise indicated.

4 | DISCUSSION

The present systematic review offered a broad reflection of the causes and effects of severe PPH among both survivors and women who died as a consequence of this complication. The likelihood of death (expressed as the mortality index) was fivefold higher among LICs and LMICs than among HICs and HMICs. These findings indicate that efforts to improve maternal outcomes from PPH must be directed toward poorly resourced countries. In addition to socioeconomic and infrastructural differences, the observed disparity in maternal deaths from PPH might be explained by differences in quality of care, access to trained healthcare personnel attending deliveries, and access to quality uterotonic agents and other emergency interventions.¹

A WHO systematic review on the global causes of maternal mortality³⁹ found that obstetric hemorrhage was the leading cause, with PPH accounting for two-thirds of all such deaths. The consequences of PPH are far wider than what is reflected in maternal death audits. Near-miss audits suggest that the information provided by maternal mortality cannot be generalized because deaths are infrequent, even among LICs.⁴⁰ Maternal deaths provide only limited information on which to base measures to improve maternal outcomes. Severe maternal morbidity from obstetric hemorrhage can have long-term effects on both a woman's health, with consequences such as renal failure and infertility, and psychological well-being. Life-threatening PPH is a test of resources and organizational effort. The availability of drugs and interventions to stop hemorrhage are equally as important as funding and policy to raise standards of health care.

TABLE 2 Comparison of severe maternal outcome indices by national level of income among the 26 studies included in the systematic review.^a

Measure	Low-income and lower middle-income countries (16 studies)	High-income and higher middle-income countries (10 studies)	P value
All-cause SMO			
Near-miss ratio per 1000 live births	33 (21–64)	7 (5–11)	<0.001
Maternal mortality ratio per 100 000 live births	469 (298–1153)	76 (35–173)	<0.001
SMO ratio per 1000 live births	38 (24–74)	8 (6–13)	<0.001
Mortality index, %	13.6 (10.8–16.3)	8.6 (4.0–15.4)	0.19
SMO caused by PPH			
Near-miss ratio per 1000 live births	6 (3–13)	2 (2–2)	0.007
Maternal mortality ratio per 100 000 live births	95 (44–220)	5 (0–10)	0.002
SMO ratio per 1000 live births	6 (3–17)	2 (2–3)	0.002
PPH as a proportion of all SMO, %	17.3 (12.3–27.5)	23.5 (17.2–38.9)	0.16
Mortality index, %	12.2 (5.2–21.5)	2.4 (0.0–5.2)	0.008

Abbreviations: SMO, severe maternal outcome; PPH, postpartum hemorrhage.

^aValues are given as median (interquartile range) unless indicated otherwise.

**TABLE 3** Severe maternal outcome for all causes of obstetric hemorrhage by national level of income.^{a,b}

Measure	Severe maternal outcome ratio per 1000 live births	Maternal mortality ratio per 100 000 live births	Mortality index, %
Low-income and lower middle-income countries (12 studies)			
Prepartum hemorrhage	5.9 (2.5–11.3)	25 (0–57)	5.7 (0.0–9.4)
Uterine rupture	2.5 (1.1–5.1)	7 (0–42)	4.5 (0.0–15.9)
Postpartum hemorrhage	6.9 (2.9–22.6)	95 (63–219)	12.2 (5.2–26.2)
All obstetric hemorrhage	14.0 (7.7–40.1)	132 (99–345)	9.0 (6.1–16.4)
High-income and higher middle-income countries (3 studies)			
Prepartum hemorrhage	0.5 (0.0–0.8)	0 (0–4)	0 (0.0–8.3)
Uterine rupture	0.2 (0.0–0.9)	2 (0–11)	7.7 (0.0–12.5)
Postpartum hemorrhage	2.4 (2.0–3.1)	2 (0–24)	0.8 (0.0–7.5)
All obstetric hemorrhage	3.0 (2.5–4.6)	3 (0–39)	1.0 (0.0–8.6)

^aPer 15 studies that described causes of obstetric hemorrhage.^bValues are given as median (interquartile range).

All the studies included in the present systematic review used hysterectomy as a near-miss marker; however, few studies used ICU admission. Although the definition of PPH can vary, and the measurement of blood loss is subjective, there is broad consensus on near-miss indicators for PPH.⁴¹ The three studies that used transfusion with one or two units of blood as part of their near-miss criteria were all conducted in LICs and LMICs.^{16,24,32} This approach gave a low threshold for near miss, but the mortality indices and maternal mortality ratios remained high, suggesting that the disparity in mortality index between LICs and LMICs versus HICs and HMICs is greater than the data show.

Atonic uterus was the most frequently reported cause of near miss in the present analysis; however, few of the studies included information on the underlying causes. Some studies found high frequencies of retained placenta and placenta accreta, suggesting local reporting bias. Overall, PPH was consistently a larger contributor to obstetric hemorrhage than was prepartum hemorrhage or uterine rupture. A systematic review on emergency postpartum hysterectomy for uncontrolled PPH⁴² found that the most common causes of bleeding were abnormal placental adhesion, which was often associated with previous uterine surgery (38%), and atonic uterus (29%). The leading causes of death after hysterectomy were hemorrhagic shock, pulmonary embolism, and septic shock.⁴² Life-threatening PPH can lead to multiorgan dysfunction, requiring more than simple measures to stop the bleeding. Intractable PPH is a complex disease process requiring a multidisciplinary approach, healthcare expertise, and a functional health system.

The rising rates of cesarean delivery worldwide are associated with an increased rate of SMO, largely attributable to PPH, with interventions such as hysterectomy and blood transfusion.⁴³ The paradox in Africa is that increased numbers of cesarean deliveries could be needed to improve maternal and perinatal outcomes.⁴⁴ As rates of cesarean delivery inevitably rise in Africa, severe outcomes resulting from this procedure can be expected. As yet, the effect of hemorrhage

related to cesarean delivery on SMO is unknown. In the present systematic review, only two studies described the SMO ratio for PPH, and the sample size in one of these studies was small.²⁷ Further studies are, therefore, needed to increase understanding of the causes and interventions used to reduce hemorrhage related to cesarean delivery.

A limitation of the present systematic review was the exclusion of sources written in languages other than English. Another limitation was the predominance of hospital-based data, which might have overestimated near-miss and mortality ratios by concentration of near-miss referrals in the numerators, and exclusion of home and midwife-unit births in the denominators. However, such bias was less likely to affect the mortality index given that most women with SMO are managed in hospitals, at least in middle-income and high-income settings.

A strength of the present analysis was that, to our knowledge, a global evidence-based estimation of SMO from PPH had not previously been done. The observed between-country disparities highlight the need for further interventions at multiple levels in LICs and LMICs, because these countries are most affected by the burden of disease. In terms of clinical policy, severe PPH must to be recognized as a complex disease, requiring multidisciplinary approaches in well-resourced units. Life-threatening PPH ideally requires the attention of critical-care specialists, obstetricians, anesthetists, and hematologists; however, these roles might be filled by generalist medical staff in low-resource settings, with innovative approaches required to prevent maternal deaths. Although much emphasis has been placed on prevention and treatment of PPH, the management and requirements of the critically ill patient should not be neglected.

In conclusion, a global effort is required to strengthen the management of PPH in LICs and LMICs. This initiative should incorporate training of healthcare workers in medical and surgical measures to stop bleeding, provide adequate facilities—e.g. blood banks, high-care facilities, and ICU facilities—to manage critically ill patients following PPH, and strengthen healthcare systems. Political will and financial commitment are both required to support this approach.



AUTHOR CONTRIBUTIONS

SM made substantial contributions to the conception and design of the work, acquisition and interpretation of the data, drafting of the manuscript, and critically revising the manuscript for important intellectual content. EB made substantial contributions to the conception and design of the work, analysis and interpretation of the data, critically revising the manuscript for important intellectual content; and final approval of the version to be published. Both authors were accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work were appropriately investigated and resolved.

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CONFLICTS OF INTERESTS

The authors have no conflicts of interest.

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SUPPORTING INFORMATION

Additional Supporting Information may be found online in the supporting information tab for this article.

Table S1. All-cause severe maternal outcome and postpartum hemorrhage among the 26 studies included in the systematic review.

Inequities in resources and preparedness for surgical complications of caesarean section in southern Gauteng hospitals

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Background. The number of maternal deaths from bleeding during and after caesarean section (BDACS) has increased in South Africa. Health-worker training and health-system strengthening are considered important prerequisites for improving maternal health outcomes.

Objectives. To determine preparedness for, and health-system constraints to, safe caesarean section in southern Gauteng hospitals.

Methods. This was a cross-sectional study in 15 hospitals. Data were collected by questionnaire from clinical heads of department in each hospital.

Results. The 15 hospitals included 5 district hospitals, 7 regional hospitals and 3 central (university academic) hospitals. The number of deliveries per hospital ranged from 893 to 44 256 for 2013 - 2014, with a total of 201 314 births and 70 095 caesarean sections (34.8%). Despite similar numbers of births, there were 20 deaths from BDACS at regional hospitals and 6 at central hospitals ($p=0.008$). Service delivery constraints included an unequal staff distribution between central hospitals and lower levels of care, as well as non-availability of essential drugs and a lack of surgical capacity to arrest severe haemorrhage at district and regional hospitals.

Conclusion. The findings of this study reflect inequity in maternity services. Compared with central academic hospitals, district and regional hospitals are inadequately prepared for the management of complications from BDACS.

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The number of maternal deaths in South Africa (SA) from bleeding during and after caesarean section (BDACS) has increased in the last triennium (2011 - 2013), and over 70% of the deaths were found to be clearly avoidable.^[1] A majority of maternal deaths in SA occur in regional and district hospitals.^[2] The National Committee on Confidential Enquiries into Maternal Deaths has recommended improvements in healthcare systems and healthcare workers' skills to improve the safety of maternity units and the ability to manage obstetric emergencies.^[2] For improving caesarean safety, a stepwise approach is suggested for the management of BDACS in the SA *Saving Mothers: Caesarean Section Monograph*,^[3] which includes the use of uterotonics, and surgical techniques to arrest haemorrhage.

Clinical audit is used for monitoring and reporting on health outcomes and process of care. Audit permits the review of adverse events, such as near-misses (women who survived life-threatening complications of pregnancy and childbirth) and maternal mortality, to review and improve quality of care. Clinical audits are based on a commitment to improve the healthcare system.^[4]

A health system is made up of staff, funding, supplies, transport, communications, and leadership.^[5] There are various models for health-system frameworks. The World Health Organization (WHO)'s health-system framework has six key components which include governance, financing, medical technologies, health workforce, information and research, and service delivery.^[6] Oliviera-Cruz *et al.*^[7] described health-system constraints to improving access to priority healthcare. The service delivery constraints include shortage and distribution of appropriately qualified staff, weak management and supervision, inadequate drugs and medical supplies, and lack of equipment and infrastructure.

Health-system strengthening is a prerequisite to achieving any improvement in health outcomes. It has been shown that focusing

on disease priorities without improving health systems does not improve overall outcomes,^[8] hence the prioritisation of healthcare system improvements, as well as health-worker training, by the National Committee on Confidential Enquiries into Maternal Deaths.^[2]

The aim of this study was to evaluate preparedness for, and health system constraints to, provision of safe caesarean section in hospitals in southern Gauteng, and to link these to hospital levels of care.

Methods

A prospective cross-sectional multicentre study was conducted in southern Gauteng, in 15 public hospitals from July 2014 to May 2015. Gauteng Province consists of Johannesburg, Pretoria and numerous surrounding towns and cities, and has the highest number of deliveries in SA per year (annual facility live births in 2013, $n=208\ 710$).^[11] Southern Gauteng is a metropolis with four districts, Ekurhuleni, Johannesburg, Sedibeng and West Rand. The districts are served by 18 government hospitals with maternity units, and with the exception of one of these (Tembisa Hospital) form part of the University of the Witwatersrand cluster of hospitals, including 3 central hospitals (all teaching hospitals in Johannesburg itself), 7 regional hospitals, and 7 district hospitals. All but 2 of the district hospitals, and all the regional hospitals, serve towns and adjacent high-density settlements to the east, west and south of Johannesburg. All hospitals receive high-risk patients who cannot be managed by clinics and midwife obstetric units. District hospital maternity units are staffed by midwives and medical officers, and may employ part-time specialists. They conduct normal and assisted deliveries, and caesarean sections, and refer patients they cannot manage to higher-level hospitals. Regional hospitals offer specialist maternity care and referral services for district hospitals. They employ specialists,

medical officers and interns, and generally have intensive care and high-care units on site. Certain patients, when a difficult birth is expected, may be referred to central hospitals. Central hospitals provide specialist obstetric care and subspecialty care. Their staffing is made up of interns, medical officers, registrars, specialists and subspecialists. Academic programmes for medical students, registrars and subspecialist trainees take place in the central hospitals. One of the central hospitals, officially considered to be a regional hospital by the Department of Health, is defined as a central hospital in this study, as it is an academic tertiary referral hospital with a large complement of specialists, and part of the University of the Witwatersrand's training platform for medical students and registrars.

Ethical approval

Ethical and institutional approval for the study was obtained from the University of the Witwatersrand's Human Research Ethics Committee, and from the Gauteng Department of Health. Individual hospital permission was received from the chief executive officers of the 17 University of the Witwatersrand cluster hospitals.

Interviews – data collection

In July and August 2014, the researcher conducted interviews with the clinical head of obstetrics in each hospital, using a structured questionnaire. The interviews set out to determine staffing, supervision and preparedness for surgical complications at caesarean section in southern Gauteng. The researcher asked questions about whether the hospitals were appropriately staffed for the number of deliveries conducted. The number of staff members was calculated according to the number of full-time staff members on the monthly current obstetric department timetable. Supervision was divided into teaching and monitoring. Teaching was assessed by determining the teaching methods in each hospital, and the number of caesarean sections done under supervision.

Monitoring was assessed according to whether maternal deaths, adverse events and maternal near-misses were discussed routinely in each hospital. Preparedness was assessed by the availability of drugs, facilities and surgical skills. Drugs were evaluated by availability in the hospital, and whether the drugs were being used according to the clinical head's knowledge. Facilities were evaluated by the availability

of a blood bank, postoperative recovery area, obstetric high-care unit, and an intensive care unit (ICU) on site.

Skills were evaluated according to the competence of the doctors in surgical procedures at each hospital. The clinical heads were familiar with their doctors' skills levels and which surgical procedures were performed in each hospital. The interview inquired about the availability of staff that could perform life-saving procedures related to BDACS, such as obstetric hysterectomy and B-Lynch compression suture 24 hours a day on 7 days per week.

Data analysis employed quantitative techniques. Maternal mortality ratio was calculated per hospital as the institutional maternal mortality ratio (iMMR). In the absence of live birth data, the denominator used for the iMMR was a live birth approximation of 0.98 times the total births, assuming a general SA stillbirth rate of 2%. Descriptive data were analysed using medians and ranges for continuous variables, and proportions with percentages or rates for categorical variables. Comparisons of categorical data were made using the χ^2 test, and pairwise correlation was done using scatter plots with Spearman's rank

correlation for non-parametric data. Statistical significance was indicated by $p < 0.05$.

Results

The study was conducted in 15 hospitals: 5 district hospitals, 7 regional hospitals and 3 central hospitals. Permission was sought from 17 hospitals, but 2 district hospital managers declined participation. In 2 hospitals the interviews were conducted with a specialist appointed by the clinical head. Four clinical heads asked to complete the questionnaire themselves, and return it to the researcher. In 11 of the hospitals the researcher was referred to the midwife in charge of the labour ward for questions about the nursing staff. The questionnaires were completed on the day of the interview. The researcher collected maternity statistics for 2013 and 2014 from the midwife in charge of the labour ward in 7 hospitals, from data capturers in 5 hospitals, and from the clinical heads in 3 hospitals. The statistics for 2014 were collected from February to April 2015.

In the 15 hospitals there were 201 314 births in 2013 and 2014, with 70 095 caesarean sections (34.8%). The total number of births at each of the hospitals

Table 1. Full-time staffing and obstetric outcomes in 15 hospitals in southern Gauteng, 2013 - 2014, by levels of care

	District (N=5)	Regional (N=7)	Central (N=3)
<u>Aggregated data per level of care</u>			
Total births, <i>n</i>	25 254	89 243	86 678
Maternal deaths, <i>n</i>	10	186	11 ^c
iMMR per 100 000 live births	40	213	13 ^c
Caesarean sections, <i>n</i>	5 919	30 833	33 343
Hospital caesarean section rate, %	23.4	34.5	38.5
Maternal deaths from BDACS, <i>n</i>	0	20	6
Obstetric specialists, <i>n</i>	1	12	51
All doctors, <i>n</i> *	16	105	18 ^c
Doctors, <i>n</i> /10 000 births per annum	9.9 ^c	23.5	43.4
Specialists, <i>n</i> /10 000 births per annum	0.0 ^c	2.7	11.8
<u>Hospital data, median (range)</u>			
Midwives	18 (12 - 29)	28 (12 - 39)	55 (44 - 204)
Medical interns	0 (0 - 0)	5 (2 - 7)	21 (17 - 25)
Medical officers	3 (2 - 4)	10 (3 - 10)	5 (2 - 10)
Registrars	0 (0 - 0)	0 (0 - 2)	17 (13 - 27)
Obstetric specialists	0 (0 - 1)	1 (1 - 4)	12 (11 - 28)
All doctors	3 (2 - 5)	16 (8 - 20)	52 (46 - 90)
Hospital caesarean section rate	25.6 (16.2 - 36.2)	36.6 (25.3 - 42.4)	37.0 (33.3 - 48.5)
iMMR per 100 000 live births	43 (0 - 62)	204 (77 - 350)	136 (47 - 240)

* Doctors listed are those allocated to obstetrics and gynaecology sections or departments in their hospitals.

^cN=4, excludes data for one district hospital that opened in April 2014.

ranged from 893 to 44 256, with a median of 9 063. Caesarean section rates ranged from 16.2% at a district hospital to 48.5% at a central hospital (Table 1). The overall maternal mortality ratio was highest at regional hospitals (213 per 100 000 live births) (Table 1). While the number of total births at regional and central hospitals was similar, BDACS accounted for 20 maternal deaths at regional hospitals and 6 at central hospitals ($p=0.008$). The number of obstetric doctors per 10 000 births was 9.9 at district hospitals, 23.7 at regional hospitals and 43.4 at central hospitals. The corresponding numbers for obstetric specialists were 2.7 and 11.8 for regional and central hospitals, respectively. However, the proportion of obstetric doctors per 10 000 births at the 15 hospitals did not correlate significantly with the hospital maternal mortality ratios ($p=0.68$) (Fig. 1).

Ten hospitals (66.7%) trained interns, and 4 hospitals (26.7%) trained registrars. Eleven hospitals (73.3%) had at least one full-time specialist (range 1 - 28). The total number of doctors ranged from 2 in a district hospital with 4 654 births to 97 in the tertiary hospital that had 44 256 deliveries in 2013 and 2014.

The skill of teaching caesarean section technique was reserved for the most senior doctors in each hospital. All hospitals taught by observation and supervision, 6 hospitals (40.0%) also used videos, and none used models. Three hospitals (20.0%) stipulated a minimum number of caesarean sections that a new doctor had to perform under supervision prior to operating independently. All the hospitals held regular perinatal review meetings, at which maternal deaths were discussed. The 3 central hospitals, as well as 2 regional

hospitals, held weekly meetings, and the remaining hospitals held monthly meetings. Nine hospitals (60.0%) reported that they also presented maternal adverse events in their meetings. Three hospitals (20.0%) discussed all maternal near-miss cases from BDACS at the meetings. Collaboration between hospitals, beyond referral, was limited to occasional attendance by regional and district hospital specialists at central hospital perinatal review meetings. There were no outreach programmes (e.g. specialist support visits) in place from higher levels to lower levels of care.

Oxytocin and misoprostol were available in all 15 hospitals. Ergometrine was only available in 10 hospitals (66.7%) and

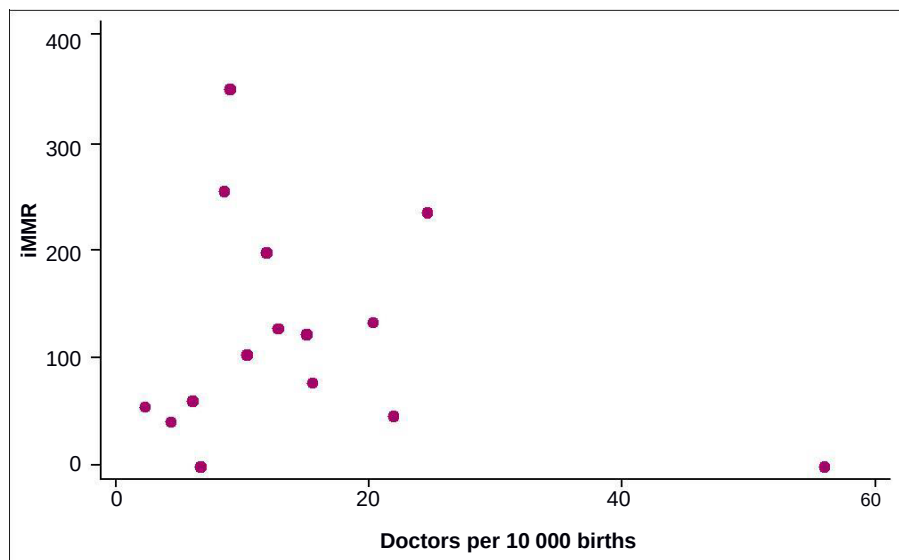


Fig. 1. Scatter plot showing institutional maternal mortality ratio per 100 000 live births (iMMR) for 15 southern Gauteng hospitals correlated to numbers of doctors as a proportion of births at each hospital (Spearman's correlation coefficient $r=0.12$, $p=0.68$).

Table 2. Preparedness for life-threatening surgical complications of caesarean section in hospitals in southern Gauteng

	District (N=5, n (%))	Regional (N=7, n (%))	Central (N=3, n (%))
<u>Available drugs</u>			
Oxytocin and misoprostol	5 (100)	(100)	3 (100)
Ergometrine	4 (80)	(57.1)	3 (100)
Tranexamic acid injection	3 (60)	(100)	3 (100)
Prostaglandin F2-alpha	1 (20)	(14.3)	3 (100)
<u>Ability to perform procedures</u>			
B-Lynch compression suture	3 (60)	(42.8)	3 (100)
Obstetric hysterectomy	3 (60)	(100)	3 (100)
<u>On-site facilities</u>			
Blood bank	0	(85.7)	3 (100)
High-care unit	1 (20)	(100)	3 (100)
24-hour recovery	2 (40)	(71.4)	3 (100)
24-hour theatre	4 (80)	(85.7)	3 (100)

prostaglandin F2-alpha was available in 5 hospitals (33.3%). Tranexamic acid injection was available in 13 hospitals (86.7%); however, only 2 of these hospitals (15.4%) reported ever using it for obstetric patients. The central hospitals had all the uterotonic drugs available. Prostaglandin F2-alpha was only available in 1 district hospital, and 1 regional hospital. Only 4 of the 7 regional hospitals (57.1%) had ergometrine in stock (Table 2).

All the hospitals performed caesarean sections; however, 2 (13.3%) did not operate on all days of the week because of staffing shortages. On-site blood banks functioned in 9 hospitals (60.0%), and the rest, including all the district hospitals, relied on emergency blood kept in refrigerators on site. One

district hospital had an obstetric high-care unit. One central hospital did not have an ICU on site (Table 2).

Emergency skills to arrest obstetric haemorrhage were evaluated according to whether the staff were available on a 24-hour basis to perform these procedures in each hospital. Uterine balloon tamponade (Bakri balloon or condom balloons) had never been done in 12 hospitals (80.0%), and B-Lynch compression sutures had never been done in 6 hospitals (40.0%). None of the informants could recall ever performing a uterine tourniquet procedure using a Foley catheter at their hospitals. In two of the hospitals (13.3%), the informants stated that

none of the doctors was skilled to perform emergency hysterectomy during and after caesarean section (Table 2).

Discussion

A clear message has emerged of inequities in Gauteng maternity services. These inequities, mostly between regional hospitals and teaching centres, are unfortunate, given the relative sophistication of Gauteng Province in SA, with its medical schools and high-level central hospitals. As in the remainder of the country, the majority of maternal deaths occurred in district and regional hospitals, where medical staffing and facilities are most lacking. The relationship between overall maternal mortality and staffing levels per hospital is complex, and did not show any correlation, but there was a significant difference in numbers of maternal deaths related to BDACS between regional and central hospitals, with similar caesarean section rates. Observing overall maternal mortality ratios alone may therefore mask preventable maternal mortality, as is the case with BDACS. While the ideal is that there should be no deaths at all from BDACS, one would expect more deaths, not fewer, in central hospitals, given that high-risk obstetric patients, both preoperatively and postoperatively, should be cared for at high-level hospitals. The high maternal mortality in regional hospitals is therefore of concern. The inequities were greatest in medical staffing, and most obvious with specialist obstetricians. The central hospitals had twice as many doctors and more than four times more specialists per delivery than regional hospitals. It should of course be accepted that central teaching hospitals need more specialists than regional hospitals, but the difference here still amounts to a serious maldistribution of skilled human resources. In that context, the absence of any formal outreach activities from the central hospitals seems regrettable.

The inequities are further reflected in the relative lack of preparedness of regional and district hospitals for dealing with severe BDACS. Essential second-line drugs, such as tranexamic acid and prostaglandin F₂-alpha, and especially ergometrine, were not available in several institutions, remarkably in three of the regional hospitals where difficult caesarean sections might be done. The inability to perform B-Lynch compression sutures at several regional hospitals was also notable. These deficiencies were not investigated in this study, but root cause analysis might find management failures, overburdened specialists and the lack of central hospital outreach activities to be significant culprits.

What was somewhat encouraging was the ability of all hospitals to provide emergency blood for transfusion. Also, all hospitals held perinatal review meetings, where maternal deaths were also discussed. Both of these successes may have resulted from implementing guidelines suggested in the Saving Mothers reports of the National Committee for Confidential Enquiries into Maternal Deaths.^[2]

Inequities in emergency obstetric care are a fact across the world, most notably between rich and poor countries,^[9] but also within countries. Differences between rural and urban obstetric services^[10,11] are well described, as are the extreme differences between private and public healthcare overall in SA.^[12] However, there appear to be no reports of inequities in public obstetric services within a city region, such as southern Gauteng. Possible drivers of the inequity include university advocacy for optimal care in its training hospitals, unattractiveness to doctors of regional hospitals in economically depressed towns away from Johannesburg, budgetary constraints in the provincial health service, poor co-ordination of hospital referral systems, and management weakness at lower levels of care. Further research should investigate these and other possibilities relating to caesarean section preparedness, as well as emergency obstetric care as a whole. This study was limited by its focus on caesarean sections safety

in terms of resource limitations and outcomes, without consideration of upstream determinants of these deficiencies. Another limitation relates to the once-off cross-sectional nature of the evaluation, which cannot assess trends in resource capacity at the hospitals. However, the data stand as facts that suggest inequitable resource allocation for emergency obstetrics, which may be a problem in other SA metropolitan areas that have medical schools.

Several immediate interventions should be considered to improve caesarean section safety at the hospitals in southern Gauteng. Most of these relate to recommendations in the national Confidential Enquiries into Maternal Deaths report from 2008 to 2010:^[2] (i) human resources needs and norms must be investigated, perhaps using the Workforce Indicators of Staffing Need (WISN) approach introduced to SA in 2012,^[13] to create and fill obstetric specialist and medical officer posts in the regional and district hospitals; (ii) all maternal deaths and cases of near-miss related to caesarean section bleeding should be audited and discussed at regular perinatal review meetings; (iii) training in caesarean section technique needs to be formalised at district and regional hospitals, including using training videos, with a minimum of 10 caesarean sections done under supervision before 'solo' caesarean sections can be attempted;^[14] (iv) all midwives and obstetric doctors in the hospitals must be exposed to ESMOE (Essential Steps in Managing Obstetric Emergencies) training, which includes modules on surgical skills and obstetric haemorrhage;^[15] and (v) sustainable emergency obstetrics outreach programmes from the central to the regional and district hospitals must be implemented and sustained, with university and provincial government support.

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RESEARCH ARTICLE

Open Access



Why women bleed and how they are saved: a cross-sectional study of caesarean section near-miss morbidity

S. Maswime^{1*}  and E. J. Buchmann²

Abstract

Background: Maternal deaths from 'bleeding during and after caesarean section' (BDACS) have increased in South Africa, and have now become the largest sub-cause of deaths from obstetric haemorrhage. The aim of this study was to describe risk factors and causes of near-miss related to BDACS and interventions used to arrest haemorrhage and treat its effects.

Methods: Cross-sectional prospective study in 13 urban public hospitals in South Africa, from July to December 2014.

Results: There were 93 cases of near-miss related and 7 maternal deaths related to BDACS. The near-miss rate was 2.1/1000 live births, and the case fatality rate was 3.5/10 000 caesarean sections. Associated near-miss risk factors were previous caesarean section in 60% of multiparas, pre-operative anaemia (55%), abruptio placentae (20%) and placenta praevia and/or accreta (20%). Atonic uterus (43%) was the most frequent anatomical cause of bleeding for near-miss, followed by surgical trauma (29%). The median duration of the operations resulting in near-miss was 90 min, with 81% noted as difficult by the surgeon. Interventions in cases of near-miss included second-look laparotomy (46%), hysterectomy (41%), B-Lynch brace suture (9%), intensive care unit admission (32%) and red cell transfusion ≥ 3 units (21%).

Conclusion: Cases from maternal near-miss from BDACS were frequently associated with pre-operative risk factors. Extensive life-saving interventions were required during and after the operations. An important factor in initiating the sequence of interventions is the realisation by the surgeon that the caesarean section is difficult, so that the progression from uneventful operation to near-miss to death can be arrested.

Keywords: Near-miss, Caesarean section related haemorrhage, Bleeding during and after caesarean section

Background

The safety of caesarean sections has recently come into question in South Africa. Maternal death resulting from 'bleeding during and after caesarean section' (BDACS) is becoming increasingly frequent. The triennial reports of the government's confidential enquiries into maternal deaths recorded 78 such deaths in 2002–2004, 140 in 2005–2007, 180 in 2008–2010, and 221 in 2011–2013 [1–4]. Maternal death from BDACS is now the largest sub-cause of death from obstetric haemorrhage in South Africa [4]. The increase in maternal deaths has been attributed to

a rising national caesarean section rate, but this increase exceeded the rise in caesarean section rate, which increased from 12.7% in 2001/02 to 20.8% in 2012/13 [5]. Other possible reasons, for which data are lacking, related to changes in health care quality, such as a lower standard of surgical skill with increased risk of bleeding [6], failure to detect antepartum risk factors, and possibly substandard labour management, anaesthesia and post-operative care.

Globally, there are insufficient data on maternal deaths related to BDACS, especially in terms of clinical and surgical detail. Even with the recent increase in deaths, these events are so rare that meaningful prospective studies are difficult to do. A helpful alternative is to study 'near-miss' related to BDACS. A maternal near-miss is a woman who survives severe complications

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during pregnancy, childbirth or postpartum. The study of near-miss is an increasingly useful tool in obstetric clinical audit, because of the larger number of cases available for study compared with maternal deaths, and because valuable information can be obtained on how clinical and surgical and clinical management obstacles are overcome after the onset of an acute complication [7].

To our knowledge, there has been no published scientific work focusing on maternal near-miss related to BDACS. Studies or audits on near-miss could improve understanding of the evolution of severe bleeding at caesarean section, and describe opportunities taken and missed to control the bleeding and treat its consequences. The information gained may inform quality improvement and interventions to reduce near-miss and death from BDACS.

The aim of this study was to determine the risk factors and causes of near-miss related to BDACS and to describe the clinical and surgical interventions undertaken.

Methods

This was a cross-sectional prospective study in 13 government hospitals in southern Gauteng province, South Africa, from July to December 2014. Ethical approval was obtained to conduct this study from the University of the Witwatersrand's Human Research Ethics Committee. Informed written consent was obtained from the participants.

The city of Johannesburg is the geographic and economic centre of southern Gauteng province. There are 18 government hospitals with maternity services in southern Gauteng, with about 100 000 births per annum. Three of these hospitals are university-attached tertiary referral hospitals. The 13 hospitals in the study included the three tertiary hospitals, as well as seven regional referral hospitals, and three district hospitals. The district hospitals are staffed by non-specialist doctors and have relatively small case loads. The regional hospitals all have at least one specialist, as well as medical officers who are responsible for most of the daily clinical activities. The tertiary hospitals are better resourced in terms of equipment and facilities, and include university faculty staff and residents training to become specialists.

The World Health Organization (WHO) Intervention criteria were used to identify cases of near-miss, and were modified to suit this population [7]. Only near-misses related to BDACS were included in this study. A near-miss related to BDACS was any woman with a gestational age ≥ 24 weeks, or who delivered a baby weighing ≥ 500 g, who had a caesarean section with a combined intraoperative and postoperative blood loss ≥ 1000 mL, and at least one of the following: red cell blood transfusion ≥ 3 units, emergency hysterectomy, repeat laparotomy, transfer

to a higher level of care, started or restarted postoperative ventilation, use of inotropic drugs, acute dialysis, cardiopulmonary resuscitation and admission to an intensive care unit. Women with ruptured uterus, extra-uterine pregnancy, and where another cause of haemorrhage was the primary reason for bleeding, were excluded.

