

**Determinants of adverse pregnant outcomes in Mutare district clinics,
Manicaland Province, Zimbabwe.**

By

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Declaration

I declare that the dissertation titled “**Determinants of adverse pregnant outcomes in Mutare district clinics, Manicaland Province, Zimbabwe.**” which I hereby submit for the degree Master of Public Health to the University of Pretoria is my own original work and where other people’s work has been used, it has been properly acknowledged and referenced. Neither this work, nor any part of it, has been submitted to any other tertiary institution for any degree or diploma.

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May the hand of God be upon you all
Blessmore Vimbai Chaibva

Dedication

This dissertation is a special dedication to all women who have seen themselves through the nine months of joy, anxiety and expectation of an addition to their families. This joy however is cut short at the end of the period after the baby has been termed stillbirth or only a few days after giving birth they have to say goodbye to a precious neonate who has just deceased. They ask many questions which remain unanswered. I hope that the findings of this study will help in ensuring that factors that can be addressed from the facility level are rectified so that women come out of the hospital with joy unspeakable.

I also dedicate this work to my late grandfather, Hundivenga Munhanga, a man of God who stood by me in prayer. Grandfather, your love, teachings will always be in my heart. I know you were always in the prayer closet for me. I miss you and may your soul rest in eternal peace. Your life here on earth was well spent and I celebrate what God has done in my life through your teachings.

Executive summary

Globally, neonatal mortality, and still births are major public health problems. Though preventable, nearly three million babies die every year in their first month of life and a similar number are stillborn, accounting for 7% of global burden of disease, which is higher than the burden of Human Immunodeficiency Virus / Acquired Immunodeficiency Syndrome (HIV/AIDS). Up to 50% of all deaths within the first month occur within the first 24 hours of life, and up to 75% occur in the first week.

Zimbabwe's Neonatal Mortality Rate (NMR) rose from 33/1000 deaths per 1000 live births in 1990 to 39/1000 in 2012. The country is far from reaching Millennium Development Goal 4 (MDG4) on child survival as the pattern on rising NMR is evident in districts like Mutare. Though interventions like result based financing (RBF), increase in midwifery training, provision of Basic Emergency Obstetric and Neonatal Care (BEMNOC) have been implemented in the district, the district has a high NMR of 55.2 deaths per 1000 live births.

This study aims to explore the determinants of adverse pregnancy outcomes in Mutare facilities. The primary objective of the research is to determine if pregnancy outcomes differ by socio-economic, maternal, neonatal, delivery and health system factors.

The study will employ a retrospective cross-section analytical approach. Records of pregnant women who delivered at 7 sampled facilities during the period January 2014 to June 2014 will be reviewed. The working definition for adverse pregnancy outcomes for this study will be women who had a fresh still birth or early neonatal deaths.

The results from the study will be presented as a report in partial fulfilment of the requirements for the award of the degree on Master of Public Health by the University of Pretoria. A presentation of the results will be made to the Health Executive of Mutare districts as well as Manicaland Province. The results will also be published in a reputable journal and availed for public consumption.

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List of acronyms

AIDS	Acquired Immunodeficiency Syndrome
ANC	Antenatal Care
APH	Antepartum Hemorrhage
BEMNOC	Basic Emergency Maternal Neonatal Obstetric Care
DHE	District Health Executive
DHIS	District Health Information System
ENND	Early Neonatal Death
HIV	Human Immunodeficiency Virus
ICD	International Classification Division
IMAI	Integrated Management of Adolescent and Adult Illness
IMPAC	Integrated Management of Pregnancy And Childbirth
IPTp	Intermittent Preventive Treatment of malaria in pregnancy
LBW	Low Birth Weight
MDG	Millennium Development Goal
MICS	Multiple Indicator Cluster Survey
MOHCC	Ministry of Health and Child Care
MRCZ	Medical Research Council of Zimbabwe
NMR	Neonatal Mortality Rate
NVD	Normal Vertex Delivery
PHE	Provincial Health Executive
PIH	Pregnancy Induced Hypertension
PMD	Provincial Medical Director
RBF	Result Based Financing
RTI	Reproductive Tract Infection
SSA	Sub-Saharan Africa
WHO	World Health Organization
ZDHS	Zimbabwe Demographic Health Survey

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PART ONE: RESEARCH PROTOCOL

1.0 Introduction and literature review

Background information

Definition and epidemiology of pregnancy outcomes

Perinatal outcomes refer to life events that occur to a newborn infant from the age of viability (28 weeks) and the first week of life.¹ The transition of a fetus immersed in amniotic fluid and totally dependent on placenta to a squalling air-breathing baby is a source of wonder to the family.² However the transitional process is not always smooth and can result in adverse events to the mother or baby. Pregnancy outcomes vary from pregnancy to pregnancy and can be: a healthy live baby, a low birth weight baby (LBW), prematurity in the baby, a stillborn, intra-uterine fetal death, early neonatal death and late neonatal death. Usually the health of the mother and newborn are inseparable and the most severe adverse outcomes of pregnancy include:- the death of the baby or the mother and in some cases both mother and baby.

The ICD-10 (International Classification of Diseases 10th revision) classifies stillbirths as a loss of a fetus ($\geq 500\text{g}$) from natural causes or a loss after the 22nd week of pregnancy. Early neonatal deaths (ENND), is defined as deaths that occur within the first seven days of life. Zimbabwe registers and captures fresh stillbirths, macerated stillbirths and early neonatal deaths as pregnancy outcomes in District Health Information System version 2 (DHIS2). Due to limited data, the working definition for adverse pregnancy outcomes for this study includes fresh stillbirths and early neonatal deaths.

Every pregnancy intends for a child, however tragic events to the affected mothers and families like still births and neonatal deaths are common, especially in low and middle income countries. Nearly, 3 million third trimester stillbirths occur every year with low and middle-income countries bearing 98% of the burden.³ On the other hand, a similar number of children die within the first 28 days of life. While still births rates are less than 5 per 1000 live births in high income countries, these rates are at

least 25 deaths per 1000 live births in low and middle income countries. Of those that die within the first month of life, almost 50% die within 24 hours and 75% within first 7 days of life.⁴

The figure below highlights pregnancy outcomes.

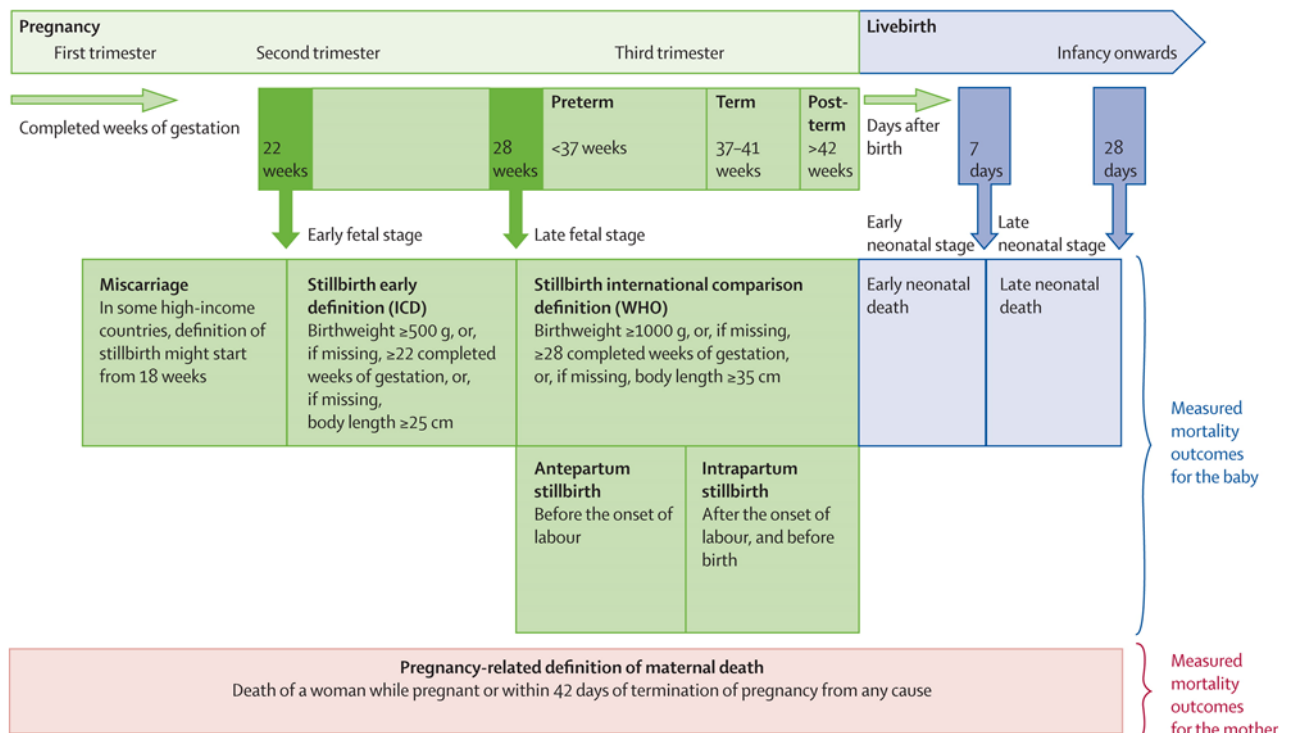


Figure 1: Definition of pregnancy outcomes:

Defining stillbirths and associated pregnancy outcomes for international comparison: Definitions from ICD, tenth revision. ICD=International Classification of Diseases. The Lancet 2011; 377:1448-1463 (DOI:10.1016/S0140-6736(10)62187-3

Global burden child mortality

Globally, under five mortality has reduced by 47% from 90 (CI 89, 92) deaths per 1000 live births in 1990 to 48 (CI 46, 51) in 2012.⁵ However, this is far from achieving the MDG4 target of reducing under-5 mortality by two-thirds from the 1990 baseline. Furthermore, there is wide variability in the rates of reduction in under-5 mortality within regions and countries. While most regions have reduced under-5 mortality by at least 50%,¹ sub-Saharan Africa (SSA) rates of decline were 35%.⁶

While under-five mortality is on the decline globally, there is an increase in deaths during the neonatal period. The world's neonatal mortality rate declined from 33 deaths per 1000 live births in 1990 to 21 in 2012, a 37% decline compared to a

decline from 90 to 48 deaths per 1000 live birth in under 5 mortality a 47% decline. Consequently, the proportion of under-five deaths that occur within the first month of life (the neonatal period) has increased 19 percent since 1990, from 37 percent to 44 percent, because declines in the neonatal mortality rate are slower than those in the mortality rate for older children.⁵

Adverse pregnancy outcomes and burden to the health care

Measurement of maternal, infant and child outcomes are basic indicators of a country's socio-economic, and level of health care.⁷ Pregnancy monitoring from antenatal care, delivery and postnatal requires a complete health system from human resources, to governance and infrastructure. Because pregnancy complications (ante- and intra- partum) are often unpredictable they require a timely, rapid, skilled response and availability of tertiary obstetric services that are well coordinated by a team of midwife, obstetrician and paediatrician. Poor coordination of health activities, human and resources towards a pregnancy can result in adverse outcomes, e.g. stillbirths, neonatal and maternal deaths.

Stillbirths and neonatal deaths

Stillbirths and neonatal mortality are pregnancy outcomes of public health concern. Approximately 3 million⁸ stillbirths and a similar number of neonatal deaths are recorded worldwide yearly with low and middle income countries contributing, 98% of the cases. This accounts for about 7% of the global burden of disease, which is greater than that contributed from vaccine preventable diseases and malaria.⁹ Regional and inter-country still births and neonatal mortality rate variations are quite substantial. While, high income countries have a stillbirth rate of 4 deaths per 1000 live births, low and middle income countries have recorded nine times the rate. Inter-country variations have been recorded in Nigeria, where rural northern communities of Nigeria recorded higher stillbirths compared to teaching hospitals in southern Nigeria.^{10,11}

Though stillbirths and neonatal mortality contribute greatly to child mortality, there is low recognition of the problem by policy makers at national and international levels. Outreach, family-community and facility based care when universally available have been shown to avert a 42-75%¹² neonatal mortality worldwide yet the burden of stillbirths and neonatal mortality is on the increase.

Risk factors/determinants of adverse pregnancy outcomes

Various factors which are of a public health concern have been shown to influence pregnancy outcomes. These can be divided into four major groups that are: socio-economic, maternal and health care factors.

The risk factors include:

Socio-demographic factors: maternal and paternal education,^{13,14} parity,^{15,16,17} gravidity, age of sexual debut, marital status,¹⁸ inter-pregnancy interval (IPI).¹⁹⁻²¹

Maternal factors: age,²²⁻²⁴ maternal medical history (obesity and diabetes, hypertension, HIV/AIDS),^{16,25,26} pre-pregnancy weight, reproductive tract infection, malaria, smoking and alcohol consumption.²⁷

Previous pregnancy outcomes: previous spontaneous or induced abortion,²⁸

Neonatal factors: sex of the neonate,²⁹⁻³¹ gestational age,¹⁶ birth weight, 5 minute apgar score,

Socio-economic factors: parental occupation,³² household income,¹³ education

Health care factors

Delivery factors: mode of delivery,^{24,32} complications during delivery/ mother referred for delivery services,^{24,32} births attended by a trained birth attendant,³³ place of delivery,^{22,24,34} use of partograph, free delivery services.²⁴

Pre-delivery factors: availability and use of ante-natal care (ANC) services- prenatal care onset, frequency and timing of ANC, number of ANC visits,³⁵⁻³⁸ booking status,³⁹ drug taking or use of plants during pregnancy.⁴⁰

Levels of prevention

The risk factors for pregnancy outcomes are multifactorial and only some of them are preventable or treatable.¹⁶ Primary prevention of adverse outcomes include proper nutrition for the woman to minimize maternal obesity a risk factor for adverse pregnancy outcome, cessation of factors like smoking and alcohol consumption.

During the entire period of pregnancy, methods that can be used to prevent adverse pregnancy outcomes are available. These include: immunization against tetanus toxoid, folic-ferrous micronutrient supplementation, Intermittent Preventive Therapy (IPTp) for malaria. Routine screening of and treatment of reproductive tract infections (RTI), and syphilis can prevent adverse outcomes like preterm births. Identification

and early treatment of maternal malaria is important in prevention of severe outcomes like maternal deaths and stillbirths.

In Zimbabwe, adverse pregnancy outcome prevention strategies are through a continuum of care. These include; 4 focused antenatal visits for the pregnant women, integrated management of adulthood illness/ integrated management of pregnancy and childbirth (IMAI/IMPAC), deliveries assisted by skilled birth attendances, postnatal care visits at day 3,7. The country has also embarked on increased training of health workers in BEMNOC, training more midwives, building waiting mother's shelter to ensure that pregnant women can easily access emergency services if need arises. Another strategy that has shown an increase in health facility deliveries is removal of maternity user fees.

Literature review

Introduction

Globally, neonatal mortality is a major public health problem. Though preventable, nearly three million babies die every year in their first month of life and a similar number are stillborn. Within the first month, up to one half of all deaths occur within the first 24 hours of life, and 75% occur in the first week.⁴¹ Neonatal mortality accounts for 7% of the global burden of disease which is higher than the burden of HIV/AIDS.

Sub-Saharan Africa has been termed the most dangerous continent for a baby to be born. The regional neonatal mortality for 2012 was 32 deaths per 1000 live babies contributing, 38% of global neonatal deaths. While 3 million neonates die globally, in Nigeria alone 255 000 neonates die a year.⁴² The highest NMR, 66 deaths per 1000 live births, has been recorded in Liberia. Half of Africa's 1.16 million neonate deaths occur in just five countries – Nigeria, Democratic Republic of the Congo, Ethiopia, United Republic of Tanzania and Uganda.

Zimbabwe, has a rising NMR and is far from reaching MDG4 on child survival. Since 1990 to 2012 the NMR has increased from 33 per 1000 live birth to 39 per 1000 live births. According to the 2010/11 Zimbabwe Demographic Health Survey (ZDHS) the infant mortality rate was 57 deaths per 1,000 live births while the overall under-5 mortality rate for the period is 84 deaths per 1,000 live births. Sixty-eight percent of all deaths to children under-5 in Zimbabwe take place before a child's first birthday, with 37 percent occurring during the first month of life.⁴³

The health structure in Zimbabwe is divided into primary, secondary, tertiary and quaternary levels. Administratively, the hierarchy is from facility, district, provincial and national level. For example, Mutare district is made up of 48 primary health centres, one secondary health facility (Sakubva maternity hospital) and one tertiary health facility (Mutare Provincial Hospital).

District mortalities have also shown an increasing perinatal mortality. Marondera, a district in Mashonaland East, one of the ten provinces of Zimbabwe, recorded an increase in perinatal mortality of 58.6/1000 and 64.6/1000 live births in 2007 and 2008 respectively.⁴⁴ Mutare district recorded 534 (stillbirths + ENND) against 9673 (institutional live births) in 2013 which translated to 55.2 deaths per 1000 live births.⁴⁵

Maternal programs in Mutare District

Mutare district, one of the seven districts in Manicaland is managed by local authority (city), the government and rural district council. The city (local authority) has 9 primary health facilities and a population of 190 314 while district caters for 263 433 people. The expected births for Mutare City and district are 7900 and 10994 respectively.

Primary health care provision at the facilities includes general outpatient consultation, HIV testing and counselling among others. Reproductive health services include family planning services, antenatal care, delivery and postnatal care. Only two of the city clinics provide basic emergency obstetric services - BEMNOC and conduct deliveries while 44 of the facilities (includes 1 secondary and 1 tertiary institution- Mutare Provincial Hospital) provide BEMNOC.

Mutare district maternal services are subsidised through Results Based Financing (RBF) since 2011. Provision of funds through the results based financing program in Mutare district is set to improve the availability, accessibility and quality of key reproductive and child health services and their optimum utilization. RBF means that women can get maternal services at the facilities free of charge and the facility is re-funded through the program (RBF).

Various indicators meant to improve maternal and child survival are being tracked through RBF. Pregnancy indicators that are being monitored include antenatal care visits, pregnant women screened for syphilis, delivery attended by skilled health worker in health institutions and post natal care.

The theory of RBF is financing for results and is set to encourage managers to take responsibility. Health facility managers are empowered to find solutions to solve specific problems and they have the freedom to make decisions of how best to use their revenue, which inputs to buy and from which independent supplier. For example, some facilities decided to build waiting mothers homes as a means to ensure that pregnant women are close to the health facility and basic obstetric care. Despite all these interventions the district recorded a high number of stillbirths and early neonatal deaths (55.2 deaths per live births).

RBF is also there to retain human resources for health. The staff receive 40% of the cash pay-out made to the facility as part of staff individual performance bonuses for results achieved. Though RBF was meant to improve the quality of services to pregnant women and improve pregnancy outcomes, the district had a high number of fresh stillbirths and early neonatal deaths (55.2/1000 deaths per live births) in 2013 which were mostly attributed to poor quality of services at the institutions.

Defining the research problem

Neonatal mortality remains a major contributor to death among children younger than 5 years in Zimbabwe. While under 5 mortality rate rose from 74/1000 live birth in 1990 to 90/1000 in 2012 the NMR increased from 31/1000 live births to 39/1000 in 2012. MICS 2014 showed a continued rising NMR trend from 20 deaths per 1000 live births in 2000 to 29 deaths per 1000 live births in 2014 The rising NMR in Zimbabwe despite interventions is a cause for concern as the country is far off from achieving MDG4 target of child survival.

The country embarked on various strategies which stretched throughout the continuum of care from pre-natal to post natal care. In order to improve access to pre-natal and delivery services by pregnant women, the country removed user fees. Peer reviews of maternal and perinatal audits were introduced as a way to improve the quality of antepartum services. Despite these efforts neonatal rates have been on the increase.

Manicaland province recorded the highest number of perinatal deaths in the country in 2013. According to DHIS2 data, the province recorded 1540 perinatal deaths, against 44 610 (42 875 Institutional and 1735 home) deliveries. However, this could be an underestimate due to the poor vital registry system.

DHIS2 data for the period January to June 2013, Manicaland province recorded 493 adverse pregnancy outcomes, against 20869 deliveries. Mutare district contributed close to 40% of the adverse pregnancy outcomes. The district recorded 4690 births out of expected births of 5497 and they also recorded 197 adverse pregnancy outcomes (stillbirths and fresh neonatal deaths)

Despite existing interventions to curb perinatal mortality data on the determinants of high perinatal mortality (adverse pregnancy outcomes) for the province and district is scanty. This study set out to establish the determinants of adverse pregnancy outcomes in Mutare district, and therefore recommend interventions that can be adopted to improve pregnancy outcomes in the district.

Conceptual framework

The Mosley and Chen conceptual framework for the study of child survival in developing countries was adapted, based on available data from the registers used by the Ministry of Health and Child Care (MOHCC) in Zimbabwe. Figure 2 shows the framework used in this study along with the selected possible predictors of neonatal mortality in Zimbabwe.

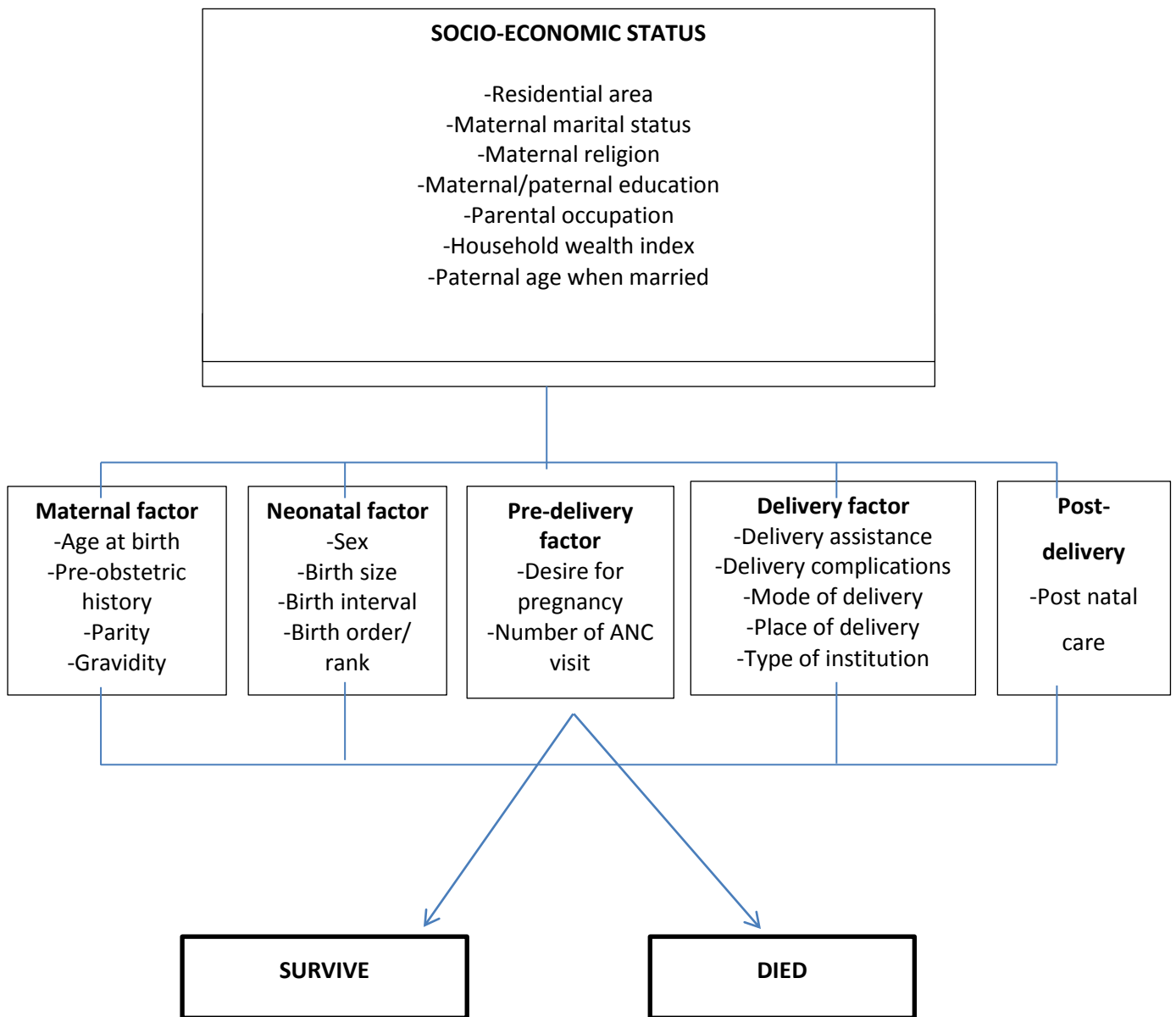


Figure 2: Mosley and Chen Conceptual framework

Conceptual framework for factors influencing pregnancy outcome **adopted from Mosley and Chen**

Research problem

Mutare district has a high proportion (55.2 deaths per 1000 live births) of adverse pregnancy outcomes. High adverse pregnancy outcomes contribute to high infant mortality which might result in the country failing to meet MDG4 target by 2015.

Research question

The research sought to establish the determinants of adverse pregnancy outcomes in Mutare district so as to inform the district to target their interventions in order to reduce the mortality.

Relevance of study

Maternity outcomes are indicative of the health care delivery system. A high rate of adverse pregnancy outcomes reflects a poor health delivery system and is therefore a public health concern. The study sought out to establish the determinants of adverse pregnancy outcomes and therefore, inform the district on appropriate strategies and interventions that can assist in reducing adverse pregnancy outcomes and thereby improve the services offered by the district.

Aims and objectives

Broad objective

The study aimed to explore the determinants of adverse pregnancy outcomes in Mutare district, Manicaland Province, Zimbabwe.

Specific objective

The study aimed to investigate if pregnancy outcomes differ by socio-economic factors, maternal and neonatal factors, health system related and maternal medical history. Specifically:

- i. Socio-economic factors (e.g. residential area, maternal education)
- ii. Maternal factors (e.g. maternal age, obstetric history)
- iii. Neonatal factors (e.g. sex, birth interval)
- iv. Maternal prenatal history (e.g. number of ANC visits)
- v. Delivery factors (e.g. birth attended by a skilled birth attendant)
- vi. Post-natal services provided

Methods

Study design

A retrospective analytical cross-sectional study review was employed. A review of patient records of women who were attended at Mutare district facilities from January 2014 to June 2014 was done. Only relevant data was extracted for the study.

Operational definition for adverse pregnancy outcome included fresh still births and early neonatal deaths.

Study variables

Study outcome definition: adverse pregnancy outcome referred to fresh still births and early neonatal deaths. A fresh stillbirth was a neonate with no respiratory or circulatory signs of life at birth after 28 weeks of gestation. Early neonatal mortality included any death in the first 24 hours of life. In descriptive statistics neonatal mortality was defined as the number of neonatal deaths per 1000 live births. The explanatory variables included socio-economic and proximal determinants covering maternal, neonatal, pre-pregnancy, pregnancy and post-pregnancy factors.

Table 1: Operational definitions and categorization of the variables

VARIABLE	DEFINITION AND CATEGORIZATION
SOCIOECONOMIC DETERMINANTS	
Residential area	Residential area (1= urban 2= rural)
Maternal marital status	Marital status of mother (1=currently married 2= not married)
Maternal religion	Maternal religion (1= Christian 2=Moslem 3=Apostolic, 4= African Tradition)
Maternal education	Maternal years of schooling (as continuous variable)
Paternal occupation	Paternal years of schooling (as continuous variable)
Paternal age when married	Paternal age when married (as a continuous variable)
PROXIMAL DETERMINANTS	
Maternal factors	
Maternal age	Maternal age at childbirth (as a continuous variable)
Obstetric history	Obstetric history (1=previous Caesarean section 2=previous risk factors like eclampsia, haemorrhage, 3=previous stillbirth/neonatal death; 4=none)
Maternal medical history	Maternal medical history (1=non-HIV/AIDS; 2=HIV/AIDS, 3=HIV/AIDS plus non-HIV/AIDS, 4=none)
Maternal malaria	Malaria during pregnancy (1=yes; 2=no)
Maternal syphilis	Syphilis test results during pregnancy (1=positive; 2=negative;3=not done)

Neonatal factors	
Sex	Sex of neonate (1=female, 2=male)
Birth weight	Birth weight of neonate (grams)
Birth interval	Inter-pregnancy interval (number of years)
Parity	Parity (Integers)
Gravidity	Gravidity (Integers)
PRE-DELIVERY FACTORS	
Number of ANC visits	Number of ANC visits (Integers)
Timing of ANC visits	Timing of ANC visits (1= according to WHO recommendations, 2=not as WHO recommendations)
DELIVERY FACTORS	
Delivery assistance	Birth attendance during delivery (1=skilled health professional-midwife, obstetrician; 2=non-midwife health professional; 3=traditional birth attendant/other)
Delivery complications	Complications during delivery (1=No; 2= Yes)
Mode of delivery	Mode of delivery (1=NVD, 2= caesarean section 3= breech)
POSTNATAL SERVICES	
Post natal care	Post natal services received by neonate (1=no; 2=yes)

Study setting

The study was conducted at Sakubva Maternity Hospital, Mutare district, Zimbabwe. The hospital receives referrals from the city and rural clinics.

Study population

Records of all pregnant women who were attended to at Sakubva maternity hospital during the period January 2014 to June 2014 who met the inclusion criteria were considered for the study.

Inclusion criteria:

Women who had singleton deliveries at Sakubva maternity hospital, Mutare District during the period January to June 2014

- Women whose age is 18 years and above
- Women resident in Mutare District.

Exclusion criteria

- Women aged less than 17 years
- Women referred from other districts beside Mutare and referred from other provinces

Sampling method

A random sample of the women who delivered in Mutare district was considered for the study.

Sample size calculation

The Dobson's formula was used to calculate the sample size

$$n = z^2 p (1-p) / \Delta^2$$

Where:

n = sample size

z = maximum allowable error risk

p = proportion of women who have adverse pregnancy outcomes

(1-p) = proportion of women who do not experience any adverse pregnancy outcomes

And

Δ = absolute precision

Using a 95% confidence interval (z=1.96), Δ = 0.05 and p = 0.18 (where 18% of women had an adverse pregnancy outcome)¹⁵

$$\begin{aligned} &= (1.96)^2 \frac{0.18 \times 0.82}{(0.05)^2} \\ &= 227 \end{aligned}$$

Assuming a response rate of 80% (analogous to completeness of records)

$$n = (1/0.8) * 227$$

$$n = 283$$

the minimum sample which was required in the study is 300.

Measurement

Routine paper managed data from January to June 2014 was used in the study.

Records of women who were attended to at Sakubva maternity hospital from

January to June 2014 were used so as to ensure validity of the study. Missing data was completed through calling the women via telephone.

Data Management and Analysis

Patient database in Mutare district is manual. Data, variables necessary for analysis were extracted from manual registers, perinatal deaths forms to Excel. Data was then imported to Stata 13 for analysis. The final analysis was under the guidance of the mentors.

Descriptive statistics were computed for all variables. STATA 13.0 (Stata Corp, College Station, TX) was used to summarize data, compare variables and test hypotheses by generating means, frequencies, proportions, p-values and 95% confidence intervals (CI).

Univariate and multivariable logistic regression was applied. The Univariate identified individual factors that influence the outcome of measure (Survive or died).

Multivariate logistic regression was used to model the joint effects of all the factors that influence pregnancy outcome. The problem of multiplicity was addressed.

Ethical considerations

Ethical approval for the study was obtained from the University of Pretoria Research Ethics Committee and Medical Research Council of Zimbabwe (MRCZ).

No personal identifiers such as names and registration numbers of patients appeared in the final report to ensure confidentiality and anonymity. Identification (registration) numbers were used to aid in the analysis of data and as reference.

Only the researchers directly involved in this study had access to the data and only for the purpose of this study.

No physical harm was inflicted since no human specimens were extracted from participants.

Permissions

Permission to access records was obtained from the Provincial Medical Director: Manicaland Province and the District Medical Officer Mutare District.

Logistics and time schedule

The Gantt chart attached in Appendix 1 shows the management of the project with regards to time.

Budget/ resources

Appendix 2 shows and estimated budget of ZAR 21380.00 for the study which was funded by the researcher.

Reporting of results

The findings of this study were presented as a research report in partial fulfilment of the requirements for the award of the degree of Master of Public Health (MPH) at the University of Pretoria. A copy of the report was also be presented to the Health Executive of the District and Manicaland Province -DHE and PHE respectively. The results were forwarded to a reputable journal for peer review and publication and for general public.

Ms B. V. Chaibva was the first author and Prof Beke, Prof Olorunju and Dr Nyadundu were second, third and fourth authors respectively.

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Appendix 1: Study Gantt Chart

Activity	June	July	August	Sept	Oct
Final draft of protocol					
Presentation to UP Research Ethics Committee					
Approval from UP REC					
Presentation to Medical Research Council of Zimbabwe MRCZ					
Approval from MRCZ					
Permission from PMD					
Preparation for data collection					
Data collection and entry					
Preparation for data analysis					
Data analysis					
First draft of final report					
Final draft of report					

Appendix 2: Estimated Study Budget / Resources

Budget Item	Quantity	Units	Unit Cost (ZAR)	Total Cost (ZAR)
Photocopying and Printing				
Research protocol (7 copies)	7	Copies	40	280
Research report	2	CDs	50	100
Research report Paper	4	Copies	250	1000
Questionnaire – codebook	1000	Copies	2	2000
Toner	1	Containers	600	600
Miscellaneous				2000
Sub-Total				7180
Communication				
Internet and communication	5	Months	500	2500
External hard drive & USB	2		900	1800
Sub-Total				4300
Data Collection				
Travel to and from site	10	Days	150	1500
Travel- South Africa and Zimbabwe	2		4000	8000
Sub-Total				9500
Dissemination of data				
Posters	2		800	1600
GRAND TOTAL				21380

0 **PART TWO: JOURNAL ARTICLE**

1 **2.1 Cover Letter**

2 Faculty of Health Sciences
3 School of Health systems and Public Health
4 HW Snyman Building (North)
5 31 Bophelo Road
6 Gezina
7 Pretoria

8
9 16th December 2014

10 The Editor
11 BMC Pregnancy and Childbirth

12
13 **REF: SUBMISSION OF MANUSCRIPT**

14
15 Dear Sir/Madam,

16
17 Please find attached our manuscript entitled “**Determinants of adverse pregnant**
18 **outcomes in Mutare district Clinics, Manicaland Province, Zimbabwe**” by
19 Chaibva B V, Beke A, Olorunju SAS and Nyadundu S, a research article for
20 consideration for publication in your journal.

21
22 We believe the results presented in the manuscript provide insight into the
23 development of appropriate strategies and interventions to help to reduce stillbirths
24 and neonatal deaths and contribute to lower mortality among under five children.

25
26 All authors listed have approved the manuscript and declared no competing
27 interests. We declare that this manuscript has not been published in any scientific
28 journal or meeting and is not being considered for publication by another journal.

29
30 Thank you for your consideration. Please address all correspondence to me by e-
31 mail: bvchaibva@gmail.com.

32
33 Yours sincerely,

34
35 Blessmore V Chaibva

36

37 **2.2 Manuscript**

38

39 **Determinants of adverse pregnant outcomes in Mutare district clinics,**
40 **Manicaland Province, Zimbabwe.**

41 Blessmore V Chaibva^{1*}, Andy Beke¹, Steve AS Olorunju², Simon Nyadundu³

42

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78 **Abstract**

79 **Background:** Perinatal deaths are adverse pregnancy outcomes that account for
80 about 7% of global burden of disease, with developing countries contributing about
81 98% of deaths. This study aimed at determining the factors associated with adverse
82 pregnancy outcomes among women at Sakubva hospital, Mutare district, Zimbabwe
83 from January to June 2014.

84 **Methods:** A retrospective review of 346 patient records, of women who delivered at
85 Sakubva hospital and those referred from Mutare district facilities to Mutare
86 Provincial Hospital, between January and June 2014. Multilevel logistic regression
87 using a backward hierarchical approach was performed to compare twenty-four
88 variables associated with outcome. Variables with more than 80% data available
89 were considered for analysis. Stata 12.0 was used to analyse the data.

90 **Results:** Of the 346 women included in this study, 54 (15.61%) experienced an
91 adverse pregnancy outcome (stillbirth or early neonatal death). Delivery by non-
92 normal vertex method (caesarean section or breech presentation) has a four times
93 odds of adverse pregnancy outcomes compared to those who delivered a cephalic
94 presentation by normal vertex delivery (OR= 4.26; $p<0.001$). Experiencing
95 pregnancy associated complications has a 5 times risk of an adverse pregnancy
96 outcome compared to no complications (OR=5.85; $p<0.001$). Neonatal birth weight
97 of less than 2500grams was marginally significantly (OR = 2.48; $p=0.053$) associated
98 with adverse pregnancy outcome.

99 **Conclusions:** Clearly, the determinants of adverse pregnancy outcomes in Mutare
100 are; non-normal vertex delivery methods, complications during pregnancy/birth and
101 low birth weight (<2500grams). Firstly, identification of complications and breech
102 presentation during the third trimester by midwives should be recognised as high risk
103 and these are to be monitored closely or referred to gynaecologist for assistance.
104 Secondly, management of low birth weight neonates has proven interventions which
105 include special baby care unit and kangaroo care which Sakubva could implement to
106 improve survival of these neonates. Lastly, further research is critical to identify the
107 root cause of association of method of delivery (caesarean section) and adverse
108 pregnancy outcomes.

109

110 **Key words:** Perinatal deaths, adverse pregnancy outcomes, Mutare district, stillbirth

111 **Background**

112

113 Worldwide, nearly 3 million third trimester stillbirths occur every year and a similar
114 number of children die within the first 28 days of life.^{1, 2} These account for
115 approximately 7% of global burden of disease which is higher than that from
116 HIV/AIDS.³ Low and middle-income countries bear 98% of the burden with sub-
117 Saharan Africa reporting the highest burden globally.^{4, 5} In sub-Saharan Africa about
118 14% of all births could result in stillbirths.⁶ Most deaths (43%) among the under-fives
119 occur within the first month of life (the neonatal period).⁷

120 Zimbabwe's 2010/11 Demographic Health Survey (ZDHS) reported an infant
121 mortality rate of 57 deaths per 1,000 live births while the overall under-5 mortality
122 rate for the period was 84 deaths per 1,000 live births. There has been an increase
123 in neonatal mortality ratio (NMR) from 33 to 39 deaths per 1000 live births from 1990
124 to 2012.⁸ Zimbabwe Multiple Indicator Cluster Survey (MICS) 2014 also showed an
125 upward trend in NMR from 20 deaths per 1000 live births in 2000 to 29 deaths per
126 1000 live births in 2014.⁹ The rising NMR in Zimbabwe is occurring despite the
127 various interventions that include: subsidising maternal services through Results
128 Based Financing (RBF) which has resulted in removal of direct user fees. Peer
129 reviews of maternal and perinatal audits were introduced as a way to improve the
130 quality of services throughout the management of pregnancy. These efforts may be
131 contributing factors towards the overall downward trend in under-five mortality.⁹
132 However, Zimbabwe is far off from achieving the Millennium Development Goal 4
133 (MDG4) target of child survival due to the increasing neonatal mortality despite an
134 overall decrease in under 5 mortality. Therefore an understanding of the risk factors
135 and determinants of neonatal deaths would assist in addressing child survival
136 challenges.¹⁰

137 Risk factors that have been shown to influence adverse pregnancy outcomes, like
138 neonatal deaths, can be categorized into socio-demographic factors,¹¹⁻¹⁷ maternal
139 factors,¹⁸⁻²¹ previous pregnancy outcomes,²² neonatal factors,²³ socio-economic and
140 health system related factors.²⁴⁻³⁰ There is sparse data on the prevalence and
141 determinants of adverse pregnancy outcomes in sub-Saharan Africa.

142 This study's operational definition for adverse pregnancy outcome included fresh
143 and macerated still births and early neonatal deaths. The study aimed to identify the
144 risk factors for adverse pregnancy outcomes in Mutare district, Zimbabwe.

145 Identification of risk factors for adverse pregnancy outcomes may contribute to
146 reduction in infant mortality by ascertaining factors that can be modified by
147 appropriate public health interventions.

148 **Methods**

149 **Study design and setting**

150 Mutare district population is served by a network of health facilities: primary,
151 secondary and tertiary health centres. The study area was Sakubva and Mutare
152 Provincial Hospital in Manicaland Province, Zimbabwe. The hospitals manage clients
153 from Mutare's urban and rural population. Sakubva hospital receives and manages
154 clients from the rural and city primary facilities. It also, refers clients to Mutare
155 Provincial Hospital a tertiary institution. All referrals from Sakubva were followed up
156 at Mutare Provincial Hospital and considered as part of the study.

157 A retrospective cross-sectional analysis was done on the "delivery register" of
158 childbirths in Mutare district, from the period January 1st to June 30th, 2014. Other
159 records used were patient's admission notes and antenatal (ANC) registers. All
160 women who met the inclusion criteria and delivered within the period January to
161 June 2014 were eligible to participate. For each birth record, information on socio-
162 demographics, maternal factors like previous obstetric history, neonatal information
163 (sex, birth-weight) and delivery factors which included attendance by a skilled health
164 worker, mode of delivery) and post natal factors were extracted.

165 The main outcomes examined in this study were stillbirths and early neonatal
166 deaths. Stillbirth was defined in accordance with World Health Organisation-agreed
167 definition of stillbirth for international comparison as death of a fetus weighing at
168 least 500 g or after 22 completed weeks of gestation occurring before the complete
169 expulsion or extraction from its mother [ICD-10]. Early neonatal death was defined,
170 for the purposes of this study, as death that occurred within the first seven days of
171 life.

172 Data from registers was double entered into Excel, cleaned and transferred to
173 Stata 12.0 (Stata Corp, Texas, and USA) for analysis. Descriptive statistics was used
174 to analyse categorical data.

175 Chi2 tests were used for univariable comparisons of dichotomous data to measure
176 association between outcome and variable data (more than five observation

177 expected in all cells) or Fisher's exact test (five or fewer expected observations in
178 one or more cells).

179 Mantel- Haenszel test of homogeneity was used to establish effect modification or
180 confounding among variables. Univariable analysis was performed to examine the
181 association of each variable with adverse pregnancy outcome. Factors significant at
182 $p = 0.05^{31}$ were considered into multivariate logistic. Multivariate regression was
183 modelled using the backward stepwise approach. Evaluation of the model was done
184 using the Pearsons GOF, ROC curve analysis. Effects of outliers was analysed
185 using the m-asymptotic residuals method. The model was checked for statistical
186 interactions and adequacy before being approved as final. The p values for all
187 hypothesis tests were two-sided and significance was set at $p < 0.05$.

188 **Ethical approval**

189 The ethical clearance was granted by the University of Pretoria, Faculty of Health
190 Sciences Research Ethics Committee as well as the Medical and Research Council
191 of Zimbabwe. Permission to conduct and access patient records was obtained from
192 the Provincial Medical Directorate, Manicaland Province and the District Medical
193 Office, Mutare District Zimbabwe. Confidentiality of records was adhered to and
194 there were no personal identifiers used in the final report.

195 **Results and discussion**

196 The total number of records sampled was 427 of which 81 were discarded due to
197 more than 80% of the data being missing. Of the discarded records, 3.2% had an
198 adverse pregnancy outcome, 8.6% had complications and 6.2% had delivered by
199 non-vertex delivery methods. Three hundred and forty six records were then
200 analysed. The study was limited to Sakubva and Mutare Provincial hospitals due to
201 logistical challenges. Of the 346 records sampled 54 (15.61%) records had an
202 adverse pregnancy outcome (stillbirth or neonatal death) while 292 (84.39%) were
203 live births.

204 **Background and characteristics of participants**

205 The age of the women in the study ranged from 17 to 43 with a mean age of 26
206 (SD: 6.42). Seventy two percent (72.43%) were aged between 20-34 years old and
207 13.78% were 35 years old and above. Majority of the women (62.10%) in the study
208 sample attended to at Sakubva or referred to Mutare Provincial hospital (from
209 Sakubva hospital) resided in urban areas, while 37.90% were resident from rural

210 areas and was mostly referred for maternal services. The majority of the women
211 sampled (97.92%) were currently married while 2.08% were separated, divorced or
212 single. Close to 98% of the study population were Christians (either Pentecostal or
213 orthodox, apostolic sect), 1.38% Moslem and 0.46% belonged to the African
214 Tradition religion. Though the data on education was minimal (maternal education
215 n=73) it showed that education among the women was widespread with none of the
216 women having had no form of education. Twenty two percent of the women had
217 some form of primary education and more than 60% secondary education. Of the
218 346 women sampled only 12.7% were formally employed as teachers, cashier or
219 nurse aide while 87.3% were involved in informal trading or were housewives.
220 Paternal variables were not analysed due to unavailability of data.

221 **Reproductive health characteristics**

222 In terms of reproductive health characteristics, 67% had no history of previous
223 complications while 33% had experienced a complication like stillbirth, neonatal
224 death or abortion. Delivery by caesarean section in the previous pregnancy was
225 recorded as previous complications. Also, 15% of the women sampled were HIV
226 positive while 2% of the women had non-HIV chronic conditions like hypertension,
227 asthma, and psychosis prior to pregnancy. Approximately 8% of the women had an
228 episode of malaria (n=64) and 3% had tested positive for syphilis (n=34) during the
229 duration of the pregnancy. The median parity and gravidity were 1 and 2
230 respectively. The inter-pregnancy interval between the delivery under review and the
231 previous births was analysed with a median interval of 4 (IQR 2-7).

232 **Neonate demographics**

233 Approximately, fifty one percent of the neonates were female and 49% male. The
234 interquartile weight range for the neonates was 2700 to 3400 grams with a mean
235 weight of 3000g (SD= 599.26). The mean gestation age of the women was 37 weeks
236 while the minimum and maximum were 24 and 43 respectively.

237 **Delivery factors**

238 The study was conducted at Sakubva hospital, due to the many referrals occurring
239 from primary health care centres to Sakubva. Referrals out from Sakubva where
240 followed up at Mutare Provincial hospital and therefore included in the study. Most of
241 the adverse pregnancy outcomes in the district occur at the two hospitals. Seventy
242 six percent of the women had a normal vertex delivery (NVD), 18%, caesarean

243 section and 5% breech presentation deliveries. Of these deliveries 63% experienced
 244 pregnancy associated complications like pregnancy induced hypertension (PIH),
 245 prolonged labour and foetal distress. Majority of deliveries (94%) were attended to by
 246 a skilled health professional, midwife or doctor and the rest by non-skilled
 247 professional. Skilled professional was defined as either a midwife or doctor as this
 248 could be identified from the register.

249

250 **Table 2: Socio-demographic characteristics of women delivering at Sakubva hospital, January**
 251 **to June 2014.**

Variable	N (%)	%	95% Confidence interval
Residential area	n=343		
Urban	213	62.10	0.57 – 0.67
Rural	130	37.90	0.33 – 0.43
Marital status	n= 288		
Not married	6	2.08	0.004 – 0.037
Married	282	97.92	0.96 – 1.00
Maternal religion	n=217		
Non-Apostolic	144	66.36	0.60 -0.73
Apostolic	73	33.64	0.27 – 0.40

252 p<0.05

253 Descriptive statistics was divided into:

254 **Table 2:** Socio-demographics

255 **Table 3:** Reproductive, maternal, neonatal and health system factors

256

257 The majority of the patients (88.15%) delivered at Sakubva hospital a secondary
 258 level facility while 11.85 were referred to Mutare Provincial Hospital, a tertiary level
 259 hospital for further management. Reasons for referrals included, complications of
 260 pregnancy, need for blood transfusion among others. Non- normal vertex delivery
 261 (NVD) in this study was categorised as caesarean section deliveries for various
 262 reasons (including breech) or delivery of a breech presentation (termed breech
 263 delivery).

264

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267

268 **Table 3: Reproductive, maternal, neonatal, and health system characteristics of women**
 269 **delivering at SDH, January- June 2014.**

Variable	N (%)	%	95% Confidence interval
Maternal age	n= 341		
<20	47	13.78	0.10 - 0.17
20-34	247	72.43	0.68 – 0.77
35 +	47	13.78	0.10 – 0.17
Obstetric history	n= 282		
None	190	67.38	0.62 – 0.73
Present	92	32.62	0.27 – 0.38
HIV status	n= 303		
Negative	257	84.82	0.81 -- 0.89
Positive	46	15.18	0.11 – 0.19
Neonatal sex	n = 333		
Male	166	49.85	0.44 – 0.55
Female	167	50.15	0.45 – 0.56
Birth weight	n= 322		
<2500g	47	14.60	0.11 – 0.18
2500 – 4000g	269	83.54	0.79 – 0.88
4000+	6	1.86	0.004 – 0.033
Gestational age	n =316		
≥32	303	95.89	0.94 – 0.98
<32	13	4.11	0.02 – 0.06
Parity	n=334		
0	109	32.63	0.28 – 0.38
1-3	195	58.38	0.53 – 0.64
4+	30	8.98	0.06 – 0.12
Gravidity	n= 333		
<4	260	78.08	0.74 – 0.83
≥4	73	2.92	0.17 – 0.26
Birth attendant	n= 337		
Unskilled	18	5.34	0.03 – 0.08
Skilled	319	94.66	0.92 – 0.97
Delivery complications	n= 334		
None	121	36.23	0.31 – 0.41
Present	213	63.77	0.59 – 0.69
Delivery method	n = 338		
NVD	260	76.92	0.72 – 0.81
Non - NVD	78	23.08	0.19 – 0.28

270 p<0.05

271 NB: unskilled referred to any professionals who are not a doctor or midwife.

272

273

274 **Test of association**

275 An analysis of the association of variables using the chi square test and Fischer's
 276 exact test showed significant association of some maternal, neonatal, reproductive
 277 and health system factors while none of the socio-demographic factors were
 278 significantly associated.

279 **Logistic regression**

280 The variables were analysed after grouping them into three broad categories: A
 281 socio-demographics, B: maternal (pre, intra, post-partum period) pre-pregnancy and
 282 delivery factors and C, neonatal and child related factors.

283

284 **Table 4: Bivariate analysis (Crude Odds Ratio) for Socio-demographic characteristics**
 285 **associated with adverse outcomes among women who delivered at SDH, January – June 2014.**

Variable	Crude OR	p-value	95% CI
Residential area			
Urban	Reference		
Rural	0.90	0.708	0.49 – 1.66
Marital status			
Married	Reference		
Not married	1		
Maternal religion			
Non Apostolic	Reference		
Apostolic	1.40	0.347	0.69 – 2.85

286 P<0.05

287 All the socio-demographic factors were not significant on binary logistic analysis.

288

289 **Table 5: Bivariate analysis for health care system factors associated with adverse outcomes**
 290 **among women who delivered at SDH, January- June 2014**

Variable	Crude OR	p-value	95% CI
Birth attendant			
Skilled	Reference		
Unskilled	0.66	0.583	0.15 –2.94
Delivery method			
NVD	Reference		
Non- NVD	5.26	0.000	2.83-9.78
Delivery complications			
None	Reference		
Present	3.78	0.001	1.72 – 8.33

291 p<0.05

292 Health facility type was not analysed due to the difference in levels of care between
 293 the two facilities. Tertiary level facilities manage patients that have been referred by
 294 secondary level while secondary manages those referred by primary level. Health
 295 system factors that were significantly associated with adverse pregnancy outcome
 296 on bivariate analysis are: none normal vertex delivery (OR = 5.26; 95% CI: 2.83 –
 297 9.78) and delivery complications (OR= 3.78; 95%CI: 1.72- 8.33). Birth attendant was
 298 not significant.

299

300 **Table 6: Bivariate analysis for maternal, neonatal factors, reproductive**

Variable	Crude OR	p-value	95% CI
Maternal age			
20-34	Reference		
<20	0.33	0.076	0.10 – 1.12
35+	1.16	0.722	0.52 – 2.57
Obstetric history (poor)			
None	Reference		
Present	0.74	0.385	0.38 – 1.45
HIV status			
Negative	Reference		
Positive	0.79	0.616	0.31 – 1.98
Neonatal sex			
Female	Reference		
Male	1.34	0.346	0.73 – 2.45
Neonatal birth weight			
2500 - 4000	Reference		
<2500	3.73	0.000	1.82 – 7.68
4000+	3.98	0.119	0.70 – 22.68
Gestational age			
≥32	Reference		
<32	10.22	0.000	3.19 – 32.77
Parity			
1-3	Reference		
0 (nulliparous)	0.95	0.886	0.48 – 1.87
≥4	2.56	0.036	1.06 – 6.15
Gravidity			
<4	Reference		
≥4	1.69	0.115	0.88 – 3.26

301 p<0.05

302 Maternal age and HIV status were not significantly associated with adverse
 303 pregnancy outcomes on bivariate analysis. Neonatal factors significantly associated
 304 with adverse pregnancy outcome were gestation age less than 32 weeks (OR=

305 10.22; 95%CI: 3.19 –32.77) and birth weight less than 2500 grams (OR= 3.73, 95%
 306 CI 1.82 – 7.68). Parity and gravidity were not significant.

307 Hierarchical backwards approach was employed in multivariable logistic regression
 308

309 **Table 7: Multivariable analysis of factors associated with adverse pregnancy outcomes.**

Variable	OR	95% CI	p-value
Delivery method			
NVD	Reference		
Non-NVD	4.24	2.02 – 8.92	0.000
Complications during pregnancy			
None	Reference		
Present	6.04	1.90 – 19.22	0.002
Neonatal birth weight			
2500 – 4000	Reference		
<2500	2.48	0.99 – 6.19	0.053
Gestational age			
≥ 32 weeks	Reference		
< 32 weeks	3.89	0.83 – 18.21	0.084
Parity			
1-3	Reference		
≥ 4	2.89	0.88 – 9.50	0.080

310 p<0.05

311
 312 Variables that were independently associated with adverse pregnancy outcomes in
 313 our study were, other delivery methods that were not NVD (OR= 4.24; 95%CI 2.02 –
 314 8.92), presence of complications during delivery (OR= 6.04; 95% CI; 1.90 – 19.22).
 315 Neonatal birth weight less than 2500g was marginally significant (OR: 2.48 p=0.053)
 316 Women who delivered a baby by other methods not normal vertex delivery section
 317 were 4.2 times more likely to experience an adverse pregnancy outcome (stillbirth or
 318 neonatal death) than those who delivered by normal vertex delivery. Also,
 319 experiencing complications like PIH, eclampsia during pregnancy/delivery had close
 320 to 6 times risk of an adverse pregnancy outcome compared to no complications.
 321 Lastly, the odds of a perinatal death were 2 times more on a neonate delivered
 322 weighing less than 2500g compared to a neonate of weight greater than 2500g.

323 Post regression tests carried out showed a ROC curve area of 0.80 indicating good
 324 predictive power of the model. There was good agreement between the model
 325 estimates/ predictions and the observed risks of adverse pregnancy outcomes in the

326 population. Analysis of the m-asymptotic residuals revealed that there were no
327 model outliers influencing the parameter estimates unduly. Therefore the model was
328 valid in estimating the risk factors for adverse pregnancy outcomes from socio-
329 demographic, maternal and neonatal & child variables.

330 **Discussion**

331 Our study has shown that the prevalence of adverse pregnancy outcomes
332 (stillbirths and early neonatal deaths) at Sakubva hospital in Mutare district for the
333 period January to June 2014 was 15.61%. Method of delivery other than normal-
334 vertex-delivery of cephalic presentation (i.e. caesarean section or breech
335 presentation) and presents of complications during pregnancy/delivery (e.g.
336 eclampsia, pregnancy induced hypertension) are important independent predictors of
337 adverse pregnancy outcomes in Mutare district. Neonatal birth weight of
338 <2500grams was marginally significant as a factor associated with adverse
339 pregnancy outcome.

340 The observed adverse pregnancy outcome prevalence rate of 15.6% is
341 comparable to other study findings conducted within the region.^{19, 31} High neonatal
342 mortality have been recorded in sub-Saharan Africa, Asia and Latin America, where
343 about 25% of stillbirths are most likely to result from complications of birth.³² In
344 Tanzania,¹³ the prevalence of stillbirths and intra-uterine deaths was reported as
345 18% while Nigeria²⁰ reported a 7.9% prevalence of perinatal deaths. In addition,
346 South Africa has a 13% prevalence rate of adverse pregnancy outcomes.³³ The
347 factors contributing to this high prevalence in low-to-medium countries in Africa are
348 varying from human resources, nutrition and health systems. Shortages of an
349 appropriate number of well performing health workers, (human resources for health),
350 shortages of essential medicines, supplies and equipment³⁴ could be possible
351 reasons for high prevalence of adverse outcomes in Mutare. Other possible factors
352 include, poor nutritional status, lack of antenatal care and a number of behaviours
353 which are associated with low-socioeconomic status.³⁵ Health system factors that
354 might contribute to high prevalence of pregnancy outcomes include geographical
355 barriers to health care (distance to nearest health facility), user fees and health care
356 worker attitudes.³⁶

357 The independent predictors of adverse pregnancy outcomes identified in this study
358 have been previously documented. There was a strong association between method

359 of delivery other than normal vertex delivery of a cephalic presentation (breech
360 presentation delivery or caesarean section) and adverse pregnancy outcomes.

361 Other studies have shown an increased risk of neonatal mortality and morbidity
362 with delivery by either elective or emergency caesarean section,^{37,38, 39} and delivery
363 of a breech presentation by vaginal method.⁴⁰ It is common in our low-resource
364 setting for caesarean section to be instituted after prolonged and unsuccessful
365 vaginal delivery which might increase the risk of adverse outcomes.⁴¹ Adverse
366 pregnancy outcomes association with caesarean section delivery could also be due
367 to the fact that many caesarean sections have been performed as emergencies
368 without proper preparations.⁴² Also; caesarean section delivery has been associated
369 with risks of pre-rupture of membranes and therefore contributes to the high perinatal
370 deaths. Morbidity associated with caesarean section delivery is higher as the
371 neonates require more oxygen compared to NVD.

372 Firstly, method of delivery (vaginal delivery of breech presentation, emergency or
373 elective C/S) has been shown to contribute to outcomes that undermine early
374 childhood development of the newborn.⁴² High adverse outcomes in vaginal delivery
375 of a breech presentation have been associated with complications such as cord
376 prolapse, aspiration of amniotic fluid, and complications associated with difficulties of
377 delivering the after-coming resulting in greater risk among vaginal delivery in breech
378 presentation compared with vaginal delivery in cephalic presentation.⁴³ The
379 caesarean section rate at Sakubva maternity hospital was 238 deliveries by
380 caesarean section out of total deliveries of 1732 during the period, January to June
381 2014,⁴⁴ which might be due to a high referral rate from other facilities.

382 On another hand, caesarean section delivery, when appropriately instituted has
383 been shown to be protective of perinatal deaths.³⁹ Good caesarean delivery
384 practices require technical, appropriate and timely decision-making to produce
385 favourable results. However these aspects of caesarean section delivery were not
386 established in this study. Caesarean section challenges that contribute to adverse
387 outcomes could occur before, during and after the surgical procedure. The current
388 study however could not establish the timing of caesarean section from the registers.
389 Therefore, this finding is difficult to interpret and calls for further studies to
390 understand the root cause of delivery method being associated with adverse
391 pregnancy outcomes.

392 Secondly, women who experienced complications (cord prolapse, mal-
393 presentation, antepartum haemorrhage (APH), eclampsia, prolonged labour, and
394 pregnancy induced hypertension) had a six times odds of an adverse pregnancy
395 outcome compared to women who did not experience any form of complication. This
396 finding is in consistence with an earlier study conducted in Marondera district,
397 Zimbabwe⁴⁵ and other studies in the region, Tanzania,⁴⁶ Nigeria⁴⁷ and globally
398 China.^{48, 49} Pregnancy associated conditions like gestational diabetes or
399 hypertension have well recognised adverse effects on pregnancy outcomes.⁵⁰
400 Placental insufficiency in hypertension during pregnancy, cord prolapse,
401 malpresentation, could explain the high risk of adverse pregnancy outcome among
402 women who experienced complications. Also, intra-uterine bleeding due to
403 antepartum haemorrhage are some of the causes of anaemia in pregnancy that
404 result in neonatal death due to oxygen deficiency.⁵¹

405 Lastly, low birth-weight (LBW) <2500 grams has been documented as a risk of
406 adverse pregnancy outcome. Our study showed that neonates with a weight <
407 2500grams were almost twice at risk of adverse outcomes (OR=2.48 p=0.053)
408 though marginally significant. This finding has been established in previous
409 studies.⁴⁷ Neonates born with low birth weight are at increased risk of neonatal
410 deaths due to hypoglycaemia, hypocalcaemia and hypothermia. Successful
411 interventions to care for low birth weight and preterm babies include special baby
412 care unit (SBCU), exclusive breastfeeding and skin-to-skin care “kangaroo mother
413 care.” which is part of the care for these neonates at Sakubva hospital. Sakubva
414 hospital has been practising kangaroo mother care since 2012 and therefore this
415 needs to be intensified.⁴⁴

416 The current study did not show any association between socio-demographic
417 factors: residential area (rural or urban), marital status and adverse pregnancy
418 outcomes. Though residential areas of low-socio-economic⁵² status have been
419 shown to influence delivery outcome, the current study did not gather information on
420 economic status of the women.

421 The study suffered from the limitation of being facility based. Hospital based
422 studies may underestimate the true perinatal mortality. A community study is
423 recommended. The study being cross- sectional by design did not capture the
424 events for the nine months duration of pregnancy. Another limitation was, as a

425 retrospective analysis, the study was limited to the available data in the delivery
426 register which excluded such factors as paternal education and paternal age when
427 married. Information of outcomes was also limited to the duration the neonate was at
428 the facility and referrals out before seven days could not be followed up to ascertain
429 if perinatal death occurred. A lot of the data was missing which is an indication of
430 poor record keeping at the facility.

431 Though malaria is endemic in the province (Manicaland) the study had a low
432 sample size of 64 for this variable and therefore no meaningful conclusion could be
433 established on the variable. The record of malaria were limited to the delivery time,
434 therefore there is need for further studies to investigate specific variables like malaria
435 and syphilis.

436 Calling of patients, health worker interview to fill in missing data might have
437 subjected the study to recall bias. Our findings in Mutare cannot be generalised to
438 the rest of the population due to selection bias, however can be generalised to
439 similar hospitals within the province. Notwithstanding these limitations, the study
440 identifies important factors associated with adverse pregnancy outcomes in this low
441 resource setting.

442 **Conclusion**

443 In conclusion, early identification of complications of pregnancy during antenatal
444 care visits is critical toward the reduction of adverse pregnancy outcomes. Breech
445 presentation identification by midwives during the third trimester of pregnancy should
446 be recognised as high risk and therefore must be closely monitored or referred for
447 further management. Prioritization of admission to waiting mother's shelter of women
448 identified to have complications and those with breech presentation of neonate
449 should be considered in the district. Furthermore high risk pregnancies should be
450 referred to the obstetrician at the earliest time possible for further assistance. It is
451 also recommended that partners support gynaecologists so that they can be
452 available and improve management of complicated cases.

453 Further research on delivery method is recommended to understand the root causes
454 of its association with adverse pregnancy outcomes.

455

456

457

458 Abbreviations

459 ZDHS, Zimbabwe's 2010/11 Demographic Health Survey; NMR, Neonatal Mortality Ratio; MDG, Millennium
460 Development Goal; HIV/AIDS, Human Immunodeficiency Virus/ Acquired Immunodeficiency Syndrome.

461
462 Competing interests

463 The authors declare that there are no competing interests.

464
465 Author's contributions

466 BVC conceived and designed the study. BVC, SASO, SN analysed the data. BVC wrote the paper. All authors
467 read and approved the final manuscript

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- 673 **Appendices**
- 674 **Appendix 1: Data capturing sheet**
- 675 **Appendix 2: University of Pretoria Ethical Approval**
- 676 **Appendix 3: Medical Research Council of Zimbabwe Ethical Approval**
- 677 **Appendix 4: Manicaland Provincial Medical Directorate Letter of no Objection**
- 678 **to Conduct Research**
- 679 **Appendix 5: Mutare District Permission letter to access records**
- 680 **Appendix 6: PMC Pregnancy and Childbirth Manuscript Guidelines**
- 681

**Determinants of adverse pregnancy outcomes in Mutare health facilities,
Manicaland Province, Zimbabwe.****Section A – Socio- economic factors**

Q1. Women residential area

- 1 Rural
- 0 Urban

Q2. Social/ marital status of women

- 1 Currently married
- 0 Not married (divorced/ Separated / Widowed/ Single)

Q3. Maternal religion

- 0 Non Apostolic
- 1 Apostolic

Q4. What is the maternal education level –years of education

-
- 1 None (0-≤1)
 - 2 Primary (1- 7 years)
 - 3 Secondary (7-12)
 - 4 Tertiary (≥ 13)

Q5. What is the maternal occupation

- 1 Formal
- 0 Informal

Q6. Paternal years of education – years of education

Q7. Paternal age when married

Section B-Proximal determinants**B1. Maternal factors**

Q8. Maternal age at delivery

Q9. Obstetric history

- 0 Nil
- 1 Adverse obstetric history

Q10. HIV status

- 0 Negative
- 1 Positive

Q11. Malaria during pregnancy

- 1 Positive
- 0 Negative

Q12. Syphilis test results during pregnancy

- 1 Positive
- 0 Negative

B2. Section Child related

Q13. Sex of neonate

- 1 Female
- 0 Male

Q14. Birth weight of neonate

- 0 2500-4000g
- 1 <2500g
- 2 >4000g

Q15. What was the gestation age of the infant

- 1 < 32 weeks
- 0 ≥32 weeks

Q16. Inter-pregnancy interval

- 1 ≤2years

12163733- Chaibva B. V.

0 >2years

Q17. Parity

0 1, 2nd and 3rd parity

1 Nulliparous

2 ≥4 parity

Q18. Gravidity

1 < 4

0 ≥ 4

B4-Delivery factors

Q21. Birth attendance during delivery

1 Skilled health professional-midwife, obstetrician, doctor

0 Unskilled

Q22. Complications during delivery

0 None

1 Present

Q23. Mode of delivery

0 NVD

1 Non-NVD

Q25. Type of health facility

1 Secondary health institution

0 Tertiary institution

B5-Post natal services

Q26. Post natal services received by neonate

0 No

1 Yes

The Research Ethics Committee, Faculty Health Sciences, University of Pretoria complies with ICH-GCP guidelines and has US Federal wide Assurance.

- FWA 00002567, Approved dd 22 May 2002 and Expires 20 Oct 2016.
- IRB 0000 2235 IORG0001762 Approved dd 22/04/2014 and Expires 22/04/2017.



UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Health Sciences Research Ethics Committee

4/09/2014

**Approval Certificate
New Application**

Ethics Reference No.: 296/2014

Title: Determinants of adverse pregnant outcomes in Mutare District Clinics, Manicaland Province, Zimbabwe

Dear Ms Blessmore V. Chaibva

The **New Application** as supported by documents specified in your cover letter for your research received on the 17/07/2014, was approved by the Faculty of Health Sciences Research Ethics Committee on the 27/08/2014.

Please note the following about your ethics approval:

- Ethics Approval is valid for 1 year
- Please remember to use your protocol number (**296/2014**) on any documents or correspondence with the Research Ethics Committee regarding your research.
- Please note that the Research Ethics Committee may ask further questions, seek additional information, require further modification, or monitor the conduct of your research.

Ethics approval is subject to the following:

- The ethics approval is conditional on the receipt of 6 monthly written Progress Reports, and
- The ethics approval is conditional on the research being conducted as stipulated by the details of all documents submitted to the Committee. In the event that a further need arises to change who the investigators are, the methods or any other aspect, such changes must be submitted as an Amendment for approval by the Committee.

We wish you the best with your research.

Yours sincerely

Dr R Sommers; MBChB; MMed (Int); MPharMed.

Deputy Chairperson of the Faculty of Health Sciences Research Ethics Committee, University of Pretoria

The Faculty of Health Sciences Research Ethics Committee complies with the SA National Act 61 of 2003 as it pertains to health research and the United States Code of Federal Regulations Title 45 and 46. This committee abides by the ethical norms and principles for research, established by the Declaration of Helsinki, the South African Medical Research Council Guidelines as well as the Guidelines for Ethical Research: Principles Structures and Processes 2004 (Department of Health).

☎ 012 354 1677 ☎ 0866516047 ✉ deepeka.behari@up.ac.za 🌐 <http://www.healthethics-up.co.za>
✉ Private Bag X323, Arcadia, 0007 - 31 Bophelo Road, HW Snyman South Building, Level 2, Room 2.33, Gezina, Pretoria



REF: MRCZ/B/709

24 September 2014

Blessmore Chaibva
University of Pretoria
South Africa

RE: Determinants Of Adverse Pregnancy Outcomes In Mutare District, Manicaland Province

Thank you for the application for review of Research Activity that you submitted to the Medical Research Council of Zimbabwe (MRCZ). Please be advised that the Medical Research Council of Zimbabwe has **reviewed** and **approved** your application to conduct the above titled study.

This approval is based on the review and approval of the following documents that were submitted to MRCZ for review:-

- a) Study proposal
- b) Data Collection Tools

- **TYPE OF MEETING** : Expedited
- **EFFECTIVE APPROVAL DATE** : 24 September 2014
- **EXPIRATION DATE** : 23 September 2015

After this date, this project may only continue upon renewal. For purposes of renewal, a progress report on a standard form obtainable from the MRCZ Offices should be submitted three months before the expiration date for continuing review.

- **SERIOUS ADVERSE EVENT REPORTING:** All serious problems having to do with subject safety must be reported to the Institutional Ethical Review Committee (IERC) as well as the MRCZ within 3 working days using standard forms obtainable from the MRCZ Offices or website.
- **MODIFICATIONS:** Prior MRCZ and IERC approval using standard forms obtainable from the MRCZ Offices is required before implementing any changes in the Protocol (including changes in the consent documents).
- **TERMINATION OF STUDY:** On termination of a study, a report has to be submitted to the MRCZ using standard forms obtainable from the MRCZ Offices or website.
- **QUESTIONS:** Please contact the MRCZ on Telephone No. (04) 791792, 791193 or by e-mail on mrcz@mrcz.org.zw

Other

- Please be reminded to send in copies of your research results for our records as well as for Health Research Database.
- You're also encouraged to submit electronic copies of your publications in peer-reviewed journals that may emanate from this study.

Yours Faithfully

MRCZ SECRETARIAT
FOR CHAIRPERSON
MEDICAL RESEARCH COUNCIL OF ZIMBABWE



PROMOTING THE ETHICAL CONDUCT OF HEALTH RESEARCH

Telephone: 60624/60655
Fax: 60698/64401



Reference:

PROVINCIAL MEDICAL DIRECTOR
MANICALAND
P.O. Box 323
Mutare

University of Pretoria
Faculty of Health Sciences
Research Ethics Committee
School of Health Systems & Public Health
HW, Synman Building (North)
31 Bophelo Road
Gezina
Pretoria

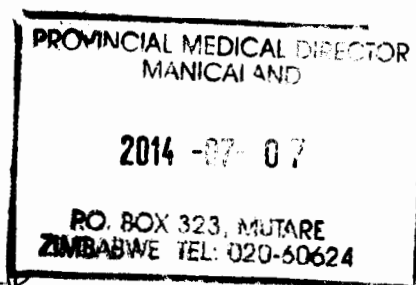
Dear Sir/Madam

REF: DECLARATION OF NO OBJECTION TO CONDUCT RESEARCH~Ms B V CHAIBVA

This serves to inform that the Manicaland Provincial Medical Director has granted Ms. B V Chaibva permission to conduct her research titled: "Determinants of adverse pregnancy outcomes in Mutare district, Manicaland Province, Zimbabwe."


We therefore declare that we have no objection to her accessing patient records to facilitate her research provided that approval of her protocol is granted first by the University of Pretoria, Research Ethics Committee and secondly by Medical Research Council of Zimbabwe.

Yours sincerely



P T Mafaune
Dr P T Mafaune

Manicaland Provincial Medical Director

Permission to access Records /  ta base at Health
Facilities in Mutare Urban

To: Provincial Medical Director
Manicaland Province

From: The Investigator
Mutare Facilities

Dr Mafaune

B V Chaibva

Re: **Permission to do research at Health Facilities in Mutare Health Facilities**

I am a Master of Public Health student with the University of Pretoria. I am requesting permission to conduct a study on the Determinants of adverse pregnancy outcomes in Mutare Health facilities that involves access to patient records.

The request is lodged with you in terms of the requirements of the Promotion of Access to Information Act. No. 2 of 2000.

The title of the study is: Determinants of adverse pregnancy outcomes in Mutare health facilities

The researcher requests access to the following information:

Access to the clinical files, record book and the data base.

I intend to publish the findings of the study in a professional journal and/ or at professional meeting like symposia, congresses, or other meetings of such a nature.

I intend to protect the personal identity of the patients by assigning each patient a random code number.

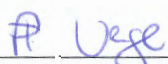
I undertake not to proceed with the study until I have received approval from the Faculty of Health Sciences Research Ethics Committee, University of Pretoria, and the Medical and Research Council of Zimbabwe.

Yours sincerely

Permission to do the research study at Mutare Health Facilities and to access the information as requested, is hereby approved.

Provincial Medical Director
Manicaland Province

Dr MAFAUNE


Signature of the PMD



To: The District Medical Officer
Mutare District
Zimbabwe

From: Blessmore V Chaibva
University of Pretoria
Faculty of Health Science
School of Health Systems and Public Health
HW, Synman Building (North), 31 Bophelo Road, Gezina,
Pretoria
South Africa

Dear Sir

Re: Permission to do research at Mutare Health facilities

THE TITLE OF THE STUDY IS: DETERMINANTS OF ADVERSE PREGNANCY OUTCOMES AT MUTARE HEALTH FACILITIES, MANICALAND PROVINCE, ZIMBABWE

The request is lodged with you in terms of the requirements of the Promotion of Access to Information Act. No.2 of 2000.

I am a student with the University of Pretoria, pursuing my Master of Public Health Degree (MPH) Epidemiology and Biostatistics- Monitoring and Evaluation sub-track programme. I am working with Prof Andy Beke, my academic supervisor from the University of Pretoria, School of Health System and Public Health. I hereby make a request on behalf of all of us to conduct the above mention research at Facilities in Mutare facilities.

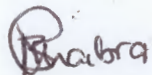
The research is a retrospective cross-sectional analytical study that involves access to patient clinical files, record book and databases with records from January 2014 to June 2014 on all pregnant women who were attended at health facilities.

We intend to publish the findings of the study in a professional journal and/ or at professional meeting like symposia, congresses, or other meetings of such a nature.

We intend to protect the personal identity of the patients by assigning each patient a random code number.

We undertake not to proceed with the study until we have received approval from the Faculty of Health Sciences Research Ethics Committee, University of Pretoria.

Yours sincerely





Permission to do the research at ~~Mutare~~ Health Facilities and to access the information as requested, is hereby approved.

Name and title of Medical Officer: DR TALENT MAPHOSA
DISTRICT MEDICAL OFFICER

Signature of the DMO

MIN. OF HEALTH & CHILD W/FARE
DISTRICT MEDICAL OFFICER
MUTARE DISTRICT
07 JUL 2014
P.O. BOX 3093, MUTARE
ZIMBABWE TEL: 020-65494/

Instructions for authors

Research articles

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Through a special arrangement with [LabArchives](#), LLC, authors submitting manuscripts to BMC Pregnancy and Childbirth can obtain a [complimentary subscription to LabArchives](#) with an allotment of 100MB of storage. LabArchives is an Electronic Laboratory Notebook which will enable scientists to share and publish data files in situ; you can then link your paper to these data. Data files linked to published articles are assigned digital object identifiers (DOIs) and will remain available in perpetuity. Use of LabArchives or similar data publishing services does not replace preexisting data deposition requirements, such as for nucleic acid sequences, protein sequences and atomic coordinates.

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Authors linking datasets to their publications should include an [Availability of supporting data](#) section in their manuscript and cite the dataset in their reference list.

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General guidelines of the journal's style and language are given [below](#).

Overview of manuscript sections for Research articles

Manuscripts for Research articles submitted to *BMC Pregnancy and Childbirth* should be divided into the following sections (in this order):

- [Title page](#)
- [Abstract](#)
- [Keywords](#)
- [Background](#)
- [Methods](#)
- [Results and discussion](#)
- [Conclusions](#)
- [List of abbreviations used](#) (if any)
- [Competing interests](#)
- [Authors' contributions](#)
- [Authors' information](#)
- [Acknowledgements](#)
- [Endnotes](#)
- [References](#)
- [Illustrations and figures](#) (if any)
- [Tables and captions](#)
- [Preparing additional files](#)

The **Accession Numbers** of any nucleic acid sequences, protein sequences or atomic coordinates cited in the manuscript should be provided, in square brackets and include the

corresponding database name; for example, [EMBL:AB026295, EMBL:AC137000, DDBJ:AE000812, GenBank:U49845, PDB:1BFM, Swiss-Prot:Q96KQ7, PIR:S66116].

The databases for which we can provide direct links are: EMBL Nucleotide Sequence Database ([EMBL](#)), DNA Data Bank of Japan ([DDBJ](#)), GenBank at the NCBI ([GenBank](#)), Protein Data Bank ([PDB](#)), Protein Information Resource ([PIR](#)) and the Swiss-Prot Protein Database ([Swiss-Prot](#)).

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Title page

The title page should:

- provide the title of the article
- list the full names, institutional addresses and email addresses for all authors
- indicate the corresponding author

Please note:

- the title should include the study design, for example "A versus B in the treatment of C: a randomized controlled trial X is a risk factor for Y: a case control study"
- abbreviations within the title should be avoided

Abstract

The Abstract of the manuscript should not exceed 350 words and must be structured into separate sections: **Background**, the context and purpose of the study; **Methods**, how the study was performed and statistical tests used; **Results**, the main findings; **Conclusions**, brief summary and potential implications. Please minimize the use of abbreviations and do not cite references in the abstract. **Trial registration**, if your research article reports the results of a controlled health care intervention, please list your trial registry, along with the unique identifying number (e.g. **Trial registration**: Current Controlled Trials ISRCTN73824458). Please note that there should be no space between the letters and numbers of your trial registration number. We recommend manuscripts that report randomized controlled trials follow the [CONSORT extension for abstracts](#).

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Three to ten keywords representing the main content of the article.

Background

The Background section should be written in a way that is accessible to researchers without specialist knowledge in that area and must clearly state - and, if helpful, illustrate - the background to the research and its aims. Reports of clinical research should, where

appropriate, include a summary of a search of the literature to indicate why this study was necessary and what it aimed to contribute to the field. The section should end with a brief statement of what is being reported in the article.

Methods

The methods section should include the design of the study, the setting, the type of participants or materials involved, a clear description of all interventions and comparisons, and the type of analysis used, including a power calculation if appropriate. Generic drug names should generally be used. When proprietary brands are used in research, include the brand names in parentheses in the Methods section.

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Results and discussion

The Results and discussion may be combined into a single section or presented separately. Results of statistical analysis should include, where appropriate, relative and absolute risks or risk reductions, and confidence intervals. The Results and discussion sections may also be broken into subsections with short, informative headings.

Conclusions

This should state clearly the main conclusions of the research and give a clear explanation of their importance and relevance. Summary illustrations may be included.

List of abbreviations

If abbreviations are used in the text they should be defined in the text at first use, and a list of abbreviations can be provided, which should precede the competing interests and authors' contributions.

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A competing interest exists when your interpretation of data or presentation of information may be influenced by your personal or financial relationship with other people or organizations. Authors must disclose any financial competing interests; they should also reveal any non-financial competing interests that may cause them embarrassment were they to become public after the publication of the manuscript.

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When completing your declaration, please consider the following questions:

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- In the past five years have you received reimbursements, fees, funding, or salary from an organization that may in any way gain or lose financially from the publication of this manuscript, either now or in the future? Is such an organization financing this manuscript (including the article-processing charge)? If so, please specify.
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sufficiently in the work to take public responsibility for appropriate portions of the content. Acquisition of funding, collection of data, or general supervision of the research group, alone, does not justify authorship.

We suggest the following kind of format (please use initials to refer to each author's contribution): AB carried out the molecular genetic studies, participated in the sequence alignment and drafted the manuscript. JY carried out the immunoassays. MT participated in the sequence alignment. ES participated in the design of the study and performed the statistical analysis. FG conceived of the study, and participated in its design and coordination and helped to draft the manuscript. All authors read and approved the final manuscript.

All contributors who do not meet the criteria for authorship should be listed in an acknowledgements section. Examples of those who might be acknowledged include a person who provided purely technical help, writing assistance, or a department chair who provided only general support.

Authors' information

You may choose to use this section to include any relevant information about the author(s) that may aid the reader's interpretation of the article, and understand the standpoint of the author(s). This may include details about the authors' qualifications, current positions they hold at institutions or societies, or any other relevant background information. Please refer to authors using their initials. Note this section should not be used to describe any competing interests.

Acknowledgements

Please acknowledge anyone who contributed towards the article by making substantial contributions to conception, design, acquisition of data, or analysis and interpretation of data, or who was involved in drafting the manuscript or revising it critically for important intellectual content, but who does not meet the criteria for authorship. Please also include the source(s) of funding for each author, and for the manuscript preparation. Authors must describe the role of the funding body, if any, in design, in the collection, analysis, and interpretation of data; in the writing of the manuscript; and in the decision to submit the manuscript for publication. Please also acknowledge anyone who contributed materials essential for the study. If a language editor has made significant revision of the manuscript, we recommend that you acknowledge the editor by name, where possible.

The role of a scientific (medical) writer must be included in the acknowledgements section, including their source(s) of funding. We suggest wording such as 'We thank Jane Doe who provided medical writing services on behalf of XYZ Pharmaceuticals Ltd.'

Authors should obtain permission to acknowledge from all those mentioned in the Acknowledgements section.

Endnotes

Endnotes should be designated within the text using a superscript lowercase letter and all notes (along with their corresponding letter) should be included in the Endnotes section. Please format this section in a paragraph rather than a list.

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All references, including URLs, must be numbered consecutively, in square brackets, in the order in which they are cited in the text, followed by any in tables or legends. Each reference must have an individual reference number. Please avoid excessive referencing. If automatic numbering systems are used, the reference numbers must be finalized and the bibliography must be fully formatted before submission.

Only articles, datasets, clinical trial registration records and abstracts that have been published or are in press, or are available through public e-print/preprint servers, may be cited; unpublished abstracts, unpublished data and personal communications should not be included in the reference list, but may be included in the text and referred to as "unpublished observations" or "personal communications" giving the names of the involved researchers. Obtaining permission to quote personal communications and unpublished data from the cited colleagues is the responsibility of the author. Footnotes are not allowed, but endnotes are permitted. Journal abbreviations follow Index Medicus/MEDLINE. Citations in the reference list should include all named authors, up to the first 30 before adding '*et al.*'. Any *in press* articles cited within the references and necessary for the reviewers' assessment of the manuscript should be made available if requested by the editorial office.

Style files are available for use with popular bibliographic management software:

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All web links and URLs, including links to the authors' own websites, should be given a reference number and included in the reference list rather than within the text of the manuscript. They should be provided in full, including both the title of the site and the URL, in the following format: **The Mouse Tumor Biology**

Database [<http://tumor.informatics.jax.org/mtbwi/index.do>]. If an author or group of authors can clearly be associated with a web link, such as for weblogs, then they should be included in the reference.

Examples of the *BMC Pregnancy and Childbirth* reference style

Article within a journal

Koonin EV, Altschul SF, Bork P: **BRCA1 protein products: functional motifs.** *Nat Genet* 1996,**13**:266-267.

Article within a journal supplement

Orengo CA, Bray JE, Hubbard T, LoConte L, Sillitoe I: **Analysis and assessment of ab initio three-dimensional prediction, secondary structure, and contacts prediction.** *Proteins* 1999,**43**(Suppl 3):149-170.

In press article

Kharitonov SA, Barnes PJ: **Clinical aspects of exhaled nitric oxide.** *Eur Respir J*, in press.

Published abstract

Zvaifler NJ, Burger JA, Marinova-Mutafchieva L, Taylor P, Maini RN: **Mesenchymal cells, stromal derived factor-1 and rheumatoid arthritis [abstract].** *Arthritis Rheum* 1999, **42**:s250.

Article within conference proceedings

Jones X: **Zeolites and synthetic mechanisms.** In *Proceedings of the First National Conference on Porous Sieves: 27-30 June 1996; Baltimore*. Edited by Smith Y. Stoneham: Butterworth-Heinemann; 1996:16-27.

Book chapter, or article within a book

Schnepf E: **From prey via endosymbiont to plastids: comparative studies in dinoflagellates.** In *Origins of Plastids. Volume 2*. 2nd edition. Edited by Lewin RA. New York: Chapman and Hall; 1993:53-76.

Whole issue of journal

Ponder B, Johnston S, Chodosh L (Eds): **Innovative oncology.** In *Breast Cancer Res* 1998, **10**:1-72.

Whole conference proceedings

Smith Y (Ed): *Proceedings of the First National Conference on Porous Sieves: 27-30 June 1996; Baltimore*. Stoneham: Butterworth-Heinemann; 1996.

Complete book

Margulis L: *Origin of Eukaryotic Cells*. New Haven: Yale University Press; 1970.

Monograph or book in a series

Hunninghake GW, Gadek JE: **The alveolar macrophage**. In *Cultured Human Cells and Tissues*. Edited by Harris TJR. New York: Academic Press; 1995:54-56. [Stoner G (Series Editor): *Methods and Perspectives in Cell Biology*, vol 1.]

Book with institutional author

Advisory Committee on Genetic Modification: *Annual Report*. London; 1999.

PhD thesis

Kohavi R: **Wrappers for performance enhancement and oblivious decision graphs**. *PhD thesis*. Stanford University, Computer Science Department; 1995.

Link / URL

The Mouse Tumor Biology Database [<http://tumor.informatics.jax.org/mtbwi/index.do>]

Link / URL with author(s)

Corpas M: **The Crowdfunding Genome Project: a personal genomics community with open source values** [<http://blogs.biomedcentral.com/bmcblog/2012/07/16/the-crowdfunding-genome-project-a-personal-genomics-community-with-open-source-values/>]

Dataset with persistent identifier

Zheng, L-Y; Guo, X-S; He, B; Sun, L-J; Peng, Y; Dong, S-S; Liu, T-F; Jiang, S; Ramachandran, S; Liu, C-M; Jing, H-C (2011): **Genome data from sweet and grain sorghum (Sorghum bicolor)**. *GigaScience Database*. <http://dx.doi.org/10.5524/100012>.

Clinical trial registration record with persistent identifier

Mendelow, AD (2006): **Surgical Trial in Lobar Intracerebral Haemorrhage**. *Current Controlled Trials*. <http://dx.doi.org/10.1186/ISRCTN22153967>

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Illustrations should be provided as separate files, not embedded in the text file. Each figure should include a single illustration and should fit on a single page in portrait format. If a figure consists of separate parts, it is important that a single composite illustration file be submitted which contains all parts of the figure. There is no charge for the use of color figures.

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- PPTX/PPT (single slide only)
- EPS
- PNG (preferred format for photos or images)
- TIFF
- JPEG
- BMP

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Each table should be numbered and cited in sequence using Arabic numerals (i.e. Table 1, 2, 3 etc.). Tables should also have a title (above the table) that summarizes the whole table; it should be no longer than 15 words. Detailed legends may then follow, but they should be concise. Tables should always be cited in text in consecutive numerical order.

Smaller tables considered to be integral to the manuscript can be pasted into the end of the document text file, in A4 portrait or landscape format. These will be typeset and displayed in the final published form of the article. Such tables should be formatted using the 'Table object' in a word processing program to ensure that columns of data are kept aligned when the file is sent electronically for review; this will not always be the case if columns are generated by simply using tabs to separate text. Columns and rows of data should be made visibly distinct by ensuring that the borders of each cell display as black lines. Commas should not be used to indicate numerical values. Color and shading may not be used; parts of the table can be highlighted using symbols or bold text, the meaning of which should be explained in a table legend. Tables should not be embedded as figures or spreadsheet files.

Larger datasets or tables too wide for a portrait page can be uploaded separately as additional files. Additional files will not be displayed in the final, laid-out PDF of the article, but a link will be provided to the files as supplied by the author.

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Preparing additional files

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Please note: All Additional files **will be published** along with the article. Do not include files such as patient consent forms, certificates of language editing, or revised versions of the main manuscript document with tracked changes. Such files should be sent by email to editorial@biomedcentral.com, quoting the Manuscript ID number.

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 - SWF (Shockwave Flash)
- Movies
 - MP4 (MPEG 4)
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Small self-contained websites can be submitted as additional files, in such a way that they will be browsable from within the full text HTML version of the article. In order to do this, please follow these instructions:

1. Create a folder containing a starting file called index.html (or index.htm) in the root.
2. Put all files necessary for viewing the mini-website within the folder, or sub-folders.
3. Ensure that all links are relative (ie "images/picture.jpg" rather than "/images/picture.jpg" or "http://yourdomain.net/images/picture.jpg" or "C:\Documents and Settings\username\My Documents\mini-website\images\picture.jpg") and no link is longer than 255 characters.
4. Access the index.html file and browse around the mini-website, to ensure that the most commonly used browsers (Internet Explorer and Firefox) are able to view all parts of the mini-website without problems, it is ideal to check this on a different machine.
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Abbreviations should be used as sparingly as possible. They should be defined when first used and a list of abbreviations can be provided following the main manuscript text.

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- Please use double line spacing.
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- Footnotes are not allowed, but endnotes are permitted.
- Please do not format the text in multiple columns.
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SI units should be used throughout (liter and molar are permitted, however).