DETERMINANTS OF STILLBIRTH IN THE FIVE GENERAL HOSPITALS OF LUSAKA, ZAMBIA: A CASE-CONTROL STUDY

BY

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A dissertation submitted to the University of Zambia in partial fulfilment of the requirements for the award of the degree of Master of Public Health

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DECLARATION

I, **Musonda Makasa**, do hereby declare that this dissertation herein presented for the degree of **Master of Public Health** is my original work and has not been previously submitted either whole or in part for any other degree at this institution of any other, nor being currently submitted for any other degree. The various sources to which I am indebted have been duly and clearly indicated in the references and acknowledgements sections.

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Musonda Makasa (Principal Investigator)

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Signed _____

Prof Wilbroad Mutale (Supervisor)

Date: _____/ _____ / _____

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CERTIFICATE OF APPROVAL

This dissertation, entitled Determinants of stillbirth in the Five General Hospitals of Lusaka, Zambia by Musonda Makasa is an approval for the part fulfillment of requirements for the award of Master of Public Health degree by the University of Zambia.

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ABSTRACT

Background: About 98% of stillbirths that occur globally are recorded in low- and middle-income countries, where south Asia and sub-Saharan Africa account for 77% of the reported cases. An estimated 2.6 million stillbirths were reported every year since 2000. Recent data suggests a 25.5% decline from 24.7 to 18.4 per 1000 live births worldwide. Despite this reduction, sub-Saharan Africa (SSA) still recorded the slowest decline. Stillbirths are a consequence of multifactorial factors, and majority of them especially in low resource setting have no causal assignment. **Objective:** The main objective of this study was to evaluate the determinants of stillbirths among women who had childbirth at the five general hospitals of Lusaka, Zambia. **Methods:** This was a multi-facility based study conducted at Kanyama, Chipata, Chawama, Matero and Chilenje. An unmatched case-control study was designed at a ratio of 1:4. Cases (stillbirths) were consecutively enrolled, and controls randomly selected within 24 hours of occurrence of a case. A structured questionnaire was used to collect data. Summary proportions and frequencies for cases and controls were obtained from descriptive statistical analyses. Univariate analysis was conducted to obtain the crude association between stillbirth and independent variables. Multiple regression was used to assess determinants of stillbirths. A p-value of <0.05 was considered sufficient evidence of an association between stillbirth and independent variables. **Results**: total of 58 cases and 232 controls were included in the analysis with a ratio of 1:4 respectively. 77.6% cases belonged to the 20 – 34 years old age group while controls accounted for 74%. 52.6% cases had attained secondary education and 51.1% were in the control group. With employment 73.7% and 70.7% were cases and controls respectively. Babies with birthweight ≥2500g had higher odds of mortality (AOR=4.49; 95%CI: 2.84-8.99) than babies with birthweight <2500g. Antepartum hemorrhage was also noted to be a risk factor (AOR = 3.18; 95% CI: 1.21 – 8.09); another finding was previous experience of stillbirth had high odd of stillbirth (AOR=3.99; 95% CI: 1.73 – 6.73) compared with their counterparts without. Additionally, women with increase in parity > 2 (AOR = 3.02; 95% CI: 1.07 – 7.54) had higher odds of stillbirth compared to women with parity ≤ 2.**Conclusion:** this study revealed that babies with higher birth weight ≥2500g had higher risk of mortality probably attributed to haemorrhage. Antepartum haemorrhage, and previous stillbirth were noted as significant determinants of stillbirth. Program implementers should consider strategies that can mitigate these determinants to reduce stillbirth.

Keywords: *Stillbirth, determinants, case-control, Zambia*

DEDICATION

This project paper is especially dedicated to my wife (Dr Musole Chipoya-Makasa) and children (Mumba, Musonda, and Mbulwe) who are the source of encouragement and inspiration for our family advancement and development in all spheres of life. I also dedicate this to my father for instilling the love of learning and education. I know this would have yet again made you very proud.

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ABBREVIATIONS AND ACRONYMS

ANC	Antenatal Care
APH	Antepartum Haemorrhage
EmONC	Emergency Maternal Obstetrics and Newborn Care
EMTCT	Elimination of Mother to Child Transmission
HIV	Human Immunodeficiency Virus
HHD	Hypertensive Heart Disease
ICD	International Classification of Diseases
LMIC	Low-Middle Income Countries
MDG	Millennium Development Goals
MMR	Maternal Mortality Ratio
MoH	Ministry of Health
MPDSR	Maternal Perinatal Disease Surveillance Report
NCD	Non-Communicable Diseases
PMR	Perinatal Mortality Rate
PMTCT	Prevention of Mother to Child Transmission
RCOG	Royal College of Obstetricians & Gynaecologists
SB	Stillbirth
SBR	Stillbirth Rate
SDG	Sustainable Development Goals
SSA	Sub-Saharan Africa
UNZA	University of Zambia
UNZABREC	University of Zambia Biomedical Research Ethics Committee
USAID	United States Agency for International Development
WHO	World Health Organization
ZDHS	Zambia Demographic and Health Survey

CHAPTER 1

INTRODUCTION

1.0 Introduction

Stillbirth is the occurrence of foetal demise with a birth weight of ≥1000g, or ≥28 completed weeks of gestation (World Health Organization, 2006).Globally, an estimated 2.6 million stillbirths were reported every year since 2000. It is also defined as complete expulsion or extraction of products of conception from its mother at a gestational age of more than 28 weeks or birth weight of more than 1000g; whereas perinatal mortality involves early neonatal death which is in the first week of life (World Health Organization, 2006; J. C. World Health Organization, 2016). According to the Royal College of Obstetricians and Gynaecologists (RCOG) and the World Health Organization International Classification for Diseases (WHO ICD), SB is also defined as a baby with a birth weight of ≥500g that is delivered with no signs of life (Royal College of Obstetricians and Gynaecologists, 2010; World Health Organization, 2012). However, for purposes of this study and to address this issue, we focused on the WHO recommended definition of stillbirth for epidemiological studies: ≥1000g birth weight or a gestational age of ≥28 weeks. The most objective measurement recommended by the WHO is use of birthweight as the first line determinant for stillbirth (Kelly *et al.*, 2021). Stillbirth rate is defined as the total number of stillbirths per 1000 total births (World Health Organization, 2015b). There are approximately 140 million births that occur globally among women per year without notable risk factors or complications to themselves or their babies before and during labour (World Health Organization, 2006, 2016). Recent data suggests that there has been a 25.5% decline of stillbirth rate from 24.7 to 18.4 per 1000 live births worldwide (Blencowe *et al.*, 2016). Despite this reduction at a global level, sub-Saharan Africa (SSA) still recorded the slowest decline, with an estimated stillbirth rate of 28.7 per 1000 live births. Approximately 98% of stillbirths were notably in low- and middle-income countries (LMIC) where south Asia and SSA accounted for 77% of the reported cases (McClure *et al.*, 2015; Blencowe *et al.*, 2016).

Stillbirth is associated with several social and economic consequences. The duration of pregnancy is not an easy journey, and the expectation of the baby not only by the immediate family but by society as well suddenly results in a tragic and painful outcome. The negative impact is at many

levels, not only the family but also questions about the quality of obstetrics care services (Gopichandran, Subramaniam and Kalsingh, 2018). There are challenges in family relationships, especially in African settings where stillbirth is stigmatized and affect the psychological well-being of the affected families. Stillbirth has negative social constructs that are deeply rooted in many African societies. They as a result end up being missed in national vital statistics especially when it occurs in the community resulting in underestimating the magnitude of the problem. It is estimated to be more than double the financial cost of a live birth (Burden *et al.*, 2016). The determinants of stillbirths are multifactorial, and a significant proportion have unknown etiology. This is attributed to limited comprehensive population based surveys regarding the definite cause of stillbirth (Pinar *et al.*, 2009). Literature suggests various interlinked determinants of stillbirth are common across most LMICs (Goldenberg *et al.*, 2016) and may reflect the quality of obstetrics care available during pregnancy and childbirth. Stillbirths occur due to the complex interaction of socio-demographic, behavioural and obstetrics factors (World Health Organization, 2006; Akombi and Renzaho, 2019; Kelly *et al.*, 2021). In high-income countries (HIC), literature shows that some of determinants of stillbirths include placental conditions, fetal/placental pathologies, antepartum haemorrhage (,APH) and a higher proportion are unexplained (Reinebrant *et al.*, 2018). Whereas determinants in LMIC include maternal age (less than 20 and above 35 years of age), high birth weight, low education level, increased parity, and poor antenatal care,, history preterm birth, APH, and history of stillbirth (Aminu *et al.*, 2014; Saleem *et al.*, 2018). Stillbirth varies across countries and its magnitude fluctuate from time to time. Also, the determinants of stillbirth maybe context-specific especially in developing countries.

In Zambia, evidence from anecdotal data suggest that stillbirth is a public health challenge. For example, a study conducted in selected health facilities of Lusaka urban more than a decade ago showed that determinants of stillbirth were prior history of stillbirth, APH, extremes of birthweight (<2500g or >4000g), increased maternal age, caesarean and breech deliveries (Stringer *et al.*, 2011). More recent data estimated 30.5 stillbirths per 1000 live births in certain parts of the country (Serbanescu *et al.*, 2019). However, the last Zambia Demographic Health Survey (ZDHS) only reported the perinatal mortality rate for the previous 5 year period under review of 33 per 1000 live births but not specifically stillbirth rate (Central Statistics Office (Zambia), 2018). In response to the challenges in the provision quality health services and care, the Zambian government established five general hospitals in the year 2015 in Lusaka urban which are equipped

with basic obstetric delivery services to improve maternal and perinatal outcomes (Japanese embassy Zambia, 2018) . One of the priorities set in the Zambia National Health Strategic Plan for 2017 – 2021 is to reduced stillbirth to less than 12 deaths per 1000 live births by 2030 in keeping with WHO target. It is important that Zambian program implementers prioritized health services that are deemed effective to improve maternal and perinatal outcomes. To reduce stillbirth, assessment of its determinants is key to generate program data that can be utilized for decision-making to fill the gaps in the provision of maternal and perinatal health services and care. Therefore, we aimed to assess the determinants of stillbirths in the five selected general hospitals in Lusaka, Zambia.

1.1 Statement of the problem

Under normal conditions, women must give birth to live babies and remain in a healthy state themselves but this is not the case in most places worldwide. This made the United Nations (UN) to adopt a new development agenda called "Transforming our world: the 2030 agenda for sustainable development" from which stemmed the principal guidelines for the sustainable development goals (SDGs) in 2015. A global indicator framework was set out for the SDGs and targets of the 2030 agenda for which the SB mortality target by 2030 is 12 per 1000 live births (World Health Organization, 2015b). This target is now a given ideal situation on the occurrence of SBs. Despite the global decline of SBR from 24.7 to 18.4 per 1000 births from 2000 to 2015, SSA recorded the slowest decline with a SBR of 28.7 per 1000 live births (Blencowe *et al.*, 2016). A recent study in selected facilities reported that Zambia's SBR was 30.5 per 1000 live births: while the ZDHS reported perinatal mortality of 33 per 1000 live births but not stillbirth rate. The prevailing situation means that Zambia's SBR will have to undergo about 19% decline in the next few years in order to meet the SDGs. However, at this pace the SDG target of 12 per 1000 live births perinatal mortality is seemingly difficult to attain. The SB rate in Zambia remains very high presenting a huge burden on the communities and hence a major public health issue.

Causes of stillbirth are interlinked and give a reflection of the quality of obstetric and newborn care available during pregnancy, around the delivery period and immediately after. Studies show that stillbirths including neonatal mortalities occur due to complex interaction or individual level factors related to maternal life style, obstetric complications, and underlying environmental factors. These are compounded by community level factors like poor sanitation, geographical

factors as well as lack of access to quality antenatal and skilled obstetrical care services. This can be during pregnancy, labour or after delivery care for the newborn (Akombi and Renzaho, 2019).

In our environment, one of the largest studies done on this subject in Zambia was a population-based cohort study of 26 public facilities in Lusaka. Some of the findings of this study include babies born to teenage to be at risk of stillbirth. Other notable risk factors were prior history of stillbirth, preterm birth, hypertensive hearth diseases of pregnancy, haemorrhage, and low Body Mass Index (Stringer *et al.*, 2015). Another study on predictors and outcomes of low birth weight done by Chibwesha *et al.* (2016) at the University Teaching Hospital (UTH) revealed low birth weight and prematurity to be associated with increased risk of SB. In rural Zambia the quality of health care services received by expectant mothers is strongly influenced their health seeking behaviour. This is suggestive that in order to improve quality service delivery for mothers and avoid stillbirths, efforts and resources should be focused on improvement of the level of services provided (Kyei, Chansa and Gabrysch, 2012). The salience of quality health care service delivery is hampered by a number of factors including decision to seek care due to individual health seeking behaviour, finances, status of women and perceived quality of care at the facility. Therefore, this study sought to examine the determinants of stillbirths among women that give birth at the 5 first general hospitals of Lusaka urban district.

1.2 Rationale

According to literature review, most of the studies previous done on this subject in Lusaka as is cited in the problem statement are not recent. In the past decade a lot of infrastructural and human resource development has taken place. The five general hospitals were constructed to alleviate from the services sort at the University Teaching Hospital. Henceforth, the observation from clinical practice is that these hospitals which were commissioned in the last 5 years are now providing more delivery services that previously (Wikipedia Contributors, 2021). Therefore, by conducting the study at these facilities, we sought to assess the determinants of stillbirths in these new facilities. Findings of this study will render information on evidenced based interventions to recommend for systems strengthening and for use in packaging health promotion, education and communication that can be recommended in the continuum of maternal and perinatal health care. Data derived is more recent and can be utilised to revise clinical practice and maternal and perinatal

healthcare policies in the country. Information obtained will also enable us to infer on what sort of further research needs to be conducted based on the outcomes.

1.3 Research questions

1. What is the prevalence of SB at the five general hospitals of Lusaka district during the period April to June 2022?

2. What are the socioeconomic and demographic factors that are associated with SB at the five general hospitals of Lusaka district?

3. What impact does medical complications in pregnancy and labour have on SB prevalence?

1.4 Objectives

1.4.1 General Objective

The main purpose/aim of this study was to examine the determinants of stillbirths among women who deliver at the first general hospitals of Lusaka district in Zambia.

1.4.2 Specific objectives

The specific objectives of this study were to:

1. Determine the prevalence of SB at the first level hospitals of Lusaka district.
2. Determine factors that are associated with SB the selected study sites.

CHAPTER 2

LITERATURE REVIEW

2.0 Literature review

Stillbirth rates remain high especially in low resource setting including Zambia most of them with few or no estimates of cause of death identified or published. Consequently, there is difficulty to assign the cause SB owing to multifactorial issues. Since the "cause of death" is the assault, injury or condition responsible for the demise, the proportion of the death due to a particular aetiology is mainly unknown due to limited comprehensive population based surveys regarding the definite cause of SB to a particular cause (Pinar *et al.*, 2009). Randomised controlled trials evidence regarding the effective interventions for the investigation and identification of causes of SB to gain more understanding on the aetiology of SB is fundamental to ensure quality maternal healthcare services (Wojcieszek *et al.*, 2018). This challenge is further compounded by the inadequate clinical information and records, and diagnostic investigation especially in low and middle income countries (Flenady, 2011; McClure *et al.*, 2015) as was cited by Wojcieszek *et al.* (2018).

2.1 Age, parity and weight

A systematic review and meta-analysis on the major risk factors for SB in high income countries in the preceding two decades identified and selected factors most frequently reported as risk factors for SB was overweight and obesity which were the highest ranking modifiable risk factors followed by advanced maternal age (>35 years) and prim parity according to (Flenady, 2011). Adolescent childbearing, in SSA, and the associated complications were analysed through a systematic literature review and meta-analysis by Grønvik and Sandøy (2018) in their review, they cited (Gibb *et al.*, 2012) and Fall *et al.*, (2015) to have shown the negative effect young maternal age has on adverse obstetric outcomes including SB and the likelihood to persist even after adjustment for socioeconomic factors.

Ganchimeg *et al.* (2013) reported a significant increase in risk of perinatal mortality in babies of teenaged mothers but recorded no significant rise in the numbers of SB. Maternal underweight was also noted to have increased the risk of low birth weight which in turn increase the odds of SB (Patel *et al.*, 2018).Notwithstanding this, Grønvik and Sandøy (2018) observed and argued that

some studies had small sample sizes, which were associated with random variations in the number of cases with complications. The other limitation reported was that births outside the facility in SSA is common and therefore the samples may not be representative of the general population, especially in the rural areas (Moyer and Mustafa, 2013; Diamond-Smith and Sudhinaraset, 2015). A study done in Zambia on determinants of SB also revealed advanced maternal age and overweight to be associated with adverse outcomes including SB (Stringer *et al.*, 2011). A retrospective analysis conducted in six different district facilities in Luapula province of Zambia on perinatal outcomes in adolescent pregnancy, most of whom were prim gravida, revealed that adolescent pregnancy especially in mothers less than 16 years of age had increased odds of perinatal mortality (Moraes, Likwa and Nzala, 2018).

2.2 Education level and employment status

A systematic analysis on national regional and worldwide estimates of SB rate, potential predictors were selected based on plausibility of association with high SBR; socioeconomic factors, demographic and biomedical factors, access to healthcare, antenatal care coverage were investigated and revealed that foetal growth restriction and preterm birth were both associated with increased odds of SB (Blencowe *et al.*, 2016). A comparison between mothers of lower socioeconomic status (SES) attending antenatal care services with those of the higher income bracket was conducted and found the lower SES group to have higher odds of developing obstetric complications like hypertensive disorders of pregnancy even after significant adjustment for adequacy of antenatal care according to Kim *et al.* (2018).

They also found that other risk factors likely to affect obstetric outcomes were occupational factors like long working hours and strenuous physical work activities and among women with lower educational level the probability of poor health seeking behaviour was higher compared to the educated. Whereas the majority of the educated women were from the higher income bracket and had better medical insurance coverage hence tended to have not only more antenatal care reviews but also better health seeking behaviour compared to the women with lower SES (Kim *et al.*, 2018). Majority of the studies in Zambia were in the rural set up where the poverty levels are very high and or high density urban set up which are predominantly of low SES (Turnbull *et al.*, 2011; Moraes, Likwa and Nzala, 2018; Miyoshi *et al.*, 2019).

2.3 Mode and place of delivery

A Meta-analysis of two large WHO multi-country databases aimed at evaluating the mode of delivery and preterm birth outcome was conducted and revealed that despite the caesarean delivery increasing the odds of neonatal intensive care unit admission, the procedure had a contrary effect. This review revealed that caesarean section instead decreased the odds of SB and perinatal mortality because of one possible explanation is that it prevented neonates from the potentially stressful labour encountered during a spontaneous per vaginal delivery (Thanh *et al.*, 2019). This finding was also supported in works done through a Randomized Control Trial (RCT) which demonstrated that preterm pregnancies between 26 to 33 weeks gestation had reduced odds of adverse outcome including SB after undergoing caesarean delivery (Wallace, Schifrin and Paul, 1984).

Increased caesarean section rate is today a timely operative intervention and procedure that often helps improve the perinatal outcomes as this was also evidenced in the Luapula province of Zambia study (Moraes, Likwa and Nzala, 2018). Studies on SB mode of delivery and the association with risk factors are few following literature review on place of delivery and the association with odds of SB notwithstanding this, a cross sectional study done in Michigan, USA, on maternal complications associated with SB delivery mode found that more than 25% of intra-uterine foetal deaths (IUFD) presented in breech presentation and also noted high rates of shoulder dystocia (Gold, 2016). In the Save Mothers, Giving Life (SMGL) 5 year's initiative implementation program and study, delays in seeking medical services known as "the first delay", was attributed to numerous factors. The study program revealed lack of planning for birth, lack of knowledge on pregnancy risk factors, poor perceptions of facility care, poor health seeking behavior including family influence and financial constraints. Following addressing these issues the program reported that the health facility deliveries rose significantly in the selected districts under the project in both countries (Serbanescu *et al.*, 2019).

2.4 Obstetric risks, medical complications and infections

Obstetric and medical complications are also associated with adverse perinatal outcomes as is illustrated in this cross-sectional observational analysis by Gold (2016) involving 543 mothers complications associated with SB conducted in the USA from a large cohort of women found high

incidences of obstetric risks like shoulder dystocia, haemorrhage, retained placenta and clinical chorioamnionitis. The table below is a summary of the maternal complications that were associated with stillbirth deliveries in the Gold (2016) study.

Table 1. 1: Primary and Secondary Delivery Complications for Stillbirths

Complication	Women # (%)
Disseminated Intravascular Coagulation	9 (2%)
Blood loss requiring transfusion	14 (3%)
Shock or hypotension	5 (1%)
Renal failure	8 (1.5%)
Respiratory failure requiring intubation	8 (1.5%)
Diabetic ketoacidosis	4 (<1%)
Sepsis	5 (1%)
Uterine rupture	2 (<1%)
Unplanned hysterectomy	2 (<1%)
Maternal death	1 (<1%)
ANY SERIOUS COMPLICATION*	33 (6%)

Source Gold et al (2016), Maternal Complications Associated with Stillbirth Delivery: a Cross-Sectional Analysis
*Includes any of those listed above since one patient may have multiple complications

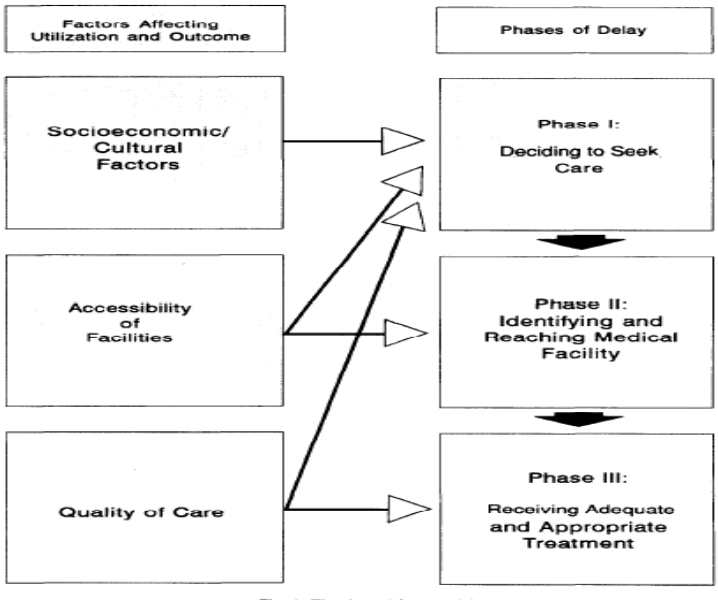
Another medical complication of note that was associated with increased risk of SB is when anaemia was recorded after 20 weeks gestation and maternal underweight (Patel *et al.*, 2018). Turnbull *et al.* (2011) described the causes of mortality during the perinatal and neonatal periods in rural Zambia to be attributed to infections. The Turnbull study used a verbal autopsy methodology and found infection was a very common cause of death across all age strata and despite reviewers' inability to assign causes due to insufficient reports details, among the listed, chorioamnionitis, intrauterine infection and maternal malaria were reported, and was no significant difference in HIV positivity when postpartum women with SB were compared with those without. Contrary to this finding, an observational study done in South Africa by Madhi *et al.* (2019) on 354 SB born to 350 women, obtainable data showed a significant proportion of HIV positive women, foetal and placental invasive bacterial infections were among the other findings. The most common causes reported in the same study were maternal medical complications like hypertensive disorders and diabetes while the main obstetric complication reported was abruption placenta.

2.5 Antenatal booking date, number of antenatal visits and distance to the facility

In low and middle income countries pregnant women tend to enrol late for antenatal care services according to Patel *et al.*, (2018), approximately one third of the pregnant women had their first antenatal visit after 20 weeks gestation of which 90% were anaemic and the majority of these women came from the lower SES bracket, usually individuals disadvantaged in terms of medical care services accessibility and utilisation and were found to be prone to adverse obstetric outcomes including perinatal mortality associated with inadequate antenatal care services (Posthumus *et al.*, 2016) cited by Kim *et al.* (2018). In another study on SB done in Germany found that women of immigrant background were at higher rates of risk factors for SB because among other risk factors inadequate antenatal care due to financial constraints and illegal immigrant status (Reime *et al.*, 2009). In a South African study in Cape Town, (Beauclair, Petro and Myer, 2014) reported on the significance of the effect of the gestation age at first antenatal care visit and the increased odds of ending up with a SB. They further argued that black women are at increased odds of experiencing adverse pregnancy outcomes including SB. However, this finding is generalized on women from lower SES households as in another study it was found and reported that SB and neonatal mortalities were as a result of poor utilization of antenatal care services including late first antenatal care visit and were also inadequately sought (Chopra and Lawn, 2009).

Thaddeus and Maine (1994) conducted a multi-disciplinary literature review to gather data that could be useful in formulating guidelines in an endeavor to prevent maternal deaths. In their findings they identified and conceptualized "three phases of delays" that resulted into maternal mortalities and other adverse outcomes including perinatal mortality. *Phase me* – was noted as the delay by the patient to decide to seek medical attention. The associated factors that lead to this include low SES, distance to facility, family including spousal influence and financial challenges. *Phase II* – Delay to reach the facility due to hindrances like geographical barriers, distance to the facility and transportation costs and poor network. *Phase III* – Delays in receiving appropriate care at facility due to among other challenges sub-optimal referral systems, lack of trained personnel and lack of equipment and shortages of supplies. The figure here below is the illustration of the conceptualized phases of delay.

Figure 2. 1: The three phases of delay model



Source: Thaddeus and Maine (1994) Too far to walk: maternal mortality in context. Social Science & Medicine

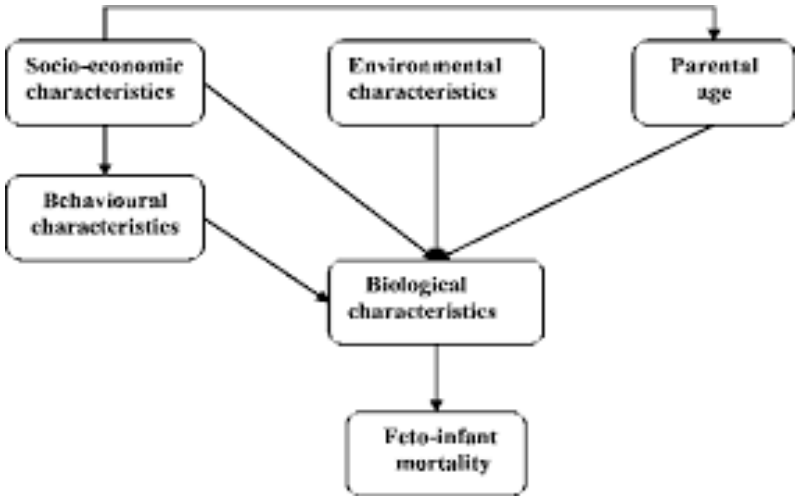
2.6 Conceptual framework

Perinatal mortalities are untimely deaths and remain a major public health challenge especially in the developing countries and have enormous socioeconomic and health complications to communities; they occur due to multi-dimensional interaction of factors relating to maternal lifestyle, and obstetric and medical complications which could be exacerbated by various socioeconomic factors (World Health Organization, 2006, 2018). This conceptual framework is adapted and built on observations from frameworks mainly influenced by (Vandresse, 1987) and Mosley and Chen (1984) who conceptualised the foetal-infant mortality models that considered numerous pathways in their development. The construction of this framework for this study is aimed at highlighting the processes and causes leading to the adverse foetal outcome. Based on this model any relation will be interpreted from an association causal relation perspective between the dependent and independent variables. This framework has 19 independent variables which have a direct or indirect impact on causal association of SB. To ease discussion the framework has been disintegrated hereafter into general pathways and specific pathways.

2.6.1 General Pathways

SB are always a result of failures associated with the biological variables, circumstances surrounding the mothers' situation including occupation or residence may influence the biological characteristics, socioeconomic variables, behavioural variables and environmental variables and affect the proximate variables of the foetus which in-turn affect risk of perinatal mortality (Vandresse, 1987; Jones, 2019) In figure 2.0 the lines represent the causal relation between variables. Where there are no direct lines does not exclude association. However, it may exclude causal association. The determinants of SB are organised into five groups of variables as is shown hereafter in figure 2.0.

Figure 2. 2: General pathway of fetal-infant mortality



Source: Vandresse, M. (1987) A Conceptual Model of Foetal – Infant Mortality

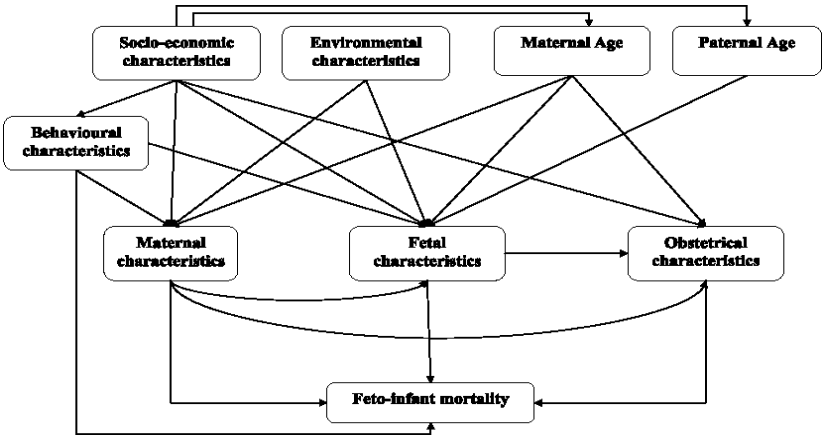
2.6.3 Specific Pathways

Considerations in this part will be on the potential relations between parental age, biological variables, socioeconomic variables, behavioral variables and SB. Unlike what is contained in figure 2.0 the biological characteristics in figure 2.1 are decomposed into maternal, fetal and obstetric characteristics. The socioeconomic variables will include marital status, educational level, occupation and employment status. The behavioral characteristics under consideration are maternal underweight, obesity, smoking, alcohol consumption, drugs and antenatal care first time consultation, frequency and calendar. The environment characteristics will indicate the region of

residence. The maternal characteristics include parity, total number of pregnancies including spontaneous abortions and extra-uterine pregnancies and previous history of SB.

The obstetric characteristics to be looked at are variables linked to complications during delivery like pre-postnatal hemorrhage, labor obstructions, and fibroids in pregnancy, mode of delivery and pre-term birth. Others are previous caesarean section, myomectomy, and premature rupture of membranes. Infections will include any manifested infections like syphilis, Hepatitis B, Tuberculosis, sepsis including malaria and or any infections of viral origin whereas the immune-status (HIV) will be a stand-alone variable. Hypertensive heart disorders (HHD), Diabetes Mellitus (DM), Anemia including sickle cell anemia and other non-communicable diseases (NCD) will be investigated under medical complications. Fetal congenital anomalies will be assessed through physical and gross characteristics and features of the newborn. They will also include features like IUGR, anencephaly, hydrocephaly, hydrops foetalis and spina bifida. There has been growing interest for paternal age as an associated increased risk factor- for congenital anomalies (Vandresse, 1987). Therefore maternal and paternal age will be taken in account as independent variables.

Figure 2. 3: Foeto-infant mortality conceptual framework



Source: Vandresse, M. (1987) A Conceptual Model of Foetal – Infant Mortality

2.6.4 Conclusion

Earlier in this chapter, the definition of perinatal mortality and SB was discussed and its enormous impact it has on the communities. Various search engines including Google scholar and PubMed were explored and a collection of important literature directly or indirectly related to this study was conducted. A global perinatal review and status was highlighted followed by continental and regional, in which of particular importance is South Asia and SSA, which are the most affected regions (Blencowe *et al.*, 2016). The Zambian situation was then reviewed and discussed through available previous studies and surveys.

The main objective of this study is to find out the role of socioeconomic and clinical factors that influence the likelihood of SB. Literature reviews have demonstrated and identified multiple risk factors and their interactive effects between these risk factors resulting in SB (Jones, 2019). To conduct this study, a modified (Vandresse, 1987) and partly (Mosley and Chen, 1984) conceptual framework model were adapted and created to suit this model in an endeavor to disentangle and decompose the complex pathways as is illustrated in the figures 2.0 and 2.1 respectively.

CHAPTER 3

METHODOLOGY

3.1 Study setting and study sites

This investigation was a multi-centre case-control study conducted at five first level hospitals of Lusaka from April to June 2022. Multi-centre studies involve more than one medical or research institution. The study sites will include Chawama, Chilenje, Chipata, Kanyama and Matero first level hospitals. The first level hospitals which are now transitioning to district hospitals (Japanese Embassy, 2018) started operating as first level hospitals around 2012 (Wikipedia Contributors, 2021). The five first level hospitals have the highest number of deliveries in the city and their catchment carters for all the most densely populated and peri-urban regions of Lusaka district. Comprehensive capture of the SBs occurring will ensue from both spontaneous vaginal delivery and operative delivery.

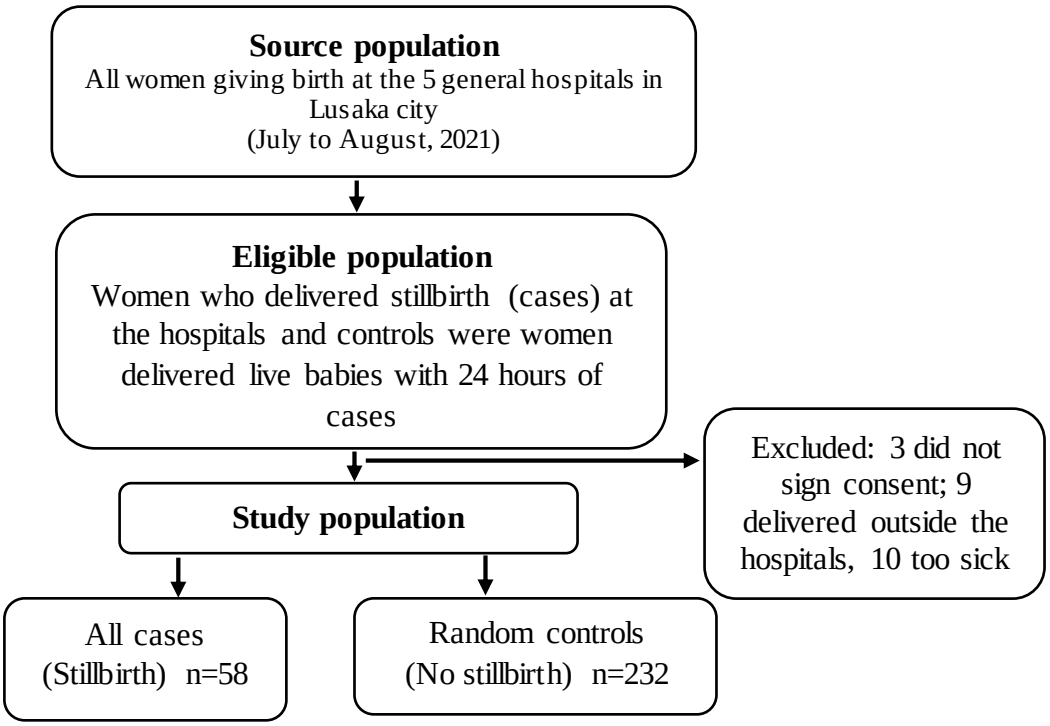
3.2 Study design

The study was aimed at evaluating the factors that are associated with stillbirth in this setting. The subjects were sampled based upon occurrence of stillbirth as cases or presence of viable birth as controls (absence of event). This was an unmatched case-control study conducted from May to June 2022 from the five public general hospitals located in Lusaka city, Zambia. The study involved use of logistic regression methods to analyze factors that are associated with stillbirth by comparing cases (Stillbirths) with controls (livebirths). Cases recruited upon identification of a case, inclusion criteria eligibility, and then successfully obtaining consent. This followed capturing controls systematically randomly selected. Lusaka city is the capital city of Zambia and is it located in the south central of the country. The estimated population of the city is 2.3 million people of which 1 million are female and 1.23 are female (UN, 2022). The projected deliveries for the year are 120, 000 based on anecdotal evidence from previous years' delivery registers. In 2018, the Zambian government through the support of the Japanese government established five general hospitals namely; Chipata, Chilenje, Matero, Kanyama and Chawama. All these hospitals are equipped with basic obstetrics services.

3.3 Study population

For this study, the stillbirth cases were selected from five general hospitals in Lusaka urban namely: Chipata, Chilenje, Matero, Chawama and Kanyama. The controls were selected from the same hospitals from the cases came from in the ratio one to four (1 case: 4 controls). Selection of cases was done consecutively for women of child-bearing age (15-49 years), fresh or macerated still birth, singleton births, birth weight of 1000 grams and above, or gestation age of 28 completed weeks. Controls were women with the reproductive age group who delivered with 24 hours of stillbirth at the same facility. Four controls were randomly selected from the sampling frame per case. We excluded those who did not sign written informed consent, delivered outside the facility and too sick to respond to the questionnaire using the figure demonstrated in the chart below shown hereafter as Figure 3.1

Figure 3. 1: Selection of study participants' flow chart



3.3.1 Inclusion

- Eligible candidates were women from all age strata with gestational age above 28 weeks seeking delivery services.
- Women who ended up with either a fresh or macerated SB at delivery at the study sites. In cases where the mothers with a stillborn did not know the estimated gestation age of the pregnancy inclusion was determined by birthweight of 1000g. This is in line with the World Health Organization (2015) definition where gestation age is not known the newborn birthweight was be used.

Eligible study participants were run through the participant information sheet, counselled and told about the study objectives. Those willing to participate, had informed consent obtained for recruitment into the study accordingly.

3.3.2 Exclusion Criteria

- All pregnant women with an abortus; or overwhelming evidence of probable cause of death like trauma not attributed to the birthing process.
- Mothers who did not consent to participating in the study; delivered out of the facility; or severely ill; not in a state to respond to the questionnaire; and or where maternal mortality was involved.
- Mothers who had neonatal demise were also not be eligible. Clients who chose not take part in the study were free to withdraw at any point during the data collection process.

3.4 Sample size

Sample size calculation was done using A G*Power software for power analysis was used (Aysel *et al.*, 2019) based on the following assumptions that three controls for per case, power of the study 80% (type II error 20%), 95% confidence interval with 5% type I error, proportional of risk factors in the control participants of 0.33% and cases with potential risk factors to stillbirth of two and half times as likely to be exposed to stillbirth compared to controls (odds ratio = 2.5). Therefore, the calculated sample size was 58 cases and 232 controls Based on the District Health Information system in 2021 Lusaka had 129,418 deliveries.

3.5 Sampling technique

Sample from each hospital was based on probability proportion to size after considering the annual stillbirth reports for each facility most recent calendar year (January to December 2020). Matero General Hospital 10 cases and 40 controls, Kanyama General Hospital 13 cases and 52 controls, Chilenje General Hospital two cases and eight controls, Chawama General Hospital 21 cases and 84 controls and Chipata General Hospital 13 cases and 52 controls. Cases were consecutively enrolled but controls were randomly sampled with 24 hours of a stillbirth from a sampling frame that was made before women are discharged in each hospital. The recruitment of the sample from the facilities into the study was conducted using probability proportional to sample size.

3.6 Study variables

The outcome variable was stillbirth coded (1=stillbirth, 0=livebirth), socio-demographic characteristics were age (≤19, 20 – 34, ≥35 years), education level (no education/primary, secondary, tertiary), marital status (married, single), employment status (employed , not employed), Christian denomination (Catholic, Pentecostal, Protestant, other); behavioral characteristics were alcohol (yes, no) smoker (yes, no), Obstetrics characteristic such as time taken to reach the facility (……) mode of transport (walking, public transport, owner transport) sex of the baby (male, female), mode of delivery (vaginal, cesarean section), parity ≤2, >2) antepartum hemorrhage (yes, no) birth weight (≤2500, >2500) history of pregnancy loss (yes, no), preeclampsia (yes, no), hypertension (yes, no) HIV status (positive, negative), history of preterm (yes, no), antenatal booking (≤12 weeks, >12 weeks) and history of stillbirth (yes, no).

3.7 Data collection tool

We developed a questionnaire based on previous studies. One of the principal investigators created an electronic questionnaire with the tool *XLS Form* and uploaded on ONA server. Data was collected using Open Data Kit (ODK) application which allows collection of data using Android-based tablets in real-time; and ODK Aggregate facilitated data storage. The investigators were constantly conducting data monitoring and management in real-time. At the end of data collection, it was downloaded in excel format and cleaned for analysis.

3.8 Data analysis

Data collection process used Open Data Kit and served on ONA server. Data was later downloaded into excel spreadsheet then exported into Stata 16 software (Stata Corp; College Station, Texas, USA) for analysis. Summary proportions and frequencies for cases and controls were obtained to descriptive statistical analyses. Univariate logistic regression analysis was conducted to obtain the crude association between stillbirth and independent variables. A p-value of ≤0.2 was used as a cut-off for independent variables that showed association with stillbirth. This was followed by multivariable logistic regression analysis to show to demonstrate association when the p-value was < 0.05. We utilized a sequential elimination of candidate determinants by checking on the strength and significance of the variable with stillbirth. Also, discrimination and calibration of the model were checked. Variables such as age and birth weight although they were collected as continuous variables they were introduced in the model as categorical variables since this is more intuitive from clinical point of view. To assess the ability of the model to allocate the appropriate risk, we calibrated the model using Hosmer and Lemeshow goodness of fit test. The interpretation of Hosmer and Lemeshow goodness of fit test was considered accurate prediction when it yielded a non-significant p- value ($p \leq 0.05$). For model stability, measured by discrimination and differentiated participants with stillbirth from those without, was assessed by using area under the receiving characteristics curve. We considered area under the curve of more than 0.7 as acceptable. (Kleinbaum and Klein, 2012). We utilized strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines in reporting this study (von Elm et al., 2007).

3.8.1 Ethical oversight

Ethical approval for this study was obtained from University of Zambia Biomedical Research Ethics Committee (reference number: 1463-2021) and further permission was obtained from the Zambia National Research Health Authority (reference number: 000050/30/03/2022). Confidentiality and privacy were maintained for the women. Assurance was made that they were free to withdraw from the study at any time without affecting their healthcare. Except for this disclosure, all information obtained in this study was confidential and used only for research purposes. Their identity was to be kept confidential as far as the law allows.

CHAPTER 4

RESULTS

4.1 Description of study participants

4.1.1 Social-demographic characteristics

In this study, there was a total of 290 participants, 58 cases and 232 controls with ratio one to four respectively. More than three-quarters of the cases (77.6%) and about slightly below three quarters of the controls (74%) belonged to age group 20 – 34 years. Slightly above half in both cases (52.6%) and controls (51.1%) had secondary education as their highest education level. Those who were not employed were 73.7% and 70.7% in the cases and controls respectively. Majority (64.7%) in the cases and 80.6% in the controls were married. More than four-fifth in cases (80.7%) and controls (85.5%) were not taking alcohol. Slightly below half (48.2%) of the cases and 52.0% of the controls were walking to the facility to access antenatal care. Majority in both cases (82.7%) and controls (92.5%) had vaginal delivery. More than three-quarters of the cases (79.2%) and control (52.4%) had less than or equal to two children. More than one-tenth (14.1%) of the cases and less than one-fifth of the controls experience vaginal bleeding. More than two-thirds of the cases (72.7%) and less than one-third of the controls (28.3%) delivered babies less than or equal to 2500 grams. In both cases and controls, less than one-fifth 17.5% and 10.7% were HIV positive respectively. Almost a quarter (24.1%) in the cases and 12.3% in the controls had history of pregnancy loss (Table 1).

Table 4. 1: Social, behavioral and obstetrics characteristics of cases and controls, Lusaka, Zambia April – June 2022.

Characteristics	Cases (n = 58)		Control (n = 232)		Total (n = 290)	
	n	%	n	%	n	%
Age (years)						
≤ 19	8	13.8	27	11.9	35	12.3
20 – 34	45	77.6	168	74.0	213	74.7
≥ 35	5	8.6	32	14.1	37	12.9
Education level						
Primary/no education	24	42.1	92	40.5	116	40.9
Secondary	30	52.6	116	51.1	146	51.4
Tertiary	3	5.3	19	8.4	22	7.8
Employment status						
employed	15	26.3	66	29.3	81	28.7
Not employed	42	73.7	159	70.7	201	71.3
Marital status						
Married	37	64.9	183	80.6	220	77.5
Single	20	35.1	44	19.4	64	22.5
Christian denomination						
Catholic	14	24.6	35	15.4	49	17.3
Pentecostal	22	38.6	102	44.9	124	43.7
Protestant	16	28.1	76	33.5	92	32.4
Other	5	8.8	14	6.2	19	6.7
Take alcohol						
Yes	11	19.3	33	14.5	44	15.5
No	46	80.7	194	85.5	240	84.5
Time taken to facility(minutes)						
≤ 60	53	94.6	206	92.8	259	93.2
>60	3	5.4	16	7.2	19	6.8
Mode of transport						
Walking	27	48.2	117	52.0	144	51.3
Public	5	8.9	37	16.4	42	14.9

Personal vehicle	24	42.9	71	31.6	95	33.8
Sex of the baby						
Male	29	50.0	114	50.2	143	50.2
Female	29	50.0	113	49.8	142	49.8
Mode of delivery						
Vaginal	48	82.7	211	92.9	259	90.9
Cesarean section	4	6.9	16	7.1	20	7.1
Parity category						
≤ 2	46	79.3	119	52.4	165	57.9
> 2	12	20.7	108	47.6	120	42.1
Antepartum hemorrhage						
Yes	8	14.1	8	3.5	16	5.6
No	49	85.9	219	96.5	268	94.4

Socio-demographic, behavioral and obstetrics characteristics of cases and controls Lusaka, Zambia, April – June 2022 continued….

Characteristics	Cases		Control		Total	
	n	%	n	%	n	%
Birth weight (grams)	40	72.7	60	28.3	100	37.4
< 2500	15	27.3	152	71.7	167	62.6
≥ 2500						
History of pregnancy loss						
Yes	14	24.1	28	12.3	42	14.7
No	44	75.9	199	87.7	243	85.3
Hypertension						
Yes	4	4.9	25	11.1	29	10.2
No	54	93.1	201	88.9	255	89.8
Preeclampsia						
Yes	7	12.1	16	7.2	23	8.2
No	51	87.9	207	92.8	258	91.8
Times taken Fansidar						
< 5	40	68.9	166	73.1	206	72.3
≥ 5	18	31.1	61	61.9	79	27.7
HIV status						
Positive	10	17.5	24	10.7	34	12.1
Negative	47	82.5	201	89.3	248	87.9
History of preterm						
Yes	2	3.5	12	5.3	14	4.9
No	55	96.5	214	94.7	269	95.1
History of stillbirth						
Yes	17	29.3	13	5.8	30	10.6
No	41	70.7	213	94.3	254	89.4
Antenatal booking (weeks)						
≤12	20	35.1	47	20.9	67	23.8
>12	37	64.9	178	79.1	215	76.2

HIV = Human immunodeficiency viru

4.2 Determinants of stillbirth

The association between each independent variable and stillbirth was assessed using binary logistic regression model. The regression showed that marital status, parity, antenatal booking, birth weight, history of pregnancy loss, history of stillbirth and antepartum hemorrhage showed significant association with stillbirth occurrence in the model. In the multivariate regression model, parity, birth weight, history of pregnancy loss and history of stillbirth remained significantly association with high likelihood of experiencing stillbirth. Women who had more than two children were 3 times (P-value of 0.036) more likely to have stillbirth than those who had less than two children (AOR = 3.02; 95% CI: 1.07 – 7.54). Women who delivered babies with birth weight equal to or more than 2500 grams were 4.45 times more likely to have stillbirth than their counterparts who had babies less than 2500 grams. (AOR = 4.49; 95% CI: 2.84 – 8.99) Those who reported a history of stillbirth were 4 times (p-value of 0.001) more likely to have stillbirth compared to women who had no history of stillbirth (AOR = 3.99; 95% CI: 1.73 – 9.73): as shown in Table 2.

Table 1**:** Determinants of stillbirth from the logistic regression model, Lusaka City, Zambia April – June 2022.

Characteristics	**COR**	**P-value**	**AOR (95% CI)**	**P-value**
Age (years)				
≤19	Ref			
20 – 34	1.10 (0.47 – 2.60)	0.817		
≥35	1.89 (0.55 – 2.61)	0.308		
Education				
Primary/no education	Ref			
Secondary	1.01 (0.55 -1.82)	0.978		
Tertiary	1.65 (0.45 – 6.04)	0.448		
Employment status				
Employed	Ref			
Not employed	0.86 (0.44 – 1.65)	0.653		
Marital status				
Married	Ref			
Single	0.44 (0.23 – 0.84)	0.013	0.57 (0.24 – 1.31)	0.184
Christian denomination				

Catholic	Ref			
Pentecostal	1.85 (0.85 – 4.01)	0.117		
Protestant	1.9 (0.83 – 4.31)	0.126		
Other	1.12 (0.33 – 3.69)	0.856		
Parity category				
≤ 2	Ref			
> 2	3.4 (1 75 – 6.91)	<0.001	3.02 (1.07 – 7.54)	0.036
APH				
No	Ref			
Yes	4.46 (1.59 7.99)	0.004	3.18 (1.21 – 8.09)	0.011
Antenatal booking (weeks)				
≤ 12	Ref			
> 12	2.04 (1.10 – 3.85)	0.031	1.65 (0.66 – 3.2)	0.353
Birth weight (grams)				
< 2500				
≥ 2500	5.52 (2.47 – 9.23)	<0.001	4.49 (2.84 – 8.99)	0.001
History of pregnancy loss				
No	Ref			
Yes	2.26 (1.10 – 4.23)	0.021	1.98 (0.72 – 3.98)	0.185
Hypertension				
No	Ref			
Yes	0.59 (0.29 – 1.16)	0.355		
Preeclampsia				
No	Ref			
Yes	1.77 (0.69 – 4.54)	0.231		
HIV status				
Negative	Ref			
Positive	1.78 (0.78 – 3.97)	0.199		
History of stillbirth				
No	Ref			
Yes	4.18 (2.01 – 5.97)	<0.001	3.99 (1.73 – 6.73)	0.004

COR = crude odds ratio; AOR = adjusted odds ratio; Ref = reference category

CHAPTER 5

DISCUSSION

5.0 Discussion

This unmatched case-control study focused on the determinants of stillbirths among women who delivered at the five general hospitals of Lusaka district, Zambia. This investigation was aimed at evaluating the distribution and determinant of fresh stillbirths and macerated stillbirth among mothers who access delivery services the aforementioned facilities. These facilities jointly serve and have the highest volume of maternity services: antenatal care and delivery services in the country. The proportion of stillbirths in Zambia is more than what is experienced in developed countries and far behind in terms of achieving the SDG goal and the Vision 2030 (MoF, 2006; World Health Organization, 2015a). This study presents results indicative of stillbirths' determinants in a setting representative of most low resource settings of LMIC like Zambia. While tremendous history achievements have been for women and children's health in the past 20 years. This is evidenced by the sharp decline in stillbirth rate since the launch of the MDGs in the year 2000. Most advanced countries have had their maternal and child health key performances indices like perinatal rate improve (Blencowe *et al.*, 2016; Frederik Frøen *et al.*, 2016).

On the other hand LMIC countries situation has had little or no change as has been pointed out in earlier chapters of this paper. This study just further consolidates what other authors have reported regarding the stillbirths situation in LMIC settings like Zambia. The results of this study showed mothers that have parity of greater than two have higher odds of experiencing stillbirth compared to those with less than two. This has also been found and reported in other studies where extremely high parous women odds ratio for stillbirth increases with unit increment in number of prior live births (Aliyu *et al.*, 2005). Babies with birth weight of above 2500 grams had high odds of demise compared to those less than 2500g. The odds of experiencing stillbirth were found to be four and half times higher among women who gave birth to babies with birth weight equal or more than 2500 grams compared to women who gave birth to babies to babies less than 2500 grams. This finding is inconsistent with a previously published article on a study done in Lusaka, Zambia, that

demonstrated low birth weight being a high risk factor for stillbirth (Chibwesha *et al.*, 2016). However, in another study done in Harare, Zimbabwe foetal demise with increase in gestation age was noted in their cohort study. The authors attributed the occurrence to later than 28 week antenatal care and missed an opportunity where screening for risk factors could have been done. Therefore, risk of stillbirth was much higher in mothers who did not have antenatal care compared to those that had had the service in the earlier gestational ages (Feresu *et al.*, 2005). Other authors have also reported higher odds of stillbirths among normal birth weight babies being associated with inadequate prenatal care which could have been a result of missed detection of foetal infection during pregnancy especially in poor resource settings (Goldenberg and Thompson, 2003). The increased risk in the latter may be explained by difficulty in delivery of a large or abnormally presenting infant during labour, leading to prolonged labour, foetal distress and death (Chuwa *et al.*, 2017)

It was noted that history of stillbirths in this study, and history of antepartum haemorrhage were significant determinants of stillbirth. This is in keeping with a previous similar but larger study done in about 26 facilities in Lusaka. In addition, to prior history of stillbirth being a determinant of stillbirth: it was observed that previous history of preterm delivery was also associated with high risk of subsequent poor outcome including stillbirth (Stringer *et al.*, 2011).

Another observation of note is antepartum hemorrhage as a determinant factor for stillbirth. This has also been demonstrated by various other authors including a study from Ethiopia which cited antepartum hemorrhage as a determinant for stillbirth (Getachew *et al.*, 2012). The authors also reported that association of antepartum hemorrhage and stillbirth could be a reflection of poor quality care during childbirth or inadequate maternity services in a particular region or facility. Bleeding in pregnancy may also result in preterm labour and delivery, foetal death due to inadequate blood supply. Therefore, active heighten and persistent monitoring strategy should be in place to identify women who are likely to experience APH especially that it may occur without warning signs.

Antenatal care booking in this study had no significant bearing on our dependent variable following regression analysis. Regardless of this, evidence suggests that pregnant women who start antenatal care early, within first trimester, have reduced odds of experiencing stillbirth than those who start after first trimester (Mekonnen Dagne, Takele Melku and Abdurkadir Abdi, 2021).

This was in line with our finding though did not reach statistical significance probably because our study was not powered for this variable. Another plausible explanation could be that late antenatal initiation does not offer sufficient time to screen and detect risks and appropriate interventions by health care professional to prevent stillbirth as was shown in the Zimbabwe study (Feresu *et al.*, 2005).

Other important discussion points that did not show statistical significance in this study are Diabetes Mellitus, anaemia, and infections like HIV, syphilis, Tuberculosis, chorioamnionitis and malaria in pregnancy. While previous studies done in Lusaka, Zambia reported significant evidence of perinatal mortality associated with infectious conditions like HIV, syphilis, chorioamnionitis and malaria (Stringer *et al.*, 2011). This study showed no statistical significance with the aforementioned infectious conditions. One plausible explanation to this is the Prevention of Mother to Child Treatment (PMTCT) program rolled out: now Elimination of Mother to Child Treatment (eMTCT). And the increase in adherence to antiretroviral drugs uptake including presumptive and prophylactic treatment of Malaria, Tuberculosis, and Cryptococci meningitis as standard care during antenatal care to all HIV positive mothers (UNAIDS, 2016). Other studies have reported conditions like being prim gravida and anaemia as some of the leading maternal causes of intrauterine demise as well as foetal congenital anomalies. However, in this investigation these variables did not show any statistical evidence as determinants of stillbirth in the regression analysis (Jamal and Agarwal, 2017). A possible explanation is that probably the study design and sample size for study could be a contributing factor as well as may a longer study duration could have given a different picture. In addition to the above, much as the study sites are able to conduct most basic obstetric procedures certain cases that have high incidence rates of intrauterine demise like DM and Sickle Cell Disease are referred to tertiary facilities. Therefore, this could have led to such high risk cases not being captured at the study sites for investigation.

There are several limitations to this study. First, there was no clinical examination of the cases reported. Therefore, the potential risk factors for antepartum stillbirth, such as placental insufficiency could not have been identified and recorded that way. For instance, women with hypertensive disorders during pregnancy are more likely to have placental compromise, and thus a higher risk for foetal death. Secondly, this is a case-control study, which can only show the

association between the various risk factors but cannot causal relationship. Thirdly, there is a possibility that maternal medical conditions were not thoroughly examined during clinical assessment prior to admission and thus risk factors like hypertensive disorders in pregnancy, diabetes may not have been properly documented. Fourth, this was a hospital-based study, thus, the background characteristics of the women with stillbirths might not be the same at the population level therefore our study cannot be generalized.

5.1 Conclusion

In conclusion the study suggest that the determinants of stillbirth are birthweight greater than 2500 grams, parity greater than two, antepartum hemorrhage and history of stillbirth. Therefore, it is recommended that active surveillance during antenatal care for women likely to develop antepartum hemorrhage and those with previous record of stillbirth should be enforced to reduce stillbirth. Also, women should be encouraged to be having fewer number of children.

5.2 Recommendations

Literature review had shown that cause of stillbirth is as a result multi-faceted and interlinked factors. These include socioeconomic, cultural, demographic, medical and obstetrics factors as well as health systems. Therefore, to have a health newborn there has to be optimal interaction of the above variables. As a matter of consequence the failure of optimal interaction of these factors not only leads to stillbirth and or perinatal mortality but assignment of the cause remains a nightmare. The closest we can come to understanding and assignment of the cause of death requires interventions like investigation to become standard practice. Post-delivery investigations on these cases to would shade more light and take a different dimension. This would involve investigations like cord blood samples for screening, placental examination and histopathology, and even post-mortems. Therefore, it important for policy makers to realize that and take deliberate actions to reduce this public health challenge. More higher powered study designs are needed to scope out the trends of this condition in our country and analyze what has and had not worked.

5.3 Conflict of interest

All authors declare no conflict of interest

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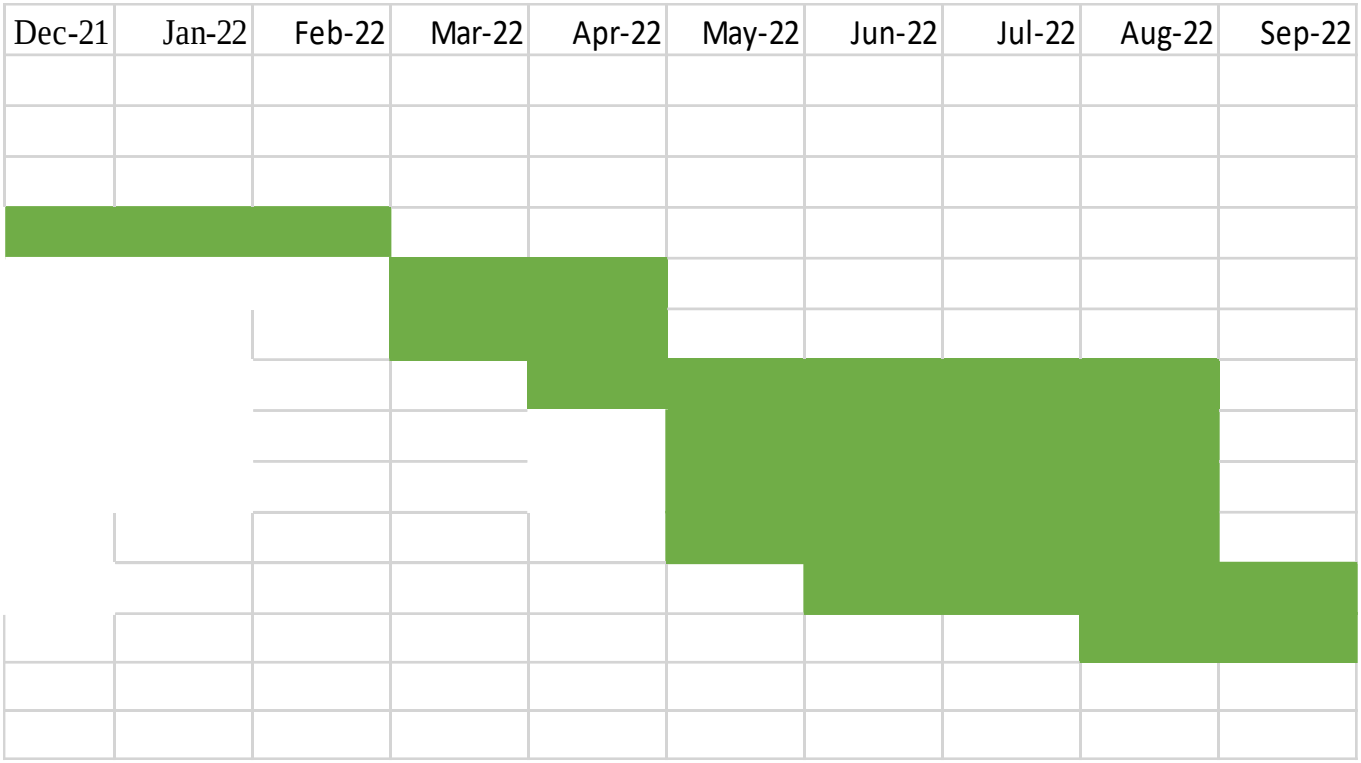
APPENDICES

Appendix 1: Work plan



Appendix 2: Budget

S/N	Item	Unit cost	No of units	Total		
1	Stationery	100	1	100		
2	Orientation	1000	1	1000		
3	Transport	20	60	1200		
4	Ethics review	1000	1	1000		
5	Contingency	0.1	13800	1380		
6	Printing	300	1	300		
7	Publication	2000	1	2000		
8	Research Assistants	500	5	10000		
9	Data bundles	200	6	1200		
	Grand Total			**18180**		

Appendix 3: Information Sheets

Participant information sheet

Research study title

Determinants of stillbirths among women who deliver at the five general hospitals of Lusaka urban district.

Principal Investigator

Musonda Makasa, Master of Public Health candidate, School of Public Health, University of Zambia, Lusaka. Contact number +260 978888435

Purpose and Background

The United Nations adopted an agenda for sustainable development goals and targeted reduction of Stillbirth mortality to 12 per 1000 live births by 2030. A Meta – analysis by Blencowe *et al.* (2016) reported that there has been global a decline from the year 2000 to 2015 from 24.7 to 18.4 per 1000 live births. However, sub – Saharan Africa stillbirth remains high 28.7 per 1000 live births, whereas in Zambia reported Stillbirth rate of 30.5 per 1000 (Serbanescu *et al.*, 2019). Most of the studies done previously on this subject in Lusaka were before the commissioning of the five general hospitals (Wikipedia Contributors, 2021). The rationale of this investigation is to find out what strides and developments that have been achieved so far in these hospitals of Lusaka urban. The information obtained will enable us to make inferences on what sort of further research needs to be conducted based on the outcomes.

Procedures:

If you agree to participate, the following things will happen:

1. We will review the relevant information from your file and hospital records. In an event of inadequate information from the patient file and records. You will undergo which will be carried out at the respective study sites. The interview will involve inquiring details about your basic biological, demographic, medical and socioeconomic situation.
2. You will not be exposed to anything outside standard medical management and treatment of your condition.
3. The information obtained is not intended and will not be used for monetary gain.
4. Your name and other detail will strictly be kept confidential, anonymised and solely research purposes. You will be assigned a study number which will be assigned to the questionnaires.

Benefits

If you agree to participate in this study, your case will be examined thoroughly, including details on your earlier discussed biological, demographic, medical and socioeconomic situation. The finding of the study will help not only inform and improve clinical best practices but basis for policy framework changes.

Risks

This process involved engaging the study participants into a sensitive discourse in view our outcome variable of interest. The experience of having a stillborn was potentially going to course emotional distress and therefore to mitigate this risk. Adequate counselling was conducted by qualified counsellors followed by thorough evaluation whether a participant fit in the inclusion criteria.

Confidentiality

The results of all the study will be discussed with you, and kept confidential unless you wish otherwise). Except for this disclosure, all information obtained in this study will be considered confidential and used only for research purposes. Your identity will be kept confidential as far as the law allows.

Right to refuse or withdrawal

Your participation in the study is entirely voluntary, and you are free to refuse to take part or withdraw at any time without affecting or jeopardizing your future medical care.

Questions

……, the researcher has discussed this information with you and offered to answer your questions. If you have further questions, you can contact him on 0977349386 or the Chairperson of Research Biomedical Ethics Committee at University of Zambia, School of Medicine on telephone 0211 256067.

Appendix 4: Consent form

INFORMED CONSENT FORM

I confirm that I have understood the information I have been given about the study. I agree to participate in this study. I confirm that I am joining the study of my free will and I can withdraw at any time without affecting the care available to me. I understand what will be required of me.

Participant's Signature.....

Or thumb Print.....

Date.....

Witness (Name and Signature).....

Date**.....**

Declaration

I (the researcher), confirm that I have explained the information fully and answered any questions.

Signed for the study team

Name…….....

Date……

Appendix 5: Questionnaire

THE UNIVERSITY OF ZAMBIA
SCHOOL OF PUBLIC HEALTH
DEPARTMENT OF COMMUNITY AND FAMILY MEDICINE

My name is Musonda Makasa. I am a student pursuing a Master of Public Health degree under the school of Public Health at the University of Zambia.

Women of reproductive age are being affected by the Fresh and Macerated Stillbirths yet there is little data explaining this disease. I am doing a research to investigate the levels of biological, demographic, medical and socioeconomic disparities among women with stillbirths and also to assess the distribution of the events among different age groups.

By answering the questions below you will be helping to provide the necessary information required for the research.

All answers are confidential and you will not be identified from the information provided. Please mark the appropriate box with a tick. Some questions require you to give a short answer.

Section 1: Demographic and socio-economic characteristics

1. What is your age at last birthday?
   …….

2. What is your marital status?

1. Single
2. Married
3. Divorced
4. Widow

3. How old is your partner?
   ……

4. What is your weight in Kg's?
   …….

5. How many children do you have?

   ……

6. What denomination do you belong to?

    1. Roman Catholic
    2. Jehovah's Witness
    3. Seventh day Adventist
    4. Pentecostal
    5. Other (Specify) ……..

7. What is the highest level of education you have attained?

    1. No education
    2. Primary (Grade1-7)
    3. Secondary (Grade 8-12)
    4. Tertiary (college/university)

8. What is your employment status?

    1. Formal
    2. Informal
    3. Unemployed

9. What is your average monthly income?

    1. Less than K2,000
    2. Between K2,000 and K5,000
    3. Between K5,000 and K10,000
    4. Above K10,000

10. How would you describe the area where you live?

    1. High density
    2. Medium density
    3. Low density

11. Do you own the house you are living in?

    1. Yes
    2. No

12. What is the total number of people living in your household?
    ……

13. Do you own a vehicle?

    1. Yes
    2. No

14. Is your home more that 5km from the hospital?

    1. Yes
    2. No

Section 2: Determinants (health-related) of stillbirth

15. Do you drink alcohol?

    1. Yes
    2. No

16. Do you smoke cigarettes?

    1. Yes
    2. No

17. Do you partake in any illegal/illicit drugs?

    1. Yes
    2. No

18. Did you experience any bleeding during this pregnancy?

    1. Yes
    2. No

19. When did you start going for ANC?
    ……..

20. How many times did you have ANC check-ups before delivery?
    …….

21. Are you Hypertensive?

1. Yes
2. No

22. Did you have Pre-Eclampsia during this pregnancy?

1. Yes
2. No

23. Did you have Eclampsia during this pregnancy?

1. Yes
2. No

24. Are you Diabetic?

1. Yes
2. No

25. Have you ever suffered from Tuberculosis?

1. Yes
2. No

26. What is your HIV status?

1. Negative
2. Positive

27. What was you previous mode of delivery?

1. Vaginal birth
2. Caesarean birth

28. Have you had a preterm baby before?

1. Yes
2. No

29. Tick the symptoms you have experienced before

1. Miscarriages (Abortions)
2. Anaemia
3. Sickle – Cell Anaemia
4. Cardiovascular Condition
5. COVID -19 infection during pregnancy
6. History of COVID-19
7. Dizziness during menstruation

Section 3: Prevalence of stillbirths

30. Have you ever had a stillbirth?

    1. Yes
    2. No

31. Were you treated for that stillbirth?
    1. Yes
    2. No

32. How many stillbirths have you ever had?
    ……

33. Were there any gross anomalies?

    1. Yes
    2. No

34. Were these anomalies treated?
    1. Yes
    2. No

Appendix 6: Research Ethics Letter of Approval

UNIVERSITY OF ZAMBIA

BIOMEDICAL RESEARCH ETHICS COMMITTEE

Telephone: +260 977925304 Ridgeway Campus

Telegrams: UNZA, LUSAKA P.O. Box 50110

Telex: UNZALU ZA 44370 Lusaka, Zambia

Fax: + 260-1-250753 E-mail: unzarec@unza.zm

Federal Assurance No. FWA00000338 IRB00001131 of IORG0000774

23rd March, 2022

Your REF. No. 1463-2021

Dr. Musonda Makasa,

University of Zambia,

School of Public Health,

P.O Box 50110,

Lusaka.

Dear Dr. Makasa,

RE: DETERMINANTS OF STILLBIRTHS AT TERTIARY AND FIRST LEVEL HOSPITALS IN LUSAKA DISTRICT, ZAMBIA (REF. NO. 1463-2021)

The above-mentioned research proposal was presented to the Biomedical Research Ethics Committee on 19th February, 2022. The proposal is **approved**. The approval is based on the following documents that were submitted for review:

a) Study proposal

b) Questionnaires

c) Participant Consent Form

APPROVAL NUMBER: REF. 1463-2021

This number should be used on all correspondence, consent forms and documents as appropriate.

- **APPROVAL DATE: 23rd March 2022**
- TYPE OF APPROVAL: Standard
- **EXPIRATION DATE OF APPROVAL: 22nd March 2023**

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

 SERIOUS ADVERSE EVENT REPORTING: All SAEs and any other serious challenges/problems having to do with participant welfare, participant safety and study integrity must be reported to UNZABREC within 3 working days using standard forms obtainable from UNZABREC.

 MODIFICATIONS: Prior UNZABREC approval using standard forms obtainable from the UNZABREC 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 UNZABREC using standard forms obtainable from the UNZABREC Offices.

 NHRA: You are advised to obtain final study clearance and approval to conduct research in Zambia from the National Health Research Authority (NHRA) before commencing the research project.

 QUESTIONS: Please contact the UNZABREC on Telephone No. +260977925304 or by e-mail on unzarec@unza.zm.

 OTHER: Please be reminded to send in copies of your research findings/results for our records. You are also required to submit electronic copies of your publications in peer-reviewed journals that may emanate from this study. Use the online portal: unza.rhinno.net for further submissions.

Yours sincerely,

Sody Mweetwa Munsaka, BSc, MSc., PhD

CHAIRPERSON

Tel: +260977925304

E-mail: s.munsaka@unza.zm

Appendix 7: NRHA letter of authority to conduct research

Tell: +260211 250309 | Email: znhrasec@nhra.org.zm | www.nhra.org.zm
Chalala Office Lot No. 18961/M, Off Kasama Road, P.O. Box 30075, LUSAKA
Paediatric Centre of Excellence, University Teaching Hospital, P.O. Box 30075, LUSAKA

NATIONAL HEALTH RESEARCH AUTHORITY

Ref No: NHRA000050/30/03/2022 Date: 30th March, 2022
The Principal Investigator,
Musonda Makasa,
University of Zambia,
Lusaka, Zambia.

Dear Musonda Makasa,

Re: Request for Authority to Conduct Research

The National Health Research Authority is in receipt of your request for authority to conduct research titled **"Determinants of Stillbirths among Women Who Deliver at First Level Hospitals in Lusaka District of Zambia."**
I wish to inform you that following submission of your request to the Authority, our review of the same and in view of the ethical clearance, this study has been **approved** on condition that:
1. The relevant Provincial and District Medical Officers where the study is being conducted are fully appraised;

2. Progress updates are provided to NHRA quarterly from the date of commencement of the study;

3. The final study report is cleared by the NHRA before any publication or dissemination within or outside the country;

4. After clearance for publication or dissemination by the NHRA, the final study report is shared with all relevant Provincial and District Directors of Health where the study was being conducted, University leadership, and all key respondents.

Yours sincerely,
Prof. Godfrey Biemba
Director/CEO
National Health Research Authority

UN. (2022). *World Population Prospects*. United Nations Department of Economic and Social Affairs Population Division. https://population.un.org/wpp/