The researcher trained obstetric staff in each hospital on how to identify a near-miss from BDACS. Each time such a case was identified, a staff member notified the researcher telephonically. The researcher then travelled to the hospital and screened the file for study eligibility. Data were collected from maternal case records, and supplemented, where necessary, from patients themselves or from staff. Informed consent was obtained from the patients. Data collected from the clinical notes were antenatal history, details about the previous pregnancy and blood test results, reason for admission, clinical management, and events leading to the decision for caesarean section. Details about the caesarean section, the findings and the complications were recorded, as well as postnatal observations and interventions. The researcher made regular visits to all hospitals to ensure ongoing surveillance. Numbers of maternal deaths related to BDACS were also recorded.

A sample of 100 near-misses related to BDACS was envisaged to provide reasonable confidence intervals for observed percentage frequencies. With a sample of 100 subjects, an observed percentage has 95% confidence limits that are not more than 10% above and below it. Data analysis employed quantitative techniques, using Stata version 11 software (Statacorp, College Station, TX, USA). Descriptive data were analysed using medians, ranges and interquartile ranges for continuous variables, and proportions with percentages for categorical variables. Comparisons of categorical variable frequencies were made using Fisher's exact test. A p -value < 0.05 was used to determine statistical significance.

Results

The hospitals reported 93 near-misses related to BDACS, as well as 7 maternal deaths. The total number of deliveries at all the hospitals was 46 775, of which 20527 were caesarean sections (43%). The near-miss related to BDACS rate was therefore 2.1 per 1000 (93/43474) live births, and the BDACS-related case fatality rate was 3.4 per 10 000 caesarean sections.

Obstetric data and risk factors for near-misses are shown in Table 1. Teen pregnancy ($n = 2$) and parity ≥ 4 ($n = 5$) were infrequent. Twenty women were nulliparous and 73 were multiparous. Forty-four (60.3%) of the multiparous women had previous caesarean sections. Anaemia prior to caesarean section (haemoglobin level < 11.0 g/dL) was found in 49 of 89 women tested (55.1%). Thirty-six women (40.4%) were HIV

Table 1 Obstetric characteristics and risk factors for maternal near-miss from bleeding during or after caesarean section ($n = 93$, unless otherwise specified because of missing data)

	Number	Percent
Maternal age (years):		
< 20	2	2.2
20–34	69	74.2
≥ 35	22	23.7
Parity:		
0	20	21.5
1–3	68	73.1
4	5	5.4
Attended antenatal clinic	83	89.2
Previous caesarean section	44	47.3
Haemoglobin level prior to caesarean section (g/dL) ($n = 89$):		
< 8.0	11	12.4
8.0–10.9	38	42.7
≥ 11.0	40	43.0
HIV infection ($n = 89$)	36	40.4
Antenatal weight ≥ 90 kg ($n = 79$)	8	10.1
Caesarean section ($n = 91$):		
Elective (planned)	11	12.1
Emergency not in labour	28	30.8
Emergency in first stage	44	48.4
Emergency in second stage	8	8.8
Hypertensive disorder of pregnancy	26	28.0
Abruptio placentae	19	20.4
Placenta praevia/accreta:		
Placenta praevia	7	7.5
Placenta accreta	9	9.7
Placenta praevia and accreta	3	3.2
Birth weight (g) ($n = 85$):		
< 1000	6	7.1
1000–2499	33	38.8
≥ 2500	46	54.1

infected. Clinical risk factors included hypertensive disorders in pregnancy in 26 (28.0%), abruptio placentae in 19 (20.4%), and placenta praevia and/or accreta in 19 women (20.4%). Nine of the 19 women with abruptio placentae had a hypertensive disorder. The main primary indications for caesarean section were fetal distress ($n = 14$; 15.1%), abruptio placentae ($n = 13$; 14.0%) and placenta praevia ($n = 12$; 12.9%). Eleven women had caesarean section for prolonged labour, 7 in the first stage of labour (7.5%) and 4 in the second stage (4.3%). Twenty-four infants were stillborn, 17 of them in association with abruptio placentae. The surgeons who started the caesarean

sections were non-specialists in 29 cases (31.2%), residents in 54 cases (58.1%) and specialists in 7 cases (7.5%). Seven caesarean sections (7.5%) were done in district hospitals, 22 (23.7%) in regional hospitals and 64 (68.9%) in tertiary hospitals.

The most frequent cause (anatomical site) of haemorrhage was atonic uterus ($n = 40$; 43.0%), followed by uterine incisional bleeding ($n = 27$; 29.0%), placental site bleeding ($n = 16$; 17.2%), bleeding at the bladder reflection ($n = 8$; 8.6%), pampiniform venous plexus bleeding ($n = 5$; 5.4%) and abdominal wall bleeding ($n = 4$; 4.3%). Two or more causes of bleeding occurred in some women. In 14 women (15.1%), the cause of haemorrhage was not specified. The causes of bleeding were compared between women with previous caesarean section, placenta praevia/accreta, abruptio placentae, and the remainder (considered as having no surgical risk). There were significant associations between placenta praevia/accreta and placental site bleeding ($p < 0.01$), and between abruptio placentae and atonic uterus ($p = 0.04$). There was a trend to more frequent pampiniform plexus and abdominal wall bleeding in women with previous caesarean section (Table 2).

The surgeons noted difficulty in 76 operations (81.7%). The duration of surgery was estimable in 80 cases, and was <60 min in 14 (17.5%), 60–119 min in 34 (42.5%) and ≥120 min in 32 (40.0%). The median duration was 90 min, with a range of 23–345 min. Forty-nine women (52.7%) received blood transfusions during their caesarean sections. Medications and procedures used to arrest bleeding (in addition to routine intravenous oxytocin) included ergometrine, misoprostol, prostaglandin F₂-alpha, tranexamic acid, B-Lynch brace suture, systematic uterine vessel ligation (devascularisation), and intrauterine balloons (Table 3). The median blood loss at caesarean section (estimated by the surgeons in 69 cases) was 1000 mL, with a range of 250–3600 mL. Second-look emergency laparotomy was performed in 43 women, of whom 18 underwent hysterectomy (total hysterectomies: $n = 38$; 40.9%) and 8 had B-Lynch compression sutures (of which 4 failed, requiring hysterectomy). Fourteen women had only resuturing or uterine vessel ligation done, and 5 required no specific haemostatic procedure. Seventy-four women (79.6%) received three or more units of red cell transfusion during their hospital stay. The median lowest postoperative haemoglobin level was 6.05 g/dL ($n = 90$), with a range of 2.8–12.5 g/dL. Thirty-six of 78 women in whom the platelet count was measured had a postoperative thrombocytopenia <100 000/μL. Seven women had severe acute kidney injury (serum creatinine ≥250 μmol/L), and 6 required dialysis. Thirty women (32.3%) were admitted to intensive care units postoperatively. Eleven women (11.8%)

Table 2 Caesarean section near-miss haemorrhage anatomical sites, according to presence or absence of specific prior surgical risk factors

	Previous caesarean section only (<i>n</i> = 23)	Placenta praevia/accreta (<i>n</i> = 19) – includes 13 previous caesarean sections	Abruptio placentae (<i>n</i> = 19) – includes 8 previous caesarean sections	No surgical risks anticipated (<i>n</i> = 32)
Uterine incision	5	5	3	14
Atonic uterus	9	4	14*	13
Placental site	1	14*	0	1
Bladder reflection	1	3	2	2
Pampiniform plexus	3	0	1	1
Abdominal wall	3	1	0	0
Not specified	3	1	2	8

*Comparison for placental site bleeding, placenta praevia/accreta v. no surgical risks: $p < 0.01$

*Comparison for atonic uterus, abruptio placentae v. no surgical risks: $p = 0.04$

received inotropic drugs. Ten women (10.8%) were transferred by ambulance to higher levels of care.

The seven maternal deaths included a case of placenta accreta with previous caesarean section, who required a hysterectomy, and one woman with placental abruption who died four days postoperatively from multi-organ dysfunction. The remaining five women had no surgical risk factors, and all had intraoperative blood loss ≤ 700 mL.

Discussion

This study, from a middle-income urban setting, found that about one in 216 caesarean sections are complicated by severe morbidity from bleeding, and that about 1 in 14 women with severe morbidity progress to maternal death. The near-miss definition seemed appropriate as applied in this study, providing a sample of women

severely affected by bleeding, evidenced by a very low median postoperative haemoglobin level of 6.05 g/dL.

The most important common risk factors for near-miss related to BDACS were preoperative anaemia (over half had haemoglobin < 11.0 g/dL), and previous caesarean section (in over half of multiparas). A rising caesarean section rate increases not only the number of caesarean sections currently, but adds women with previous caesarean section to those who will become pregnant in future. This is one of the reasons for calls to prevent the first caesarean section in women [8]. The HIV infection rate, while high, is not statistically significantly higher than the 28.7% prevalence in pregnant women in this part of South Africa ($p = 0.05$) [9]. Anaemia limits the body's response to blood loss, and makes any caesarean section potentially hazardous. Previous caesarean section is well known as a cause of overall surgical difficulty [10]. Accordingly, multiple causes of bleeding were found in women with previous caesarean sections, including extrauterine causes such as pampiniform plexus and abdominal wall injury. The other two important risk factor categories, abruptio placentae and placenta praevia/accreta, are uncommon conditions, yet occurred in large numbers in this series. The published literature supports our finding of uterine atony being the most common cause of post-partum haemorrhage, and placental site bleeding associated with placenta praevia/accreta [11]. Previous caesarean section itself is also associated with placenta praevia/accreta [12]. A number of women had no specific surgical risk factors, and bled severely from a variety of sources. The absence of risk factors gives no guarantee of an uncomplicated caesarean section and postoperative course.

In 76% of near-misses related to BDACS, the caesarean sections were noted by the surgeons as difficult, and early interventions were made intra-operatively. A range of life-saving options was used, usually in combination, to manage the source and effects of bleeding. Medical management included utero-tonics, tranexamic acid,

Table 3 Intraoperative interventions during caesarean section in cases of near-miss haemorrhage (*n* = 93 unless otherwise specified because of missing data). Multiple interventions were used in some cases

	Number	Percent
Red cell blood transfusion (<i>n</i> = 89)		
None	40	44.9
1 unit	8	9.0
2 unit	22	24.7
≥ 3 units	19	21.3
Intramuscular or intravenous ergometrine	19	20.4
Oral or rectal misoprostol	8	8.6
Intramyometrial prostaglandin-F ₂ -alpha	10	10.8
Intravenous tranexamic acid	6	6.5
Systematic uterine vessel ligation (devascularisation)	7	7.5
Intrauterine balloon ^a	4	4.3
B-Lynch compression suture ^a	15	16.1
Hysterectomy	20	21.5

^aThree of the intrauterine balloons failed to stop the bleeding, and two of the B-Lynch compression sutures (in whom balloons were not used) failed. All five failures went on to hysterectomy

inotropic support and blood transfusion, with recourse to emergency transport if needed, and intensive care, suggesting the elements of a well-resourced functional health service. Surgical options included frequent use of uterine vessel ligation, B-Lynch compression sutures and hysterectomy, both at caesarean section and at second-look emergency laparotomy, suggesting the presence of skilled obstetric surgeons. The few attempts at intra-uterine balloon tamponade were mostly unsuccessful, but this may reflect the characteristics of this group of women. Balloon tamponade works best when placed early in severe postpartum haemorrhage after vaginal birth [13].

This study has certain strengths and limitations. Strengths were a robust near-miss definition and a sample size that allowed description of prevalence and relationships. Another strength is the clinical detail obtained from inspection of all women's clinical notes by a specialist obstetrician. The reliance on record review for clinical information is also a limitation, with some data missing. Limitations include the possibility that some near-miss cases were not included, because the researcher and the trained contacts at the hospitals could not be in attendance at all births. However, it is certain that all maternal deaths from BDACS were included, because these are subject to compulsory confidential enquiries.

Further research should focus on detail in risk factors, surgical findings and interventions. An ideal design would be a case-control study, in which near-miss cases are compared with non-near-miss caesarean sections for risk factors, surgical findings and interventions. A similar study should also be done in a resource-poor setting, where access to technological and specialist interventions is restricted, and where there are likely to be more maternal deaths.

Conclusion

Our findings show that maternal near-miss from BDACS is uncommon, but severe enough to necessitate extensive life-saving interventions. These require skilled or specialist health professionals, and a functional obstetric service with access to medication, blood transfusion, emergency transport and intensive care units. An important factor in initiating the sequence of interventions is the realisation by the surgeon that the caesarean section is difficult, so that the progression from uneventful operation to near-miss to death can be arrested.

Abbreviations

BDACS: Bleeding during and after caesarean section; g: Gram; g/dl: Gram/decilitre; HIV: Human immunodeficiency virus; mL: Millilitre; n: Number; p: Probability; v.: Versus; WHO: World Health Organization

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Availability of data and materials

Data will be available from the corresponding author.

Authors' contributions

SM: Made substantial contributions to conception and design, acquisition of data, and interpretation of data; Was involved in drafting the manuscript, revising it critically for important intellectual content; Acquired funding for the study. EB: Made substantial contributions to conception and design, and analysis and interpretation of data; Supervised the study. SM and EB: Gave final approval of the version to be published; Agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Authors' information

Not applicable.

Competing interests

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Consent for publication

Not applicable.

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CLINICAL ARTICLE

Causes and avoidable factors in maternal death due to cesarean-related hemorrhage in South Africa



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abstract

Objective: To describe risk factors, clinical events, and avoidable factors in cases of maternal death due to bleeding during and after cesarean delivery. **Methods:** A retrospective study was undertaken of the clinical records of women who delivered in seven hospitals in Johannesburg, South Africa, between January 2013 and December 2014. Maternal deaths due to cesarean-related hemorrhage during or within 42 days of cesarean delivery at 24 weeks or more were selected. Case records were audited using quantitative techniques to determine the events leading up to death. **Results:** There were 123 251 deliveries and 17 maternal deaths due to bleeding during or after cesarean (3.2 deaths per 10 000 deliveries). Risk factors included previous cesarean delivery, preoperative anemia, and placental abruption. Uterine atony and surgical trauma were the main causes of bleeding. Five (29%) women died before the cause of bleeding was found. Avoidable factors included delays in the recognition and management of shock. Thirteen (76%) women died within 48 hours of the cesarean procedure. **Conclusion:** Deaths due to bleeding during and after cesarean have multifactorial causation. Maternal healthcare systems must be strengthened, with attention to the knowledge and skills of health workers. This requires increased clinical vigilance, a rapid effective response to obstetric hemorrhage and shock, and overall health system strengthening.

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1. Introduction

Maternal deaths resulting from bleeding during and after cesarean have recently increased in South Africa: in the triennial report on confidential enquiries into maternal deaths in 2011–2013 [1], such bleeding accounted for more than one-third of maternal deaths due to obstetric hemorrhage [1]. The cause-specific case fatality rate for hemorrhage during cesarean delivery was 5.5 deaths per 10 000 cesareans performed [2]. More than 70% of the deaths were considered to be clearly avoidable [2].

An increasing rate of cesarean delivery is thought to be the main cause of the rising numbers of deaths due to cesarean-related hemorrhage in South Africa [2]. There is also concern about a lack of surgical skills to manage women with severe bleeding during and after cesarean [3]. A shortage of ambulances and appropriate referral systems is also a major concern [2,3]. Medical and nursing staff shortages, operating room backlogs, and emergency transport deficiencies are frequent challenges in local state-run health services in South Africa [4,5].

Nevertheless, maternal death due to bleeding during and after cesarean remains a rare outcome. To our knowledge, no case series has examined the clinical details and quality of care in this situation.

The aim of the present study was therefore to describe risk factors, clinical events, and potentially avoidable factors in cases of maternal death due to bleeding during and after cesarean.

2. Materials and methods

In a retrospective study, maternal deaths due to bleeding during and after cesarean that occurred at seven hospitals in Johannesburg, South Africa, between January 1, 2013, and December 31, 2014, were audited as a case series. Ethical approval was granted by the University of the Witwatersrand's Human Research Ethics Committee, and institutional permission for the study was obtained from the Gauteng Department of Health. Informed consent was not needed because it was a retrospective study of maternal death.

Three of the study hospitals are university teaching hospitals in Johannesburg with tertiary referral functions, and four are regional (secondary-level) hospitals as part of the local referral system. Hospitals in South Africa are required to keep all clinical notes in cases of maternal death. Therefore, all maternal death records were reviewed by a certified specialist obstetrician and gynecologist (S.M.) to identify the causes. Deaths due to bleeding during and after cesarean were selected for inclusion.

The case definition of maternal death due to bleeding during and after cesarean was death during or within 42 days of surgery resulting from acute hemorrhage of at least 1000 mL (as estimated and noted in

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the file by the surgeon) during or after cesarean delivery at 24 weeks of pregnancy or more [6]. Women with medical disorders or blood clotting disorders were included, as were women with placental abruption, placenta previa, and/or placenta accreta. The exclusion criteria were uterine rupture with the fetus partially or completely extruded from the uterus, and advanced extrauterine pregnancy. Women for whom bleeding before cesarean was considered to be the primary cause of maternal death were also excluded from the audit. When there was difficulty in deciding on inclusion or exclusion of a case, two researchers (S.M. and E.B.) made a decision by consensus.

Risk factors considered in data collection included age and parity, previous cesarean delivery, prenatal anemia, HIV infection, placental disorders (abruption, previa, and accreta), breech presentation, multiple pregnancy, and prolonged labor. Obesity could not be estimated because of irregular recording of height. Anemia was defined as a hemoglobin level of less than 110 g/L [7]. Prolonged labor was defined as a latent phase of more than 8 hours in hospital or an active phase of first stage of more than 12 hours [8]. The type of hospital where the cesarean occurred and the rank of the surgeon (medical officer, resident, or specialist) were also considered. Other risk factors were time of operation (day or night), day on which the operation was performed (weekend or weekday), type of anesthesia, and birth weight.

Indications for cesarean, estimated blood loss, and interventions to arrest intraoperative hemorrhage were noted. Postoperative monitoring and management of postpartum hemorrhage (PPH) were also evaluated. The cause and site of the bleeding were determined from de-tails in the medical notes and on the basis of the researcher's opinion. Difficult cases were discussed between the researchers. Details of the clinical and surgical management—especially blood transfusion, non-surgical methods to stop bleeding, compression sutures, hysterectomy, second-look laparotomy, and admission to the intensive care unit—were noted.

The Donabedian model was used to assess the quality of health care in each maternal death, looking for avoidable factors. The model supposes that the clinical outcome of a patient is influenced by health service structure (facility and resources where the outcome took place) and process (diagnosis and treatment by the healthcare workers) [9]. Avoidable factors were subdivided into process and structure. If there was a factor or factors that directly resulted in the death of a patient, then the death was deemed avoidable. Expected structure factors included blood transfusion delays, emergency transport failures, and operating room delays. Process factors included patient-related issues, such as nonattendance at prenatal clinics and refusing hospital treatment, and healthcare worker-related factors, such as failure to recognize, diagnose, and respond to intraoperative or postoperative bleeding, including deficits in routine monitoring, inadequate volume resuscitation, and failure to undertake actions to arrest hemorrhage or treat hypovolemic shock.

The study used quantitative techniques. Data were analyzed by Stata version 11 (StataCorp, College Station, TX, USA). Values were reported as mean $\pm$ SD for normally distributed continuous data, median (range) for non-normally distributed continuous data, and number (percentage) for categorical data.

3. Results

During the study period, there were 17 maternal deaths due to bleeding during and after cesarean in the seven hospitals. In total, there were 123 251 deliveries at the hospitals, 43 137 (35%) of which were by cesarean. In 14 of the 17 included deaths, the woman underwent the cesarean delivery at one of the seven study hospitals, giving a case fatality rate of 3.2 deaths per 10 000 cesarean deliveries (14/43 137) at the seven hospitals. The other three women were transferred postoperatively from district hospitals because of bleeding complications.

The mean age of the 17 women was 28.6 ± 6.7 years; two women were younger than 19 years, and three were older than 35 years (range 17–42). The median parity was two (range 0–6); there were

three primigravidas and two women with a parity of six before delivery. Four (24%) women had a previous cesarean delivery. Seven (41%) had a record of prenatal anemia. Fourteen (82%) women attended prenatal care. Four (24%) women were infected with HIV. Three (18%) cesarean procedures were done preterm (b37 weeks). Three (18%) women had labor induced, and 1 (6%) had labor augmented with oxytocin. Three (18%) women underwent the cesarean before onset of labor, and 3 (18%) had the cesarean in the second stage of labor. There was 1 (6%) multiple pregnancy and 1 (6%) singleton breech presentation. Five (29%) women had placental abruption, and 1 (6%) had placenta accreta (Table 1). There were no cases of placenta previa.

All operations were performed by non-specialists, and two were done by residents in training. All 17 deaths were associated with potentially avoidable factors. Patient-related process factors included two women who did not attend prenatal care, and a woman with severe pre-eclampsia who refused hospital admission and cesarean delivery. This woman returned 5 days later with eclampsia, placental abruption, and a resistant atonic uterus with coagulopathy. Fourteen (82%) procedures were performed from Monday to Friday, and 3 (18%) were performed during a weekend. Fifteen (88%) cesareans were booked as emergencies, and 2 (12%) as elective. Seven (41%) procedures were done during the day, and 10 (59%) at night. Thirteen (76%) women had regional anesthesia. Stillbirth occurred in 7 (41%) cases. The mean birth weight was 2518 ± 882 g (range 1270–3820).

Ten (59%) procedures were recorded as “difficult” by the operating surgeons. The median estimated blood loss was 750 mL (range 300–8000; unrecorded in two cases). Two (12%) women died during the operation. Seven women (41%) had blood transfusions during the cesarean procedure. Atonic uterus was the main cause of bleeding in 7 (41%) cases, including five women with placental abruption, followed by surgical trauma in 5 (29%) cases. The cause of bleeding remained unknown for 5 (29%) women, three of whom died in the postoperative wards before any life-saving intervention could be started.

Surgical interventions included hysterectomy during the cesarean procedure for 3 (18%) women, and B-Lynch compression suture for 1 (6%) woman. Nine (53%) women subsequently had second-look laparotomies, during which 4 (44%) women underwent a hysterectomy, and 1 (11%) woman had B-Lynch compression suture (Table 2). Balloon tamponade was not attempted in any case, nor was tranexamic acid injection used. Postoperative artificial ventilation was provided to 14 (82%) women and inotropic drugs to 15 (88%) women. Nine (53%) women were admitted to the intensive care unit. Thirteen (76%) women died within 48 hours of surgery.

Recurrent avoidable factors related to the health system included shortages of emergency blood and emergency transport, and operating room delays. Health-worker-related factors included cesarean procedures with no clinical indication (e.g. grand multiparity, and breech presentation with fetal death), failure to detect hypovolemic shock, failure to control bleeding and/or treat shock, prolonged labor with delayed intervention, and delay in performing second-look surgery (Table 3).

4. Discussion

The present study found a case fatality rate of 3.2 maternal deaths due to bleeding during and after cesarean per 10 000 cesarean procedures. This is lower than the national case fatality rate for hemorrhage during cesarean delivery (5.5 per 10 000 cesareans [2]), possibly because of the better skills and resources available in Johannesburg with its academic hospitals and socioeconomic advantages relative to the rest of South Africa. Recurring risk factors for maternal death in the present audit were prenatal anemia, placental abruption, previous cesarean delivery, and second stage of labor. Factors contributing to the deaths of these women included the perioperative management of hemorrhage by the healthcare worker and the healthcare facility. Pre-operative factors—e.g. delays in performing cesarean or non-indicated cesarean procedures—might also have had a causative role. Deaths

Table 1
Case profiles and risk factors for maternal death due to bleeding during or after cesarean delivery.

Case	Prenatal care	Previous cesarean	HIV infection	Hemoglobin, g/L ^a	Labor stage at time of cesarean	Labor prolonged	Abruptio placentae	Placenta accreta	Hospital level ^b
1	Yes	No	No	115	First	Yes	No	No	District
2	Yes	No	No	131	First	No	No	No	Tertiary
3	Yes	No	No	78	First	Yes	Yes	No	Regional
4	Yes	No	Yes	132	First	No	No	No	Tertiary
5	Yes	Yes	No	123	First	No	Yes	No	Tertiary
6	Yes	Yes	No	123	First	No	No	Yes	Regional
7	Yes	No	Yes	106	First	No	No	No	Regional
8	No	No	Yes	–	First	No	No	No	Regional
9	Yes	No	No	134	None	No	No	No	District
10	Yes	No	Yes	96	Second	Yes	No	No	District
11	Yes	No	No	116	First	Yes	No	No	Regional
12	No	No	No	–	None	No	Yes	No	Tertiary
13	Yes	No	No	72	First	No	Yes	No	Regional
14	No	No	No	–	Second	Yes	No	No	Regional
15	Yes	Yes	No	75	None	No	No	No	Regional
16	Yes	Yes	No	94	Second	Yes	No	No	Regional
17	Yes	No	No	108	First	Yes	Yes	No	Regional

^a Indicates lowest prepartum hemoglobin level recorded (if prenatal care was attended).

^b Indicates the level of care at which the cesarean procedure was done (not necessarily where the death occurred). Three women were transferred from district hospitals after cesarean delivery.

due to bleeding during and after cesarean do not arise from an isolated event, but stem from multiple factors. The common situation was a cesarean procedure with a risk factor; followed by bleeding from surgical trauma or atonic uterus, then failure to diagnose and treat shock, with a delayed second-look operation with or without hysterectomy, and ultimately death after blood transfusion and intensive care.

Studies on PPH place emphasis on the so-called golden hour and on diagnosis and treatment of shock [10]. The golden hour is the time from the onset of PPH during which resuscitation needs to begin for the patient to receive maximum benefit. The longer it takes between the onset of shock and resuscitation, the lower the chance of patient survival. According to a meta-analysis of postpartum deaths in low-income countries and the USA [11], 45% of postpartum deaths occur within the first 24 hours of surgery. In the present study, 29% of the women died within the first 24 hours, and 47% died in the following 24 hours.

In terms of whether the deaths were related to the surgical skills of the surgeons involved, 59% of the procedures were recorded as “difficult” in the surgical notes. A second-look laparotomy was necessary for four of these difficult cesareans. South Africa faces the challenge of a shortage of skilled and specialist staff [3]. Cesarean procedures could also have become more difficult owing to the increasing rate of primary cesarean deliveries and the complications related to

subsequent repeat cesarean procedures [12]. There is a need to prepare non-specialist surgeons for difficult cesarean deliveries.

The use of prophylactic oxytocin during cesarean to prevent uterine atony was not always documented, and postoperative oxytocin in the postnatal ward was not always given. In South Africa, oxytocin should be given routinely irrespective of the mode of delivery [13]. The use of second-line uterotonic drugs was poor. One woman received ergometrine, three women received misoprostol, one had intramyometrial prostaglandin F_{2α}, and no woman was given tranexamic acid, despite evidence of its hemostatic efficacy [14]. The approach to arrest hemorrhage could have been more rapid and aggressive in most of the 17 cases. Frequently, too little was done too late.

Failure to detect and treat shock was a dominant theme in the case series. Appropriate basic monitoring and emergency responses could have been better. Special measures to predict shock, and interventions to treat shock, were not in place. The non-pneumatic anti-shock garment, currently not available in South Africa, is a compression suit worn around the lower extremities by patients in shock. It is a temporary option that has been shown to reduce PPH-related deaths and morbidity in settings where delays in the management of PPH are common [15]. The shock index, defined as the heart rate divided by the systolic blood pressure (up to 0.9 is normal in obstetric patients), has been

Table 2
Causes of bleeding during and after cesarean delivery, and emergency responses.

Case	Main cause of bleeding	Pharmacological intervention	Surgical intervention	Units of red cells transfused
1	Surgical trauma: uterine artery	–	Second-look surgery with B-Lynch	7
2	Unknown	–	None	0
3	Atonic uterus (placental abruption)	Oxytocin, misoprostol	Hysterectomy at cesarean	2
4	Surgical trauma: abdominal wall	–	Second-look surgery	7
5	Atonic uterus (placental abruption)	Oxytocin, misoprostol, intramyometrial prostaglandin F _{2α}	None	9
6	Placental site (placenta accreta)	–	Hysterectomy at cesarean	7
7	Unknown	–	None	0
8	Unknown	–	Second-look surgery	3
9	Atonic uterus	Oxytocin	Second-look surgery with hysterectomy	7
10	Unknown	–	Second-look surgery with hysterectomy	5
11	Unknown	–	None	2
12	Atonic uterus (placental abruption)	Oxytocin	B-Lynch at cesarean	5
13	Atonic uterus (placental abruption)	Oxytocin	Second-look surgery	4
14	Surgical trauma: uterine incision	–	Second-look surgery	7
15	Surgical trauma: uterine artery ^a	Oxytocin	Second-look surgery with hysterectomy	10
16	Atonic uterus ^b	Oxytocin	Second-look surgery with hysterectomy	9
17	Atonic uterus (placental abruption)	Oxytocin, ergometrine	Hysterectomy at cesarean	2

^a Complicated by atonic uterus.

^b Complicated by posterior uterine wall surgical trauma.

Table 3

Avoidable factors in maternal deaths due to bleeding during or after cesarean delivery.

Case	Structure factors (health system)	Process factors (patient, health worker)
1	Emergency transport delay; no beds available in intensive care unit	Failure to identify cause of hemorrhage
2	-	Cesarean delivery not indicated; inadequate postoperative observations
3	Shortage of blood for transfusion	Failure to treat anemia during prenatal care
4	Equipment failure: ventilator malfunction	Delayed decision to perform second-look surgery
5	No beds available in intensive care unit	Patient refused hospital admission
6	-	Poor prenatal care attendance by patient
7	-	Failure to detect shock and manage the hemorrhage
8	-	Patient did not attend prenatal care; patient did not go to referral hospital; cesarean delivery not indicated; failure to detect shock
9	Referral hospital delayed in accepting transfer of the patient	Delayed decision to perform second-look surgery
10	Shortage of blood for transfusion	Delayed decision to perform second-look surgery; delayed transfer of patient to higher level of care
11	-	Inadequate intrapartum monitoring and prolonged labor; failure to detect and manage shock
12	Emergency transport delay	Patient did not attend prenatal care; failure to resuscitate patient in shock
13	Delay in starting cesarean procedure	Delayed decision to perform second-look surgery
14	-	Patient did not attend prenatal care; delayed decision to perform second-look surgery
15	-	Failure to achieve hemostasis intraoperatively
16	Delay in starting cesarean procedure	Prolonged labor with delayed intervention
17	Delay in starting cesarean procedure	Poor intrapartum monitoring; failure to diagnose placental abruption preoperatively

shown to be an accurate predictor of compensatory changes in the cardiovascular system from hemorrhage [16]. In low-resource settings, it might be recommended as a better indicator of severity of PPH than blood loss estimation [17]. More emphasis on the diagnosis and management of shock is needed in such settings.

A limitation of the present study is the small number of patients; however, death due to bleeding during and after cesarean is rare and has not been studied sufficiently. The sample was adequate to show re-curring healthcare worker and healthcare system deficiencies, although a case-control study with a control group of survivors (near-miss and uncomplicated births) would have given a better representation of why women die. Poor documentation in some of the clinical notes was also a limitation.

In conclusion, although death due to bleeding during and after cesarean is rare, it is alarming and mostly avoidable. Owing to its multi-factorial causation, death due to bleeding during and after cesarean can be avoided only by strengthening health systems and increasing clinician knowledge and skills. Clinical managers must ensure recognition of risk factors, implementation of routine precautions, and a vigilant and systematic approach to the detection and treatment of obstetric hemorrhage and its effects.

Acknowledgments

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Conflict of interest

The authors have no conflicts of interest.

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Chapter 7

Overview and implications

7.1. Overview

The number of maternal deaths from BDACS has increased in South Africa. The Saving Mothers reports have highlighted healthcare worker and healthcare system deficiencies, but lack detail on risk factors and causes. The problem appears to be multi-factorial. Recommendations are mostly aimed at reducing the caesarean section rate and improving pre-conception and antenatal care.

With increasing access to caesarean section, particularly in Africa, maternal morbidity and mortality from BDACS may increase globally.

The systematic review determined near-miss ratios and mortality indices for PPH. This had not been done before. The review confirmed that the burden of PPH was greater than expected, particularly in low and lower middle income countries. This raised questions about inequities in quality of care. Intractable PPH is a complex disease, requiring a multi-disciplinary approach in a functional healthcare system. Managing the complications of PPH requires critical care specialists, obstetricians and other specialists, but often these roles are played by generalist doctors who have not been trained sufficiently to manage such patients. More attention needs to be put into finding measures to reduce PPH, not just at clinical level, but also at policy levels. Regarding PPH from BDACS, the systematic review did not provide enough information on make any conclusions or recommendations, other than the need for further research. Limitations of the systematic review included the exclusion of non-English publications, the studies did not use the same criteria for near-miss and the study designs were different. However all studies that were included used a validated near-miss criteria and there had to be consensus about

methodology for each study between the two reviewers. The critical appraisal tool was considered by both reviewers to be unclear.

The health systems audit evaluated preparedness for provision of safe caesarean sections in 15 hospitals across southern Gauteng. The inequities in maternity services between tertiary hospitals and lower levels of care were a key finding. The maldistribution of staff between different levels of care resulted in regional and district hospitals primarily being staffed by non-specialist medical officers, and tertiary hospitals having disproportionately higher number of specialists. While district hospitals are generally configured to provide service with non-specialist doctors, this is not acceptable in regional hospitals. Ideally, outreach programmes from teaching hospitals could compensate, at least temporarily, for disparities in skills and knowledge. However, there were no outreach programmes in place at the time of the study. The absence of second line uterotonic drugs in regional and district hospitals, and the lack of competence in doing procedures such as the B-lynch brace suture are examples of serious health systems constraints. This audit highlighted inequities and health system deficiencies as possible contributors to severe morbidity or death from BDACS.

The near-miss audit revealed a near-miss rate for BDACS of 2.1/1000 live births. The risk factors for BDACS were mainly previous caesarean section and pre-operative anaemia. Questions arise about whether women with anaemia are appropriately managed during labour and pre-operatively. Although atonic uterus was the most common cause of bleeding (43%), the number of women with trauma was much higher than what was expected (29%). This may be related to the difficulty of the caesarean sections, associated with rising proportions of women with previous caesarean section, or the surgical skills of the surgeons. No other studies have looked at the causes of BDACS in this much detail. All the women with near-miss from BDACS required

at least one life-saving intervention that could not be performed at all levels of care. A limitation of this study was the modification of the WHO near-miss criteria. This was based on the lack of resources and facilities in some of the hospitals. This study was important in determining how women with life threatening BDACS survived.

In the maternal death audit all the deaths were considered avoidable. The theme of ‘too little done too late’ was recurrent. That second line uterotonics and tranexamic acid were often not used reflects non-adherence to PPH protocols, or shortage of these drugs. Nevertheless, most of the women died only after substantial attempts to save their lives, such as surgery to arrest haemorrhage, massive blood transfusion, and admission to ICU. This however confirms the complexity of the disease. When women with BDACS receive inadequate early emergency care, they may go on to suffer multi-organ dysfunction and multi-organ failure, and die because of the complications related to BDACS. The women often received inotropic support, not while they were shocked, but later as a rescue, just before they died. Acute kidney injury, liver failure, respiratory and cardiac failure are often the final events before death. The diagnosis and management of shock was generally poor, with junior staff responding simply by increasing the intravenous fluid volume. Recognition of a critically ill patient is still a challenge in our setting, and the knee-jerk response to give blood, fluids and arrest haemorrhage is frequently insufficient.

7.2. Interventions by the researcher

The findings of the study were discussed with the Director of Maternal and Child Health in Gauteng Province, and a formal meeting was held on 14 September 2016 with all the hospitals, district clinical specialist teams, and representatives from University of the Witwatersrand, University of Pretoria and Sefako Makgatho University. Recommendations

were proposed at hospital and provincial level, and a report of the findings was sent to the MEC of Health Gauteng (the political head of health services in the province). The detail of these meetings is beyond the scope of this document.

An outreach programme from CHBAH was started in two district and two regional hospitals. This entailed regularly attending morbidity and mortality meetings and ward rounds. There were also visits to other hospitals, but these were not structured, and were mostly by invitation, and were scheduled according to the researcher's availability. In addition, the researcher gave 16 presentations on measures to reduce caesarean section related haemorrhage in 10 hospitals (Table 7.1).

A weekly near-miss meeting was started at CHBAH in 2015 where all near-misses were presented, including those related to BDACs. The meetings are now well established and multi-disciplinary, attended by obstetric registrars and consultants, paediatricians, anaesthetists and intensivists. Subsequently, a near-miss follow up clinic was started in 2016 by the researcher, to monitor intermediate term complications in women who had a near-miss event during their pregnancy. Most of the patients had near-miss from PPH, not necessarily from BDACS. The women in the clinic are also screened for post-partum depression and referred to the psychiatry department when necessary.

The researcher joined the South African Peri-operative Research Group, where surgical research priorities for South Africa are discussed. The researcher motivated for BDACS to be included in the national list of priorities. BDACS were placed fourth in the group of ten national priorities. This was published in the South African Medical Journal, and the researcher was a co-author on the section on BDACS in the publication (1). Further studies will be done

by this group.

Table 7.1: List of presentations given by researcher to teach about BDACS and pregnancy related complications associated with caesarean section

Reducing caesarean section haemorrhage	Leratong Hospital
Near-miss from BDACS case presentations	Leratong Hospital
Why pregnant women die	Southrand Hospital
Management of caesarean section haemorrhage	Carltonville
Management of caesarean section related haemorrhage	Edenvale Hospital
Puerperal sepsis and pregnancy complications	Carltonville
Reducing maternal morbidity and mortality from caesarean section related haemorrhage in Southern Gauteng	Chris Hani Baragwanath Academic Hospital
How we can reduce caesarean section rate	Leratong Hospital
Third stage of labour	Leratong Hospital
Reducing maternal mortality and morbidity from caesarean section related haemorrhage	Charlotte Maxeke Johannesburg Academic Hospital
Reducing maternal mortality and morbidity from caesarean section related haemorrhage	Rahima Moosa Mother and Child Hospital
Reducing maternal mortality and morbidity from caesarean section related haemorrhage	Natalspruit Hospital
Reducing maternal mortality and morbidity from caesarean section related haemorrhage	Sebokeng Hospital
Reducing maternal mortality and morbidity from caesarean section related haemorrhage:	Tambo Memorial Hospital

8.3. Overview of the research methods

The four studies reflected different aspects of BDACS. The systematic review introduced PPH as an important contributor to near-miss but did not yield enough data on BDACS as an important cause of PPH. This had to do with the study designs reviewed, and that the majority of the studies did not classify BDACS as a separate cause of PPH. The review of maternal deaths provided valuable information on mortality from BDACS, albeit from a small number of women. The contribution of maternal deaths and near-miss provided useful clinical data, and mapped out important avoidable factors, particularly related to the healthcare worker and healthcare systems. Risk factors were identified for women developing severe BDACS, but the analysis was limited by the absence of a control group. The health systems audit presented a critical argument, that even with the best efforts, it may be challenging to manage BDACS in poorly resourced setting. The four studies highlighted proximal risk factors that could have predisposed women to BDACS, such as not attending antenatal clinic. The studies did not address patient delays and the role they play in leading to deaths from BDACS, and this was a limitation of the methodology. Nevertheless, the chapters on near-miss and maternal deaths introduced patient delays. Overall the methods used to conduct the four studies were sufficient to determine recurring patterns leading to morbidity and mortality from BDACS.

7.3. Implications of research

The recurring theme of this study is that severe BDACS is a complex disease, requiring a multi-disciplinary approach in a functional health system. The methods to arrest haemorrhage are well-known and should be within the capacity of most hospitals, yet the absence of second line uterotonic drugs and the skills to arrest haemorrhage remain a problem at all but the tertiary level of care. In addition, the management of the complications of BDACS is complex, and currently not within the capacity of district hospitals or inadequately equipped regional

hospitals. In such circumstances, timely referral and appropriate critical care becomes essential and life-saving. Failure of these components of a functioning health system can result in fatal consequences for women who suffer BDACS.

7.4. Recommendations

A global effort is required to strengthen the management of patients with severe BDACS, particularly in low- and low middle income countries. This should incorporate healthcare worker education and training, and the provision of adequate facilities, resources and systems. Obstetric protocols for PPH should focus not only on measures to arrest haemorrhage, but also on organ system support. The complications of haemorrhagic shock, affecting multiple organ systems be anticipated and aggressively prevented and managed. Fluid resuscitation, the use of inotropes, electrolyte balance, and appropriate blood component therapy should be incorporated into the obstetric approach to managing women with BDACS and multiple organ dysfunction. A synopsis of recommendations on BDACS is presented below, divided into policy, clinical care and research priorities.

7.4.1. Synopsis of recommendations in policy, clinical care and research priorities

7.4.1.1. Policy

- Training in caesarean section technique, including management of intraoperative complications, needs to be standardised and formalised at regional and district hospitals.
- Hospital transfer systems should be improved to avoid delays in referring patients with BDACS to higher levels of care.
- Deaths and near-misses from BDACS should be audited at perinatal review

meetings.

- The number of obstetric specialist posts should be increased, or existing posts filled, in regional hospitals.
- Staffing norms for midwives and doctors need to be standardised across different levels of care.
- Sustainable outreach programmes from the tertiary to the regional and district hospitals must be instituted.

7.4.1.2. Clinical

- Second-line uterotonics should be available at all hospitals offering caesarean sections.
- All medical officers who perform caesarean sections should be skilled in the B-Lynch brace suture, uterine tourniquet and balloon tamponade procedures.
- The shock index should be regularly measured in all women after caesarean section, and be taught and used as an early indicator of severe PPH.
- Diagnosis and management of shocked patients, including basic critical care, should be incorporated in PPH modules.

7.4.1.3. Research priorities

- Management of shock related to BDACS.
- A case-control near-miss audit of BDACS comparing risk factors and outcomes in a near-miss and non-near-miss group.
- A near-miss study on BDACS in a resource-poor setting with restricted access to specialists and complex interventions.

- Effects of prolonged decision-to-incision interval on maternal near-miss resulting from caesarean section.

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Appendix 1

Plagiarism certificate

MaswimePhdmanuscriptdecember061216.pdf

ORIGINALITY REPORT

%**8**

SIMILARITY INDEX

%**2**

INTERNET SOURCES

%**7**

PUBLICATIONS

%

STUDENT PAPERS

PRIMARY SOURCES

1 Maswime, Salome, and Eckhart Buchmann. "Causes and avoidable factors in maternal death due to cesarean-related hemorrhage in South Africa", International Journal of Gynecology & Obstetrics, 2016. **%7**
Publication

2 www.ajol.info **%1**
Internet Source

3 www.ncbi.nlm.nih.gov **%1**
Internet Source

EXCLUDE QUOTES ON

EXCLUDE MATCHES < 1%

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BIBLIOGRAPHY ON

Appendix 2

Ethics Clearance Certificate



R14/49 Dr TMS Maswime

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M140137

NAME: Dr TMS Maswime
(Principal Investigator)

DEPARTMENT: Obstetrics & Gynaecology
Chris Hani Baragwanath Hospital Academic Hospital

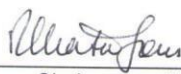
PROJECT TITLE: Reducing Maternal Morbidity and Mortality
from Caesarean Section-Related Haemorrhage
in Southern Gauteng

DATE CONSIDERED: 31/01/2014

DECISION: Approved unconditionally

CONDITIONS:

SUPERVISOR: Prof E Buchmann

APPROVED BY: 
Professor PE Cleaton-Jones, Chairperson, HREC (Medical)

DATE OF APPROVAL: 11/04/2014

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 Secretary in Room 10004, 10th floor, Senate House, University.
I/we fully understand the conditions under which I am/we are authorized 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 the application to the Committee. **I agree to submit a yearly progress report.**

Principal Investigator Signature _____

Date _____

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

Appendix 3

Gauteng permission



GAUTENG PROVINCE

HEALTH
REPUBLIC OF SOUTH AFRICA

OUTCOME OF PROVINCIAL PROTOCOL REVIEW COMMITTEE (PPRC)

Researcher's Name (Principal investigator)	Salome Maswine
Organization / Institution	University of Witwatersrand
Research Title	Reducing maternal morbidity and mortality from caesarean section related haemorrhage
Protocol number	P150214
Date submitted	05/06/2014
Date reviewed	19/02/2014
Outcome	APPROVED
Date resubmitted	N/A
Date of second review	N/A
Final outcome	N/A

It is a pleasure to inform that the Gauteng Health Department has approved your research on "Reducing maternal morbidity and mortality from caesarean section related haemorrhage."

The Provincial Protocol Review Committee kindly requests that you to submit a report after completion of your study and present your findings to the Gauteng Health Department.

Approves / not approves

Dr. B. Ikafeng

Research and epidemiology Manager

Date 23/06/2014

Appendix 4

Systematic review: Electronic Search Diary

Record ID

Name of Database Scopus

- PubMed
- Embase
- Scopus
- Grey literature

Name of article:

Authors:

Journal:

Date of publication:

PDF Name:

Acceptance:

- Title:
- Abstract
- Article

Could not find:

Appendix 5

Systematic Review: Article Screening Tool

Record ID:

Name of article:

PDF name:

Acceptable

- ☐ Yes
- ☐ No
- ☐ Unsure

If no, reason

Nearmiss ratio

- Yes
- No

Maternal death ratio

- Yes
- No

PPH SMO ratio

- Yes
- No

Caesar PPH ratio

- Yes

- No

Causes

☐ Yes

☐ No

Interventions

• Yes

• No

Appendix 6

Systematic Review: Data Extraction Form

Journal

Title

Authors

Year of audit

Nearmiss criteria used : Mantel/Fillipi/WHO/Geller/Waterstone)

Country

Rural or urban environment Rural

Urban

Not specified

Both

Hospital/Community based Hospital based

Community based

Number of hospitals

Hospitals Public

Private

Not specified

Both

Type of Study Prospective

Retrospective

Live births

Number of near-miss

Number of maternal deaths

Number of deaths due to PPH

Number of near-misses due to PPH

Near-miss criteria used for PPH Blood transfusion

Hysterectomy

Shock

ICU admission

If blood transfusion, how many units

Number of nearmiss from atonic uterus

Number of near-misses from retained placenta

Number of near-misses from caesarean section

Avoidable factors for PPH

Appendix 7

Systematic Review: Critical Appraisal Form

Record ID:

Title:

Authors (first 3):

Year published:

	Yes	No	Unclear	Not Applicable	Comment
1. Are the criteria for inclusion in the sample clearly defined?					
2. Are confounding factors identified and strategies to deal with them stated?					
3. Are outcomes assessed using objective criteria?					
4. If comparisons are being made, is there sufficient description of groups?					
5. Are outcomes measured in a reliable way?					

Included:

- ☐ Yes
- ☐ No : Reason
- ☐ Undefined

Appendix 8

Health systems audit: Hospital Data Sheet

Hospital Number:

Date:

Level of care: district/regional/tertiary

Structure

Number of hospitals referring to this institution:

Number of clinics referring to this institution:

What is the referral hospital for this hospital:

Staff: Midwives:

Advanced midwives:

Doctors in monthly maternity rotation:

Interns:

Medical officers (full time):

Medical officers (part time):

Rotating registrars:

Consultants (completed registrar training not yet qualified):

Consultants (full time specialists):

Consultants (part time specialists):

What is the rank of the most senior doctor on duty in the hospital?

Resources: Specify if not available for 24 hours 7 days a week

Blood bank:

Emergency blood:

Theatre:

Anaesthetists:

Paediatricians:

Ambulances:

High care unit:

Intensive care unit:

Dedicated post-natal caesarean section ward or section:

Post-natal clinic:

Maternal mortality audit meetings:

Near-miss audit meetings that include morbidity after CS:

Drugs and procedures used: state 'never', 'rarely', 'sometimes', or 'often'

Syntocinon:

Syntometrine:

Prostaglandin F_{2α}:

Cyclokapron:

Misoprostol:

Bakri balloon:

B-Lynch:

Hysterectomy:

Systemic devascularisation:

Condom balloon:

Uterine tourniquet:

Training: ESMOE:

Protocols:

List of visible protocols on caesarean section technique in labour ward and theatre
(Eg. PPH, B Lynch)

Who is responsible for teaching doctors how to perform caesarean sections:

How are they taught: In theatre by observation and practice:

Simulators:

Videos:

Other (specify):

Is there a rule on how many caesarean sections should a doctor assist before
learning how to operate?

How many?

Is there a rule on how many caesarean sections a junior doctor should do with a
senior before operating independently?

How many?

Process

Is there a 24 hour recovery nurse:

Postnatal care observation routines:

Use of the Early warning chart in the postnatal ward:

Is there a senior available/on call at all hours in case of emergencies

Outcome

Number of women seen in maternity in 2013:

Number of deliveries in 2013:

Number of caesarean sections in 2013:

Number of maternal deaths in 2013:

Number of caesarean section related haemorrhage deaths in 2013:

Appendix 9

Maternal Deaths Audit: Data Sheet

Patient

Study number:

Date:

Age

Parity:

Gravidity:

Gestational age (wk.):

Weight:

Known co-morbidities: Pre-eclampsia / Abruption placentae / Placenta praevia / Medical disorder
(specify):

Booked/Unbooked

Previous caesarean sections:

Complications:

Booking Hb:

Lowest antenatal Hb:

HIV: CD4: On ART:

Duration of ART (m.o.):

Number of antenatal visits:

Pre-op (<48 hr): Hb:

Platelets:

INR:

Month and year of caesarean section:

Structure

Name of Hospital:

Was this patient transferred from another hospital:

Was there a delay in transferring patient:

How many hours:

Why did patient have to be transferred:

Was there any delay in performing the caesarean section (State reason):

How many hours:

Time of booking caeser:

Process

Anaesthetic started: (GA/spinal) Anaesthetic when op finished: (GA/spinal) Operation started by (e.g. intern/M.O.):

Incision:

Previous scar wound dehiscence noted:

Note on adhesions: None / Routine / Difficult

Note on difficulty at CS: None / Some difficulty / Serious difficulty

Highest rank of doctor called to assist (e.g. MO/specialist):

Number of doctors called to assist:

Duration of caesarean section:

Time of caesarean section:

Day of the week:

Elective / Emergency in labour 1st stage / Emergency in labour 2nd stage / Emergency not
in labour

Indication for caesarean section:

Outcome

Birth weight:

Baby alive or stillborn:

Estimated blood loss noted at caesarean section:

Anaesthetic record found:

Noted haemorrhage (if applicable):

Noted fluid balance and fluids given:

Noted blood transfusion used:

Abnormal haemorrhage (≥ 1000 mL) detected AT caesarean section:

Actions noted:

Ordered blood/Rubbing up/Haemostatic sutures/B-Lynch/oxytocin/

Miso/F2Alpha/TXA/Ergot/Balloon/ Systematic devascularisation/

Hysterectomy/Tourniquet/Internal iliac ligation/CPR

Abnormal haemorrhage (≥ 1000 mL) detected AFTER caesarean section

IN THEATRE:

Actions noted:

Rubbing up/Clearing clots/Ordered blood/EUA/Relook lap/haemostatic sutures/B-Lynch/Oxytocine/Miso/F2Alpha/TXA/Ergot/Balloon/ Systematic devasc/Hysterectomy/Tourniquet/Internal iliac ligation/CPR

Abnormal haemorrhage (≥ 1000 mL) detected AFTER caesarean section

IN WARD:

Actions noted: Call for help/IV fluids/Rubbing up/Clearing clots/Ordered blood/EUA/Relook lap/Haemostatic sutures/B-Lynch/Oxytocin/Miso/F2Alpha /TXA/Ergot/Balloon/ Systematic devasc/Hysterectomy/Tourniquet/Internal iliac ligation/CPR

FIRST 24 HOURS

Total red cell transfusion (units) in first 24 hours postCS:

Additional red cell transfusion (units) after 24 hours post CS:

Was this patient transferred from another hospital within the 24 hours:

Did the patient need subsequent surgery (EUA/Relook laparotomy):

List (date/time/duration/rank of surgeon):

Day of death after CS (first 24 hours = day 0, 24-47 hours = day 1 etc):

Died: On the table/Theatre recovery/Ward/HCA/ICU/Ambulance/Other

Postop: Inotropes/Ventilation/ICU/Dialysis

Postop intake-output chart kept and completed:

Early warning chart used:

Lowest Hb during hospital stay:

Lowest Platelets during hospital stay:

Highest creatinine during hospital stay:

Summary of case:

Cause of death (from Saving Mothers options):

Organ failure dysfunction (from Saving Mothers options):

Assessment

Modifiable factors

Patient related:

Healthcare worker related: Patient related

Health systems related: Patient related:

Evaluation of Intra-operative management:

Evaluation of post-operative management in theatre:

Evaluation of post-operative management in the post-natal ward:

Appendix 10

Maternal Near-miss Audit: Data Sheet

Patient

Study number:

Date:

Age:

Parity:

Gravidity:

Weight:

Gestational age (wk):

Known co-morbidities: Pre-eclampsia / Abruption placentae / Placenta praevia / Medical disorder
(specify):

Booked/Unbooked

Previous caesarean sections (year/complications):

Booking Hb:

Lowest antenatal Hb:

HIV: CD4: On ART: Duration of ART (mo.):

Number of antenatal visits:

Pre-op (<48 hr): Hb: Platelets: INR:

Month and year of caesarean section:

Structure

Name of Hospital:

Name of hospital referred from:

Was there a delay in transferring patient:

How many hours:

Why did patient have to be transferred:

Was there any delay in performing the caesarean section (State reason):

How many hours:

Time of booking caeser:

Process

Anaesthetic started: (GA/spinal) Anaesthetic when op finished: (GA/spinal) Operation started by (e.g. intern/M.O.):

Incision:

Previous scar wound dehiscence noted:

Note on adhesions: None / Routine / Difficult

Note on difficulty at CS: None / Some difficulty / Serious difficulty

Highest rank of doctor called to assist (e.g. MO/specialist):

Duration of caesarean section:

Time of caesarean section:

Day of the week:

Elective / Emergency in labour 1st stage / Emergency in labour 2nd stage / Emergency not in labour

Indication for caesarean section:

Outcome

Birth weight: Baby alive or stillborn:

Estimated blood loss noted at caesarean section:

Anaesthetic record found:

Noted haemorrhage (if applicable):

Noted fluid balance and fluids given:

Noted blood transfusion used:

Abnormal haemorrhage (≥ 1000 mL) detected AT caesarean section:

Actions noted: Ordered blood/Rubbing up/Haemostatic sutures/B-Lynch/oxytocin/
Miso/F2Alpha/TXA/Ergot/Balloon/ Systematic devasc/Hysterectomy/Tourniquet/Internal
iliac ligation/CPR/Inotropes

Abnormal haemorrhage (≥ 1000 mL) detected AFTER caesarean section IN THEATRE:

Actions noted: Rubbing up/Clearing clots/Ordered blood/EUA/Relook lap/haemostatic
sutures/B-Lynch/Oxytocine/Miso/F2Alpha/TXA/Ergot/Balloon/ Systematic
devasc/Hysterectomy/Tourniquet/Internal iliac ligation/CPR/Inotropes

Abnormal haemorrhage (≥ 1000 mL) detected AFTER caesarean section IN WARD:

Actions noted: Call for help/IV fluids/Rubbing up/Clearing clots/Ordered blood/EUA/Relook
lap/Haemostatic sutures/B-Lynch/Oxytocin/Miso/F2Alpha /TXA/Ergot/Balloon/ Systematic
devasc/Hysterectomy/Tourniquet/Internal iliac ligation/CPR/Inotropes/dialysis

Total red cell transfusion (units) in first 24 hours postCS:

Additional red cell transfusion (units) after 24 hours post CS: Was
this patient transferred from another hospital:

Postop: Inotropes/Ventilation more than 90 min/ICU/Dialysis Postop
intake-output chart kept and completed:

Early warning chart used: Lowest Hb
during hospital stay:

Lowest Platelets during hospital stay: Highest
creatinine during hospital stay:

Summary of case:

Organ failure dysfunction (from Saving Mothers options

Assessment

Modifiable factors:

Patient related:

Healthcare worker related:

Health systems related:

Evaluation of Intra-operative management:

Evaluation of post-operative management in theatre:

Evaluation of post-operative management in the post-natal ward: