

**A study of fresh stillbirths weighing 2500 g or more
at three academic hospitals**

by

Dr. Marlene Bothma

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degree of
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DECLARATION

I, Marlene Bothma, declare that this research report is my own work. It is being submitted for the degree of Master of Medicine in the branch of Obstetrics and Gynaecology in the University of the Witwatersrand, Johannesburg. It has also been submitted to the Colleges of Medicine of South Africa in partial fulfilment of the requirements for the qualification of Fellowship of the College of Obstetrics and Gynaecology

Marlene Bothma

5 November 2014

DEDICATION

I dedicate this work to my husband Jacques, who unconditionally supports me every day.

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ABSTRACT

Background and Objectives

Globally an estimated 1.19 million stillbirths occur during labour, with almost all of these deaths occurring in low - and middle-income countries. In South Africa labour related complications are one of the top primary obstetric causes of perinatal deaths. The objectives of this study were: 1) To determine the incidence of fresh stillbirths weighing 2500 g or more at three academic hospitals; 2) To identify the direct cause, along with associated risk factors for these deaths; and 3) To identify avoidable factors relating to poor or substandard intrapartum care with specific emphasis on intrapartum fetal heart rate monitoring.

Methods

This was a prospective, cross sectional, descriptive study conducted at three obstetric units in Johannesburg, Gauteng. The hospitals were Chris Hani Baragwanath Academic Hospital, Charlotte Maxeke Johannesburg Academic Hospital and Rahima Moosa Mother and Child Hospital. Three six-month periods were sampled at each of the three hospitals consecutively, for a total eighteen month data collection period from May 2011 until October 2012. The study population was all fresh stillbirths weighing 2500 g or more born at these institutions.

Results

A total of 52 women with fresh stillbirths eligible for inclusion were identified. Twenty-three (44.2%) were nulliparous. Sixteen women (30.8%) were HIV infected. Twelve women had a previous caesarean section. The mean gestational age was 38.4 ± 2.3 weeks with a mean birth weight of 3052 ± 460 g. Six women had prolonged active phase of labour, with the cervix dilating at a rate of less than 1cm/hour. None of the patients had augmentation of labour and meconium stained liquor was found in 23 (44.2%) of the cases.

There were 30 women (57.7%) with identifiable catastrophic events relating to the intrapartum stillbirth: 16 had abruptio placentae, 7 had cord prolapse, 4 had a ruptured uterus and there were 3 cases of entrapment of the aftercoming head of breech. Twenty-two women (42.3%) had appropriate fetal monitoring and 15 (28.8%) had inadequate or no fetal monitoring. The remaining 15 (28.8%) of the 52 cases were diagnosed as intra-uterine fetal deaths on arrival at hospital. The mean time from recognition of emergency to delivery ($n=25$) was 107.8 ± 92.3 minutes. The emergency was not recognised in 12 (32.4%) of the cases presenting with live babies on admission.

Conclusion

Fresh stillbirths ≥ 2500 g are still common and may occur in normal labour, with only 57.7% of the fresh stillbirths in this study having an identifiable catastrophic event leading to the fetal demise. There appears to be a failure to detect or respond to evidence of fetal distress even in facilities with skilled staff and available resources, which points to shortfalls in the quality of intrapartum care.

1. Introduction

A stillbirth is a devastating experience for a woman and her family, even more so in babies at term. These babies are usually alive at the initiation of labour, with the expectation of a good and happy outcome at delivery. The impact and significance of a stillbirth is often underestimated and undervalued. For the family involved, this is no less a death than the death of any other child.¹ Stillbirths matter to people, and they should matter to health systems too.

A stillbirth is defined as “a death prior to the complete expulsion or extraction from its mother of a product of conception, irrespective of the duration of pregnancy; the death is indicated by the fact that after such separation the fetus does not breathe or show any other evidence of life, such as beating of the heart, pulsation of the umbilical cord or definite movement of voluntary muscles”.^{2,3} For international comparison, the World Health Organization (WHO) agreed definition (≥ 1000 g birthweight or ≥ 28 completed weeks of gestation) is used.^{2,3} A fresh stillbirth is a neonate born dead, without signs of skin disintegration, implying that the death occurred less than 12 hours before delivery.³ Because of the short duration between intrauterine death and delivery, a fresh stillbirth frequently indicates death during labour (intrapartum death).⁴

As pointed out by Lawn et al. in *The Lancet's* series on stillbirths,⁴ stillbirths remain invisible – they are not counted in the Millennium Development Goals, nor tracked by the United Nations, nor in the Global Burden of Disease metrics. Millions of families worldwide experience stillbirth, yet these deaths remain uncounted,

unsupported, and understudied. As the authors state, stillbirths can no longer be invisible or ignored – they need to count.

2. Literature review

2.1 Global estimates

At least 2.65 million third-trimester stillbirths were estimated worldwide in 2008 (≥ 1000 g birth weight or ≥ 28 weeks of gestation).⁴ Of these stillbirths an estimated 1.19 million stillbirths occur during labour, which is slightly higher than the previous worldwide estimate for 2000 of 1.02 million.^{5,6} Almost all of these deaths occur in low - and middle-income countries.⁷ In high-income (developed) countries such as Canada and Denmark, the intrapartum stillbirth rates are less than 0.5 per 1000 births for birth weight categories of 1000 g or more.⁴ In middle-income countries such as Brazil the rate is 2.6 per 1000 for birth weights of 1000 g or more.⁸ In low-income countries the intrapartum stillbirth rates are much higher, ranging from 10 per 1000 in Malawi, to as high as 15.5 per 1000 in Zimbabwe.^{5,8} In many countries in south Asia and sub-Saharan Africa the rates are 12 per 1000 or higher.⁴ The fresh stillbirth rate for South Africa is 9.67 per 1000.¹⁰ This South African estimate is taken from “Saving Babies 2006-2007” – a report on perinatal care in South Africa.⁹ Seven “Saving Babies” reports have been published, based on the South African national Perinatal Problem Identification Programme (PPIP) database. Data is sent on a voluntary basis from sentinel sites – hospitals or community health centres where deliveries are conducted. These reports are aimed at identifying modifiable factors related to perinatal care in South Africa.

In the most recent report, data submitted to the national database from the 1st January 2008 until 31st December 2009 was analysed. During this period, 275 sites from throughout the country had submitted data and just fewer than 963,000 births had been entered. This comprises approximately 52.4% of all births in health institutions recorded by DHIS (District Health Information System) (October 2010) in South Africa during this time period.

2.2 South African estimates

There were a total number of 23 547 stillbirths recorded for the two years 2008-2009 in South Africa, with 40.3% of them being fresh stillbirths. The majority of all stillbirths in the category of ≥ 1000 g occur in national central hospitals, provincial tertiary hospitals and regional hospitals. The stillbirth rates are lowest in district hospitals and community health centres. When looking at all stillbirths specifically in the weight category of ≥ 2500 g, this distribution is also true with rates being 10.9 per 1000 in national central hospitals, 10.82 per 1000 in provincial tertiary hospitals, 9.03 per 1000 in regional hospitals, 8.73 per 1000 in district hospitals and the lowest rate by far being at community health centres with 1.95 per 1000. Fresh stillbirths in the category of ≥ 1000 g have this same distribution per level of care.¹⁰

It is expected that the mortality rates increase as the level of care increases as community health centres generally care only for pregnant women with no risk factors. In higher levels of care the patient profile is drastically different because of referral of high-risk pregnancies, and is consequently associated with expected

complications for mother and fetus, whether antenatally, during labour or thereafter.

What is of interest however is that close to 40% of fresh stillborn babies weighing ≥ 1000 g were alive on admission in District Hospitals and Provincial Tertiary Hospitals. This would indicate that there was opportunity for intervention, possibly indicating a delay in treatment. On the other hand, the greater proportion of fresh stillbirths that arrive dead on admission perhaps points to either not recognising the problem or a lack of transport.¹⁰

2.3 Risk factors

2.3.1 All stillbirths

Several risk factors have been identified for stillbirths, and these differ between high-income and low- and middle-income countries. The most prevalent risk factors across all borders are low socio-economic status (including poor maternal nutrition), advanced maternal age, maternal parity (first birth and high parity)¹¹ congenitally acquired infections and hypertensive diseases, specifically pre-eclampsia and eclampsia.^{8,12}

In high-income countries the emphasis is more on pre-existing maternal diseases such as diabetes mellitus, systemic lupus erythematosus, thrombophilias and renal disease.⁸ A large proportion of stillbirths in these countries is associated with modifiable risk factors such as obesity,¹³ which is currently a growing global epidemic. Another risk factor is advanced maternal age, and overall 7-11% of

stillborn babies (or 4200 babies a year) are born to mothers aged ≥ 35 in high-income countries.¹⁴ The reason for this might be that women in high-income countries tend to delay child bearing for the reason of pursuing a career earlier on in life. Smoking in pregnancy is also more common in these high-income countries, and it is viewed as an important independent risk factor.¹¹ The majority of these risk factors could therefore be reduced with prevention strategies,¹⁵ and if successful, could have far reaching effects on improving the health and wellbeing of pregnant women in these countries. However, reducing these modifiable risk factors will be challenging, as even in the general population they are not easily dealt with.

In low- and middle-income countries antenatal risk factors include lack of adequate antenatal care, prior stillbirths, anaemia, hypertensive disease – especially poor management of preeclampsia / eclampsia, and febrile illness (malaria).^{7,8}

2.3.2 Fresh stillbirths

A large proportion of fetal deaths in low- and middle-income countries occur in the intrapartum period, usually resulting in fresh stillbirths.⁴ Risk factors are prelabour and/or prolonged rupture of membranes, prolonged labour, oxytocin augmentation of labour, malpresentation and lack of a skilled attendant at delivery.⁷

2.3.3 Fresh stillbirths $\geq$ 2500 g

Fresh stillbirths are rare and even more so in the weight category of $\geq$ 2500 g, with risk factors similar to fresh stillbirths in general.

2.4 Causes

Causes of all stillbirths may be complex and multifactorial. It is often not possible to determine a single cause due to several conditions occurring simultaneously.

2.4.1 Fresh stillbirths

Fetal emergencies such as shoulder dystocia, birth trauma, cord prolapse and uterine rupture are catastrophic events which lead to intrapartum-related birth asphyxia¹⁶ and often clearly directs the cause of the stillbirth.¹⁷ Placental abruption remains a common cause,¹⁸ with placenta/placental bed disease (pre-eclampsia and eclampsia)¹⁰ being significant contributors to abruptio and stillbirth. Even with all these causes identified, a certain number still remain unexplained.¹⁹

2.4.2 Fresh stillbirths $\geq$ 2500g

Even though fresh stillbirths in this birth weight category should be rare, the majority (35.2%) of fresh stillbirths in South Africa are occurring in this birth weight category, with the leading primary obstetric causes of death being intrapartum asphyxia and birth trauma.¹⁰

2.5 Influence of Human Immunodeficiency Virus (HIV)

The possibility of the growing HIV burden could be an associated factor and should not be overlooked. The national HIV prevalence estimate in South Africa amongst antenatal women in 2010 was 30.2%. This has remained stable with no statistical significant increase from 29.4% in 2009. When looking at the Gauteng province specifically, the provincial HIV prevalence amongst antenatal women was 30.4% in 2010 with overall prevalence stabilizing around 30.0% in the past 3 years.²⁰

Although most studies show no relationship between maternal HIV infection and stillbirths,²¹ some studies have shown that women who were HIV positive were significantly more likely to have a stillbirth, with HIV positive pregnant women being almost four times more likely to have a stillbirth than those who are HIV negative.²² CD4 counts were also shown to be inversely related to stillbirths.²³ In a study done locally in southwest Tshwane,²⁴ it was shown that perinatal deaths were occurring significantly more in HIV positive pregnant women compared to HIV negative women, with a thirty percent increased risk due to spontaneous preterm birth, infection and intrapartum asphyxia. The preterm births could be explained by the probably greater prevalence of chorioamnionitis in HIV infected women.²⁴

This poses the question whether HIV is a direct cause or only an associated factor. HIV generally causes little or no placental or fetal organ damage in utero and it is probably unlikely that HIV is directly the cause.²⁵ It is more likely that the stillbirth risk is due to overall poor maternal health status²⁶ and complications of

severe systemic illnesses like pneumonia, tuberculosis and meningitis, but the complex interplay of these factors needs to be further investigated.

2.6 Avoidable factors for stillbirth

Stillbirths are potentially avoidable, with the possibility of a different outcome if the problem was timely detected in an alive and viable baby. This might be achieved with the removal of the baby from this environment before resulting in stillbirth.

Aside from risk factors there are also patient-associated avoidable factors, administrative factors and health care provider associated factors which all play a role.

2.6.1 Probable avoidable factors related to all fresh stillbirths

Patient-associated avoidable factors:

The most common patient-associated avoidable factors in all fresh stillbirths remain delay in seeking medical attention during labour, not initiating antenatal care, booking late in pregnancy and inappropriate response to poor fetal movements (Table 1).¹⁰ Pregnant women may not be giving health care providers the opportunity to timely detect fetal compromise or distress before or during labour.

Table 1: Patient associated probable avoidable factors related to fresh stillbirths (n=1889) (from Saving Babies 2008-2009)¹⁰

Delay in seeking medical attention during labour	504	(26.7%)
Never initiated antenatal care	440	(23.3%)
Booked late in pregnancy	271	(14.3%)
Inappropriate response to poor fetal movements	203	(10.7%)
Infrequent visits to antenatal clinic	109	(5.8%)
Inappropriate response to antepartum haemorrhage	67	(3.5%)
Failed to return on prescribed date	52	(2.8%)
Inappropriate response to rupture of membranes	41	(2.2%)
Declines admission/treatment for personal/social reasons	34	(1.8%)
Attempted termination of pregnancy	17	(0.9%)

Administrative factors

With a growing population and associated economic burden, administrative factors are unacceptable but frequently unavoidable in South Africa, making the task of providing quality standard care immensely difficult. The most common of these administrative factors are a lack of transport, inadequate theatre facilities and anaesthetic delay (Table 2). The low availability of caesarean section is still common in many health care facilities in low-income countries.⁸

Table 2: Administrative factors related to fresh stillbirths (n=578) (from Saving Babies 2008-2009)¹⁰

Lack of transport – Home to institution	93	(16.1%)
Inadequate theatre facilities	80	(13.8%)
Anaesthetic delay	65	(11.2%)
Lack of transport – Institution to institution	64	(11.1%)
Personnel not sufficiently trained to manage the patient	47	(8.1%)
Insufficient doctors available to manage the patient	45	(7.8%)
Insufficient nurses on duty to manage the patient adequately	36	(6.2%)
Inadequate facilities/equipment in neonatal unit/nursery	26	(4.5%)
No accessible neonatal bed with ventilator	24	(4.2%)
Personnel too junior to manage the patient	16	(2.8%)

An adequate ratio of midwives to births impacts on both the safety and quality of maternity services. The number of midwives required to provide care in the clinical area is dependent on workload activity. Birthrate Plus® (BR+) is an evidence-based workforce planning tool used throughout the United Kingdom to calculate required midwifery staffing levels in a specific care setting. The Royal College of Obstetricians and Gynaecologists (RCOG) and the Royal College of Midwives (RCM) recommend a midwife-to-woman ratio of 1:28 for a safe level of service to ensure the capacity to achieve one-to-one care in labour (1.0-1.4 whole time equivalent midwives to woman, in labour).²⁷ The ratios recommended by the RCOG and RCM are not applicable to South Africa. In South Africa, clear standards are not available to judge adequate staffing ratios. Chronic understaffing is often being accepted as the norm thereby influencing the quality of care given especially in labour.

Health care provider associated factors

Health care provider associated factors related to fresh stillbirths are delay in referring patient for secondary/tertiary treatment, inadequate fetal monitoring, incorrect interpretation of fetal distress and no response to poor progress in labour (Table 3).^{10,16,28} The partogram is a simple and affordable tool to monitor the progress of labour,²⁹ yet it is often not used, used incorrectly or interpreted incorrectly. Poor progress in labour is therefore diagnosed late or not at all and the appropriate actions are delayed.

Table 3: Health care provider associated factors related to fresh stillbirths (n=1692) (from Saving Babies 2008-2009)¹⁰

Fetal distress not detected intrapartum; fetus monitored	236	(13.9%)
Delay in referring patient for secondary/tertiary treatment	144	(8.5%)
Fetal distress not detected intrapartum; fetus not monitored	135	(8.0%)
No response to maternal hypertension	109	(6.4%)
Medical personnel underestimate fetal size	86	(5.1%)
Management of 2 nd stage: prolonged with no intervention	84	(5.0%)
Delay in medical personnel calling for expert assistance	75	(4.4%)
Delay in doctor responding to call	58	(3.4%)
Inadequate / No advice given to mother	56	(3.3%)
Breech presentation not diagnosed until late in labour	45	(2.7%)
Poor progress in labour – partogram interpreted incorrectly	45	(2.7%)
Fetal distress not detected antenatally; fetus monitored	43	(2.5%)
Poor progress in labour, but partogram not used correctly	43	(2.5%)
Fetal distress not detected antepartum; fetus not monitored	39	(2.3%)
Poor progress in labour, but partogram not used	35	(2.1%)

2.6.2 Probable avoidable factors related to fresh stillbirths ≥ 2500 g

In South Africa the greatest number of fresh stillbirths is in the birth weight category ≥ 2500 g (35.2%). The only other category close to that is < 1000 g (25%), for which a high level of care cannot always be offered in all institutions.

The probable avoidable factors (patient associated, health care provider associated, administrative problems) related to fresh stillbirths ≥ 2500 g are similar to fresh stillbirths in general. What is important however is that the primary obstetric causes of death for fresh stillbirths ≥ 2500 g are intrapartum asphyxia and birth trauma, with 76.2% of all intrapartum asphyxia and 66.8% of all birth trauma happening in this birth weight category.¹⁰ These are therefore very important causes of fresh stillbirths ≥ 2500 g and these deaths directly relate to the quality of intrapartum care – and consequently to avoidable fetal deaths.

2.7 Fetal surveillance

Fetal surveillance during labour differs between low-risk pregnancies and high-risk pregnancies. According to the National Institute for Health and Clinical Excellence (NICE) guidelines, intermittent auscultation of the fetal heart rate is recommended for low-risk women in established labour in any birth setting.³⁰

Low-risk refers to women who enter labour at term with no medical or obstetric conditions that are associated with uteroplacental dysfunction and/or conditions that are associated with an increased risk for fetal acidemia.³¹ The American College of Obstetricians and Gynecologists (ACOG) guidelines similarly recommend that intermittent auscultation is acceptable in low-risk women and that the labour of women with high risk conditions (eg. suspected fetal growth restriction, pre-eclampsia, type 1 diabetes) should be monitored with continuous fetal monitoring.^{32,33}

Changing from intermittent auscultation to continuous cardiotocograph monitoring is advised in situations where an abnormality in fetal heart rate is detected in intermittent auscultation, the presence of meconium stained liquor, augmentation of labour, maternal pyrexia, fresh bleeding etc.³⁰ Ideally, interpretation of continuous CTG tracings should be done by an adequately trained birth attendant. CTG tracings with suspected fetal distress are associated with abnormal fetal acid-base status at the time of observation and require prompt evaluation of possible causes.³² If the abnormal fetal heart rate pattern does not resolve with appropriate corrective measures (intrauterine resuscitation), delivery should be expedited.

2.8 Influence of availability of caesarean section

A study in Dublin, Ireland by Colin *et al.* analysed trends in intrapartum fetal death over a 25 year period.¹⁹ A significant fall in rates of intrapartum fetal death was found. The reason for this was not clear but was proposed to be due to better intrapartum fetal heart rate monitoring, an increase in the number of caesarean deliveries and more stringent criteria for high-risk patients who are allowed to labour.

A clear inverse relationship between the rate of caesarean deliveries and the rate of intrapartum stillbirths has also been demonstrated in an ecologic study of stillbirth rates comparing developing and developed countries.³⁴ This showed that for every 1% increase in the rate of caesarean section deliveries from 0 to 8%, the rate of intrapartum stillbirths decreased by 1.6 per 1000 births. The trend to reduced stillbirths with increasing caesarean section rate is not sustained above 8%.^{34,35} In developing countries specifically, the intrapartum stillbirth rate correlates strongly with the percentage of births by caesarean section. The intrapartum stillbirth rate is more closely related to various measures of obstetric care and a good reflection of the quality thereof in a country. Increases in caesarean section rates up to 8% are therefore associated with significant improvements in intrapartum stillbirth rates.³⁴

3. Problem statement

In South Africa labour related complications are one of the top primary obstetric causes of perinatal deaths.³⁶ The problem seems to be mainly the failure to detect evidence of fetal distress.²⁸ Even though we have the resources needed for adequate intrapartum fetal heart rate monitoring such as cardiotocography, our unborn babies are not benefitting from their use.

The solution to the problem seems to be early identification of hypoxia during labour and appropriately expediting delivery, usually but not exclusively by Caesarean section.³⁷ Therefore, the most sensitive test of any health system is providing effective care at the time of birth and having the ability to respond quickly to intrapartum emergencies.³⁸

The incidence of fresh stillbirths weighing 2500 g or more seems to be unacceptably high even in our secondary and tertiary institutions. The babies in this birth weight category should hypothetically have the best chance of surviving especially in these facilities, but it seems to be a case of “too little too late”.

The question is whether sub-standard care is provided during labour even in facilities with skilled staff and proper equipment. This could then possibly result in intrapartum deaths occurring in what was initially thought to have been an uncomplicated labour of a normal birth weight baby. The shortfalls in intrapartum fetal surveillance with appropriate fetal monitoring not being done, or being incorrectly interpreted, need to be determined.

4. Objectives

At Chris Hani Baragwanath Academic Hospital, Charlotte Maxeke Johannesburg Academic Hospital, and Rahima Moosa Mother and Child Hospital:

To determine the prevalence of fresh stillbirths weighing 2500 g or more

To identify the direct cause, along with associated risk factors for each of these stillbirths

To identify avoidable factors relating to poor or substandard intrapartum care with specific emphasis on intrapartum fetal heart rate monitoring

5. Subjects and methods

5.1 Setting

This study was conducted at three obstetric units in Johannesburg, Gauteng. The first and largest was the Chris Hani Baragwanath Academic Hospital (CHBAH) which is situated to the south west of Johannesburg, on the southern border of Soweto. It services 2 million people and it provides half of all the hospital services in Southern Gauteng. It is a referral centre for midwife-run antenatal services in the surrounding areas of Soweto, Orange Farm and Lenasia and receives referrals from seven midwife obstetric units (MOUs) as well as South Rand Hospital. The second was the Charlotte Maxeke Johannesburg Academic Hospital (CMJAH) which is centrally located in the metropolis in Parktown. It is a tertiary/quaternary hospital and receives referrals from one MOU as well as Edenvale Hospital. The third hospital was the Rahima Moosa Mother and Child Hospital (RMMCH) situated in a previously predominantly coloured area in Coronationville, which receives referrals from one MOU. All three hospitals also take referrals from

hospitals outside Johannesburg Health District and from outside Gauteng Province. The users of each of these hospitals have differing demographic profiles by virtue of environmental and socio-economic differences.

5.2 Study design

This was a prospective, cross sectional, descriptive study.

5.3 Study population

Fresh stillbirths weighing 2500 g or more that were delivered either vaginally or by caesarean section constituted the study population. The study definition was a birth charted as a fresh stillbirth in the labour ward register and confirmed as such in the maternity case file.

5.3.1 Inclusion criteria

All singleton fresh stillborn babies weighing 2500 g or more were included irrespective of maternal illness, presentation at birth, physical trauma, gestational age or growth restriction. Stillbirths to women aged less than 18 years were included.

5.3.2 Exclusion criteria

Fresh stillbirths were excluded if: there were severe congenital abnormalities likely to have contributed to the fetal death; there was doubt in the clinical documents whether the baby was a fresh or macerated;

fetocides; delivery was at home, in a vehicle, or at an MOU or other hospital.

5.4 Sampling and sample size

All cases that were identified as eligible were investigated for six months at each of the three hospitals. The researcher was based at each hospital for six months in her registrar rotation, and collected data at each hospital in turn. This amounted to an 18 month data collection period from May 2011 until October 2012. Fresh stillbirths at CHBAH were investigated from May 2011 until October 2011; those at CMJAH were investigated from November 2011 until April 2012; and those at RMMCH were investigated from May 2012 until October 2012. The researcher based her decision for this collection period on statistics of fresh stillbirths ≥ 2500 g born at these three hospitals. She estimated that in this 18 month period she would expect to find 40-50 cases, which would be an adequate number for the purpose of the study.

5.5 Data collection

Every morning the birth registers were inspected for deliveries in the hospital in all the areas where deliveries could take place (admissions area, labour ward, obstetric theatre etc). Records of fresh stillbirths and unspecified stillbirths weighing ≥ 2500 g were noted from the registers and then further investigated by finding the mothers and the clinical details of the stillborn babies in the postnatal wards. If the stillbirths were found to be eligible for inclusion, based on the study population criteria given above, their mothers were approached to participate in

the research. Once the women agreed, by signed informed consent, to participate in the study, the researcher recorded the relevant information on a data sheet. The information recorded was found in the antenatal card and the maternity case file wherein all clinical notes are documented by nursing staff and doctors. Any uncertainty about documented information was clarified by speaking to the stillborn baby's mother, the nursing staff, the midwives, or the doctors involved in the management of the particular case.

The study data sheet is attached as Appendix A. Demographic and obstetric information consisted of the mother of the stillborn's age, gravidity, parity, booking status, booking bloods (blood group, serology for diagnosis of syphilis using rapid plasma reagin test, HIV status including CD4 count and antiretrovirals used), haemoglobin and if she had undergone any previous caesarean sections. Maternal illnesses (hypertension, diabetes mellitus, thyroid disease, pneumonia, anaemia, cardiac disease etc.) were also documented if present and specifically whether diagnosed before or during pregnancy. Gestational age was based on a best estimate using an early ultrasound scan (≤ 24 weeks) as correct if available. If there was no early ultrasound available then either the last normal menstruation period (LNMP), a late ultrasound scan (> 24 weeks), or palpation/SFH measurement at antenatal clinic was used, whichever was thought to be most accurate and correlated best with clinical examination at the time of delivery. A proven history of intrauterine growth restriction (IUGR) was documented if diagnosed by using serial ultrasonography.

Intrapartum information consisted of the symphysis-fundal height measurement of the mother, the birth weight of the baby and whether the mother had undergone induction or augmentation of labour. Prolonged labour was defined as: 1) poor progress in *the latent phase* (cervix dilated 3cm or less, not fully effaced): prolonged when it exceeded 8 hours; 2) Poor progress in the *active phase* (cervix 3 cm dilated or more, fully effaced): prolonged if the cervix dilated at a rate of less than 1 cm per hour; 3) Poor progress in the *second stage* (cervix fully dilated): no bearing down after 1 hour of full dilation, or delivery had not occurred after 45 minutes of expulsive effort in a nullipara or 30 minutes of bearing down in a multipara.³⁹ With regards to the delivery it was documented whether it was a normal vaginal delivery, an assisted vaginal delivery (forceps or vacuum) or a caesarean section, as well as the presence or absence of meconium staining of the liquor.

The researcher documented whether the baby was an intrauterine fetal death (IUFD) on arrival to the hospital, which was diagnosed by the absence of detection of a fetal heart on auscultation and confirmed by an ultrasound scan. If the baby was alive on arrival to the hospital, the time taken from recognition of emergency to delivery was calculated in minutes.

The fetus was classified as being “monitored” if there were CTG tracings (intermittent or continuous) present in the file, or documentation of the interpretation of such tracings. Fetal monitoring would also include intermittent fetal auscultation if done and subsequent findings thereof documented. The fetus

would be classified as “not monitored” if there was no documentation of any CTG tracings or fetal auscultation or interpretation of either in the file. Fetal distress was classified according to the three-tiered fetal heart rate interpretation system with the baseline rate, baseline variability, accelerations and decelerations described. Based on the contribution of all the features the whole CTG tracing is classified as category I, II or III with category III indicating fetal distress.^{32,33} The researcher looked at all the CTG tracings present in the files. If found that the tracings on which decisions were made were not classified in the correct category according to this system, these were then labelled as being “incorrectly interpreted”. Intrauterine resuscitation was defined as the implementation of one or more of the following: left lateral positioning of the mother, correcting of maternal hypotension, maternal oxygen administration, discontinuation of uterine stimulation (stopping oxytocin administration) and suppression of uterine contractions (by administering salbutamol or nifedipine).²⁹

Catastrophic events directly relating to the fresh stillbirth were documented, and included abruptio placentae, cord prolapse, uterine rupture, and birth trauma (entrapment of aftercoming head of breech, shoulder dystocia, failed instrumental delivery).

To determine the incidence of fresh stillbirths at each of the three hospitals, total numbers of births at the three hospitals during the 6-month time periods (denominator data) were obtained from the district health information system data

at the Johannesburg Health District offices in Hillbrow, Johannesburg. Data was obtained for all births, as well as the subsets of births ≥ 2500 g.

5.6 Data analysis

Data from all patients was recorded and transferred onto a data capture sheet using Microsoft Excel. The statistical programme STATA was used to analyse the data. Descriptive statistics include statements of frequencies with percentages and confidence intervals, medians with ranges, and means $\pm$ standard deviations. When differences in frequencies between groups were compared, Fisher's exact test was used, with $P < 0.05$ taken as indicating statistical significance.

5.7 Ethics

Patient confidentiality was maintained throughout. No personal details were recorded in the data sheet and each patient was allocated a study number.

Informed consent was signed by each patient with an opt-out option. (Appendix B)

Permission to perform the study was granted by authorities of all three hospitals.

Ethical clearance was obtained from the Human Research Ethics Committee

(Medical) for the University of the Witwatersrand. (Appendix C)

6. Results

During the collection period of 18 months, a total of 52 eligible fresh stillbirths for inclusion were identified. Twenty-five cases were identified at CHBAH, 14 cases at CMJAH and 13 at RMMCH (Table 4).

Table 4: Number of births and fresh stillbirths at each hospital, showing overall and weight-specific rates

	CHBAH	CMJAH	RMMCH
Total births	11952	4692	5974
Total births ≥ 2500 g	9781	3720	5050
Fresh stillbirths ≥ 2500 g	25	14	13
Fresh stillbirth ≥ 2500 g rate (FSB ≥ 2500 g / total births) (95% confidence interval)	2.09/1000 (1.35-3.09)	2.98/1000 (1.63-5.00)	2.18/1000 (1.16-3.72)
Fresh stillbirth ≥ 2500 g rate (FSB ≥ 2500 g / births ≥ 2500 g) (95% confidence interval)	2.56/1000 (1.65-3.77)	3.76/1000 (2.06-6.31)	2.57/1000 (1.37-4.40)

CHBAH = Chris Hani Baragwanath Academic Hospital, CMJAH = Charlotte Maxeke Johannesburg Academic Hospital, RMMCH = Rahima Moosa Mother and Child Hospital

The mean age of the mothers was 25.6 ± 5.5 years. The majority of patients had booked for antenatal care. Twenty three were nulliparous and 12 women had a previous caesarean section. Sixteen women were HIV infected, with 6 of them on combination antiretroviral therapy (ART) (Table 5). There were 10 women with hypertension: 9 were diagnosed in pregnancy and 1 patient was a chronic hypertensive diagnosed before pregnancy. No cases were complicated by eclampsia. There were no women with diabetes mellitus, thyroid disease, epilepsy, cardiac disease, thromboembolic disease or connective tissue disorders. There

was 1 woman who was a known asthmatic controlled on treatment. None of the women were acutely ill. The number of patients who were anaemic was 20 (38.5%).

Table 5: Antenatal maternal characteristics (n=52)

Factor	n (%)
Hospitals	
Chris Hani Baragwanath Academic	25 (48.1%)
Charlotte Maxeke Johannesburg Academic	14 (26.9%)
Rahima Moosa Mother and Child	13 (25.0%)
Age in years (mean $\pm$ SD)	25.6 $\pm$ 5.5
Parity:	
0	23 (44.2%)
1	14 (26.9%)
2	10 (19.2%)
3	2 (3.9%)
4	3 (5.8%)
Previous caesarean section	12 (23.1%)
Booked	42 (80.8%)
Unbooked	10 (19.2%)
HIV seronegative	35 (68.6%)
HIV seropositive	16 (31.4%)
On ART (Three drugs)	6 (37.5%)
On PMTCT (On zidovudine only)	10 (62.5%)
CD4 count (mean $\pm$ SD) (n=16)	482.1 $\pm$ 187.8
Haemoglobin in g/dL (mean $\pm$ SD)	11.4 $\pm$ 2
Anaemia (Haemoglobin <11.0g/dL)	20 (38.2%)
Hypertension	10 (19.2%)

The mean gestational age for all women by best estimate was 38.3 $\pm$ 2.3 weeks.

Seven women had a best estimate gestational age $\geq$ 41 weeks. The mean

symphysis-fundal height was measured to be 36.9 ± 2.8 cm, and the mean birth weight was 3038 ± 411.1 g. None of the babies weighed more than 4000 g. There were no cases of proven history of intrauterine growth restriction (IUGR). One woman presented with prolonged rupture of membranes. Four women had labour induced with oral misoprostol. The indications for induction were postdates pregnancy in two of the women, and pregnancy-induced hypertension in the other two. No women underwent augmentation of labour (Table 6).

Table 6: Intrapartum details of study participants

Gestational age in weeks by best estimate median with range mean $\pm$ SD	39 (32 – 42) 38.4 $\pm$ 2.3
Gestational age in weeks by best estimate:	<37 37-38 39-40 41 ≥ 42 8 (15.4%) 17 (32.7%) 20 (38.5%) 5 (9.6%) 2 (3.8%)
Symphysis-fundal-height median with range mean $\pm$ SD	37 (30 – 44) 36.9 $\pm$ 2.8
Birth weight in g (mean $\pm$ SD): -birth weight 2500-3499 g -birth weight 3500-3999 g -birth weight ≥ 4000 g	3038.2 $\pm$ 411.1 40 (76.9%) 12 (23.1%) 0
Intrauterine growth restriction (IUGR)	0 (0.0%)
Prolonged rupture of membranes	1 (1.9%)
Induction of labour	4 (7.7%)
Augmentation of labour	0 (0.0%)

There were 24 normal vaginal deliveries and 24 deliveries by caesarean section. There were 4 assisted vaginal deliveries, which consisted of 3 vacuum deliveries and one forceps delivery. There were 3 cases which were booked for an elective caesarean section but complicated before the booked date: 1) patient with two previous caesarean sections who was not in labour and had an abruptio placentae with an IUFD on arrival; 2) patient with two previous caesarean sections who was not in labour and presented with an IUFD on arrival; and 3) patient with one previous caesarean section who went into labour and had uterine rupture. There was one case of placenta praevia presenting with an IUFD on arrival to hospital. Apart from the first two elective cases mentioned, all other cases were confirmed to be in labour.

No women had prolonged labour in the latent phase of labour, while three women had prolonged active phase of the first stage and three had prolonged second stage of labour. Meconium staining of the liquor (MSL) was found in 23 (44.2%) women, with the majority of them having MSL of a thick consistency (82.6%) (Table 7).

Table 7: Details regarding progress of labour and delivery

Prolonged labour	6	(11.5%)
Prolonged latent phase of labour	0	(0.0%)
Prolonged active phase of first stage	3	(5.8%)
Prolonged second stage	3	(5.8%)
Meconium stained liquor	23	(44.2%)
Thin	4	(17.4%)
Thick	19	(82.6%)
Mode of delivery		
Normal vaginal delivery	24	(46.2%)
Caesarean section	24	(46.2%)
Assisted delivery	4	(7.7%)
Vacuum	3	(5.8%)
Forceps	1	(1.9%)

Fetal surveillance with cardiotocograph monitoring was done in 22 cases (42.3%). Fifteen cases (28.8%) were not monitored at all and the same number of patients presented with an intra-uterine fetal death (IUFD) that was diagnosed on arrival. Of the 22 cases that were monitored, fetal distress was diagnosed in 20 of these cases. There were 2 cases in which it was noted that there was no fetal distress and in the remaining 15 cases it is not known whether there fetal distress was present or not because there was no monitoring of these cases. Of the 25 cases in which the emergency was recognised, the mean time taken from recognition of emergency to delivery was 107.8 ± 92.3 minutes. The shortest time taken was 13 minutes and the longest time taken was 360 minutes (Table 8).

Table 8: Intrapartum fetal monitoring and interpretation, and recognition-to-delivery time interval (n=52)

Monitoring	
Monitored	22 (42.3%)
Not monitored	15 (28.8%)
IUFD on arrival	15 (28.8%)
Fetal distress	
Yes	20 (38.5%)
No	2 (1%)
Unknown because not monitored	15 (28.8%)
IUFD on arrival	15 (28.8%)
Incorrectly interpreted tracings	5 (9.6%)
Intrauterine resuscitation	5 (9.6%)
Emergency recognised	25 (48.1%)
Emergency not recognised	12 (23.1%)
IUFD on arrival	15 (28.8%)
Minutes taken from recognition of emergency to delivery	
median with range (n=25)	182 (13 – 360)
mean±SD	107.8±92.3

Intrapartum catastrophic events, providing a direct cause for the stillbirth, were recorded in 30 cases. Twenty-two cases had no direct cause identified. Of these 22 cases, 5 had presented as intra-uterine fetal deaths on arrival at hospital. The remaining 17 had a fetal heart beat present on arrival. The most frequent catastrophic event was placental abruption (n=16) (Table 9). Of the 16 cases confirmed to have abruptio placentae, 5 of the mothers were confirmed to be hypertensive.

Table 9: Causes directly related to the fresh stillbirth

Identifiable causes	
Abruptio placentae	16 (30.8%)
Uterine rupture	4 (11.5%)
Cord prolapse	7 (13.5%)
Entrapment of aftercoming head of breech	<u>3 (5.8%)</u>
	<u>30 (57.7%)</u>
No direct cause identified	22 (42.3%)
IUFD on arrival	5 (22.7%)
Fetal heart present on arrival	17 (77.3%)

The intrapartum fetal monitoring of the cases identified with intrapartum catastrophic events directly related to the fresh stillbirth are shown in Table 10. There was an equal distribution of cases who were monitored, not monitored and those presenting with an IUFD on arrival to hospital. Half of the cases of abruptio placentae presented with an IUFD on arrival to hospital.

Table 10: Intrapartum fetal monitoring of patients with intrapartum catastrophic events directly related to the fresh stillbirth (n=30)

Total intrapartum catastrophic events (n=30)	
Monitored	10 (33.3%)
Not monitored	10 (33.3%)
IUFD on arrival	10 (33.3%)
Abruptio placentae (n=16)	
Monitored	5 (16.7%)
Not monitored	3 (10.0%)
IUFD on arrival	8 (26.7%)
Uterine rupture (n=4)	
Monitored	2 (6.7%)
Not monitored	2 (6.7%)
IUFD on arrival	0 (0.0%)
Cord prolapse (n=7)	
Monitored	1 (3.3%)
Not monitored	4 (13.3%)
IUFD on arrival	2 (6.7%)
Entrapment of aftercoming head of breech (n=3)	
Monitored	2 (6.7%)
Not monitored	1 (3.3%)
IUFD on arrival	0 (0.0%)

When all identifiable causes directly related to the fresh stillbirths are excluded and reanalysed (n=22), the results are shown in Table 11. It is presumed that the babies in this group all died because of labour asphyxia. All of these cases were confirmed to be in labour.

This group contains the majority of the unbooked women – 7 out of a total of 10 women from the original 52 (P=0.08). Most of the HIV positive women are also in this group (9 out of the original 16 seropositive women) (P=0.36). Neither of these

differences was statistically significant, nor were there any statistically significant differences with respect to other risk factors.

More than half of these 22 women gave birth with thick meconium stained liquor. There were 12 women (54.6%) who were monitored of which all of them had a suspicion of fetal distress. There were 4 cases where women had at least one incorrectly interpreted tracing intrapartum, where the fetal distress was only detected at a later stage.

In 11 (50%) of the 22 cases, the emergency was recognised and the time taken from recognition of emergency to delivery was 131 ± 114 minutes. There were five patients who presented with an intra-uterine fetal death on arrival.

Table 11: Summary of fresh stillbirths not associated with catastrophic events (abruptio placentae, entrapment of aftercoming head of breech, uterine rupture, cord prolapse) (n=22)

Patient characteristics: Age in years (mean $\pm$ SD) Previous caesarean section Booked Unbooked HIV seronegative HIV seropositive On ART (Three drugs) On PMTCT (On zidovudine only) CD4 count (mean $\pm$ SD) Gestational age in weeks by best estimate Symphysis-fundal-height Birth weight in g (mean $\pm$ SD):	24.5 $\pm$ 5.2 2 (9%) 15 (68.2%) 7 (31.8%) 11 (55%) 9 (45%) 3 6 559.1 $\pm$ 149.9 38.5 $\pm$ 2.4 36.4 $\pm$ 8.3 3052 $\pm$ 459.9
Prolonged labour Prolonged latent phase of labour Prolonged active phase of labour Prolonged first stage of active phase Prolonged second stage of active phase Meconium stained liquor Thin Thick	4 (18.2%) 0 (0.0%) 4 (18.2%) 2 (9.1%) 2 (9.1%) 13 (59.1%) 1 (7.7%) 12 (92.3%)
Mode of delivery Normal vaginal delivery Caesarean section Assisted delivery Vacuum	11 (50%) 9 (40.9%) 2 (0.1%)
Monitoring Monitored Not monitored IUFD on arrival Fetal distress Yes No Unknown because not monitored IUFD on arrival Incorrectly interpreted tracings	12 (54.6%) 5 (22.7%) 5 (22.7%) 12 (54.6%) 0 (0.0%) 5 (22.7%) 5 (22.7%) 4 (18.2%)
Emergency recognised Emergency not recognised IUFD on arrival Minutes taken from recognition of emergency to delivery (mean $\pm$ SD)(n=11)	11 (50%) 6 (27.3%) 5 (22.7%) 131 $\pm$ 114

When excluding the 5 women with intra-uterine fetal death on arrival to hospital, the remaining 17 had an analysis similar to Table 7 with no significant difference in the patient profile, risk factors or cause identified.

7. Discussion

7.1 Incidence

Fresh stillbirths ≥ 2500 g are still common events occurring in our institutions. The fresh stillbirth ≥ 2500 g rate at each of the three hospitals is in keeping with the rates of 2.39/1000 found in Gauteng, and 2.89/1000 found nationally.³⁶ However, when considering that these are three academic institutions with available resources, the expectation was that their rates should have been better.

7.2 Antenatal care

The patient associated avoidable factor of not initiating antenatal care is not a dominant factor in this study with the majority of patients (80.8%) being booked patients. Nulliparity is a known risk factor for stillbirths, and in this study it was found that the majority of patients (44.2%) were nulliparous. The 31.4% of patients who were HIV seropositive is in keeping with the national and Gauteng HIV prevalence estimate. Anaemia was shown to be prevalent (38.2%) and it raises the question whether anaemia is not optimally managed antenatally with supplements and nutritional advice.

7.3 Intrapartum care

The observed gestational age range (32-42 weeks), with eight women having gestational ages estimated to be less than 37 weeks, suggests an inaccurate estimate of gestational age in some cases. Babies weighing more than 2500 g usually indicate a term or near-term pregnancy.⁴⁰ Patients with prolonged rupture of membranes, induction of labour and prolonged labour, did not constitute a large number of the patients. What was surprising was that none of the patients were augmented during labour, which was not expected.

Fetal emergencies, which clearly cause the stillbirth, are a reality with abruptio placentae being the largest group. This emphasises the role that placental or placental bed diseases play in perinatal deaths. This finding is similar to a study done in Limpopo by Ntuli et al. in which it was found that maternal hypertensive disease and abruptio placentae were important contributors to fresh stillbirths.⁴¹ Patients with a previous caesarean section should be viewed as high risk patients and managed as such. Uterine rupture in 4 of the 12 patients who had a previous caesarean section in this study, shows that the risks involved in attempting a vaginal delivery after caesarean section are not to be underestimated. Cord prolapse was a common and often unavoidable intrapartum complication, and along with entrapment of the aftercoming head of a breech, these are situations where it is difficult to change the outcome even in the hands of experienced birth attendants.

7.4 Monitoring

Thirty seven (71.2%) out of the total number of 52 cases had a fetal heart beat present on arrival to hospital. Even when excluding the 30 cases with catastrophic intrapartum events directly relating to the stillbirth, 17 (77.3%) of the remaining 22 cases presented with a fetal heart beat on arrival at hospital. This is an unacceptable high percentage of babies that were alive on admission and subsequently died before delivery, indicating a clear opportunity for intervention. It seems that probable avoidable administrative and health care provider related factors played the biggest role here.

The most serious problem seems to lie in the monitoring of patients in this study, along with consequent reactions to it. Buchmann et al. had similar findings in an enquiry into babies who died from labour-related intrapartum hypoxia in public hospitals in South Africa.²⁸ The fact that 15 patients (28.8%) were not monitored in facilities with adequate intrapartum fetal heart rate monitoring available, is not acceptable. Possible reasons for this might be that intermittent auscultation was not done due to shortages of staff, or continuous cardiotocograph tracings were not done due to shortages of equipment. There is also the possibility that the cardiotocograph tracings might have been done, but were subsequently lost from the files. This emphasizes the need for documentation of the actual interpretation of the tracing in the file itself.

The emergency was not recognised in 12 (32.4%) of the patients presenting with live babies on admission even with skilled birth attendants available, and even in

the 25 cases where the emergency was recognised, the time taken from decision to delivery was too long. The Royal College of Obstetricians and Gynaecologists (RCOG) recommend a decision to delivery interval of 30 minutes, with the urgency appropriate to the risk to the baby and the safety of the mother.⁴² In South Africa the recommendation by the National Maternity Guidelines Committee states: “Ensure that caesarean section can be performed within one hour of decision to operate”.⁴³ In this study only 8 of the cases had a decision to delivery interval of between 30 and 60 minutes, and only 4 cases had a decision to delivery interval ≤ 30 min. The reasons for delay in decision to delivery interval are most likely avoidable administrative factors like shortages of immediately available theatres, other emergencies being prioritised and anaesthetic delays. It would appear that from this study, a decision to delivery interval of ≤ 60 minutes is more attainable for these facilities.

8. Limitations

There are a number of limitations to this study. The study population is small and only representative of these three hospitals and not the entire population. There were no post-mortems done to evaluate the actual cause of death, so in a number of these fresh stillbirths the actual cause of death still remains unknown. Although it is presumed that intrapartum asphyxia is the cause of the majority of these deaths, intrapartum fetal blood gas analyses were not done, and the actual metabolic state of the fetus intrapartum was not confirmed. One of the criteria to define an acute intrapartum hypoxic event is evidence of metabolic acidosis in intrapartum fetal, umbilical arterial cord, or very early neonatal blood samples (pH

< 7.00 and base deficit >12 mmol/l).⁴⁴ This analysis cannot be done on the cord blood of a fresh stillbirth as the actual time of death is not known.

One of the biggest limitations in this study is that the evaluation of probable avoidable factors was not specifically looked at. Details regarding pre-hospital management, referral and transport of patients, were not investigated, yet could have contributed to the poor outcomes of these babies. With regard to administrative and health care provider factors, more information is needed to assess the role these factors played in the deaths of these babies. This is especially true when looking at the 15 cases which presented as IUFDs on arrival at hospital. The question is whether there were patient related avoidable factors like delay in seeking medical attention in labour, or administrative factors like the lack of recognition of the problem from referring institutions, or a lack of transport of patients either from home or between institutions.

In all three these health care facilities there are skilled birth attendants available in the form of specialist obstetricians and gynaecologists, registrars, medical officers, midwives and advanced midwives. It was not specifically looked at whether there were shortages of staff at any point in time, or which birth attendant specifically cared for the patient and what level of experience they had. This could have indicated problems in health care provider associated factors.

9. Implications for practice

Do the findings of this study suggest we should change our current protocols?

The current clinical protocol in these three academic hospitals state that every

woman should have at least one cardiotocograph tracing on arrival to the institution. It is therefore not as much a case of developing new protocols but rather implementing the current guidelines. My suggestion would be that clinical protocols regarding fetal monitoring must be available and visible in all labour wards including indications for electronic fetal monitoring and guidelines on detection and management of fetal distress. This should include at least one cardiotocograph tracing on arrival to these institutions along with documentation of the interpretation thereof by a skilled birth attendant (registrar, consultant). Adequate training in the interpretation of cardiotocograph tracings should be offered and frequently revised by all birth attendants. Regular morbidity and mortality meetings should be enforced as a forum where all fresh stillbirths are presented and discussed to identify emerging challenges, modify behaviour and subsequently prevent the recurrence of events leading to the stillbirth. In obstetric care, time is a major factor and the early recognition and timely management of obstetric complications should be the norm.

10. Implications for research

To the best of the researcher's knowledge, this is the first study in South Africa to look specifically at normal birth weight fresh stillbirths. More research needs to be done on fresh stillbirths and the contributing factors leading to the deaths of these normal birth weight babies who hypothetically should have the best chance of survival. This could lead to recommendations for improvement in intrapartum care and subsequently to less babies dying as a result of intrapartum events.

11. Conclusion

Fresh stillbirths ≥ 2500 g are still common and may occur in normal labour, with only 57.7% of the fresh stillbirths in this study having an identifiable catastrophic event leading to the fetal demise. The majority of fresh stillbirths are presenting alive on arrival at hospital, indicating an opportunity for intervention and prevention of these deaths. There appears to be a failure to detect or respond to evidence of fetal distress even in facilities with skilled staff and proper equipment.

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APPENDIX A: DATA SHEET

Appendix A: Data Sheet				
Study number _____		Hospital Code	☐	CHBH (1)
			☐	CMJAH (2)
			☐	RMMCH (3)
• MATERNAL				
History				
1. Age				
2. Parity		☐	Previous c/s (1)	
3. Gravidity				
4. Booked/Unbooked	☐	Booked (1)	☐	Unbooked (2)
5. HIV status	☐	Positive (1)	☐	Negative (2)
			☐	Unknown (99)
if POSITIVE:		CD4 count	☐	PMTCT (1)
			☐	HAART (2)
6. RPR result	☐	Positive (1)	☐	Negative (2)
			☐	Unknown (99)
7. Rh result	☐	Positive (1)	☐	Negative (2)
			☐	Unknown (99)
8. Booking HB				
9. LNMP				
10. Gestation (best estimate)		weeks		
11.1 Maternal illness	☐	Hypertension (1)	☐	Diabetes Mellitus (2)
	☐	Epilepsy (4)	☐	Anaemia (5)
	☐	Anticoagulation (7)	☐	Thromboembolic disease (8)
	☐	Jaundice (10)	☐	Pneumonia (11)
	☐	Other (13)	☐	Connective tissue disorders (12)
11.2 Diagnosed	☐	Before pregnancy (1)	☐	During pregnancy (2)
if any OTHER describe:				
Examination				
12. General appearance	☐	Well (1)	☐	Ill looking (2)
13. SFH				

	• FETAL					
15.1 Singleton/Multiple	☐ Singleton (1)	☐ Multiple (2)				
15.2 Weight	g					
16. Prolonged labour	☐ No (1)	☐ Yes (2)				
if YES:	☐ Latent (1)	☐ First Stage (2)	☐ Second Stage (3)			
17. MSL	☐ No (1)	☐ Yes (2)				
if YES:	☐ Thin (1)	☐ Thick (2)				
18. PROM	☐ No (1)	☐ Yes (2)				
19. Induction of labour	☐ No (1)	☐ Yes (2)	Reason: _____			
20. Augmentation	☐ No (1)	☐ Yes (2)				
21. Minutes taken from recognition of emergency to time of delivery			☐ Emergency not recognised (1)			
			☐ IUFD on arrival (2)			
NVD/Caesarian	☐ NVD (1)	☐ Caesarean (2)				
22. Instrumental	☐ No (1)	☐ Yes (2)				
if YES:	☐ Vacuum (1)	☐ Forceps (2)				
23. Causes						
Cord prolapse	☐ No (1)	☐ Yes (2)				
Abruption	☐ No (1)	☐ Yes (2)				
Infection (chorioamnionitis)	☐ No (1)	☐ Yes (2)				
Uterine rupture	☐ No (1)	☐ Yes (2)				
Birth trauma	☐ Aftercoming head of breech (1)	☐ Shoulder dystocia (2)				
	☐ Failed instrumental delivery (3)	☐ Other (4)				
24. Iatrogenic	☐ No (1)	☐ Yes (2)				
25. Fetal distress	☐ No (1)	☐ Yes (2)	☐ Unknown (3)			
	☐ Monitored (1)	☐ Not monitored (2)	☐ Incorrectly interpreted (3)			
	☐ IUFD (1)					
26. Intrapartum resuscitation	☐ No (1)	☐ Yes (2)	☐ N/A (3)			

APPENDIX B: Patient Information and consent form

Hello. My name is Dr. Marlene Bothma. I am a doctor in this hospital and I work in the Maternity department. I am doing research on information on why some babies are not born alive and what the reasons are for it.

My department and I would like to extend our sympathy to you for the loss of your baby. We would like to offer you counselling to help you with your grief. I am currently doing a study on mothers and babies who underwent the same experience as you did. I want to ask you if you will be willing to be part of my study. By taking part, you will not be benefitting directly from the study, but what we find out may help other mothers and babies in the future.

To take part in this study all that you have to do is allow me to look through your file and gather information regarding your pregnancy and delivery.

If you have decided to take part and then change your mind for any reason, there will be no ill-effects. You will still receive the care and counselling you are entitled to.

In taking part in this study you will not have to experience any uncomfortable or painful procedures. All we are interested in is what is documented in your file.

If you decide to participate in this study the standard of care you will receive will be the same as all the patients in the ward however you will not be given anything in return e.g. money for your participation in the study however you will be entitled to see a counsellor with whom you can discuss your feelings.

You can contact me at anytime in connection with the study. My name is Dr. M. Bothma and I can be contacted on this number at this hospital:

If you are willing to be a participant in this study, kindly sign that you have understood all that has been explained to you and that you are willing to take part in this study.

Patient name:

Patient signature:

Date:

If you are younger than 18 years of age, we need permission from your parent or guardian for you to participate in this study

Parent/Guardian name:

Parent/Guardian signature:

Date:

APPENDIX C: ETHICS CLEARANCE

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

Division of the Deputy Registrar (Research)

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

R14/49 Marlene Bothma

CLEARANCE CERTIFICATE

M110413

PROJECT

A Study of Fresh Stillbirths Weighing 2500g or more at Three Academic Hospitals (Revised Title)

INVESTIGATORS

Marlene Bothma

DEPARTMENT

Department of Obstetrics & Gynaecology

DATE CONSIDERED

06/05/2011

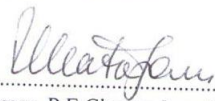
DECISION OF THE COMMITTEE*

Approved unconditionally

Unless otherwise specified this ethical clearance is valid for 5 years and may be renewed upon application.

DATE 04/09/2013

CHAIRPERSON


(Professor P E Cleaton Jones)

*Guidelines for written 'informed consent' attached where applicable

cc: Supervisor : Prof E Buchmann

DECLARATION OF INVESTIGATOR(S)

To be completed in duplicate and **ONE COPY** returned to the Secretary at Room 10004, 10th Floor, Senate House, University.

I/We fully understand the conditions under which I am/we are authorized to carry out the abovementioned research and I/we guarantee to ensure compliance with these conditions. Should any departure to be contemplated from the research procedure as approved I/we undertake to resubmit the protocol to the Committee. **I agree to a completion of a yearly progress report.**

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES