FACTORS ASSOCIATED WITH OBSTETRIC FISTULA REPAIR FAILURES AT ST. FRANCIS AND MONZE MISSION HOSPITALS, ZAMBIA, 2010—2016; A RETROSPECTIVE FACILITY BASED COHORT

By

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A dissertation submitted to the University of Zambia in partial fulfilment of the requirements of the degree of Master of Science in Epidemiology

THE UNIVERSITY OF ZAMBIA

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DECLARATION

This dissertation is the original work of **Fred Kapaya**. It has been produced in accordance with the guidelines for Master of Public Health by Research dissertation for the University of Zambia. It has not been submitted elsewhere for a degree at this or another University.

Protocol Reference No. 2017-July-o28

Ethics Committee Approval Date: 08/09/2017

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ABSTRACT

Obstetric fistula causes significant maternal morbidity especially in sub-Saharan African. In Zambia the prevalence is about 0.53%. Despite a number of women receiving corrective surgery for fistula at a number of hospitals in Zambia, there is paucity of data on the quality of care. This study was conducted to determine the overall proportion of fistula repair failures and identify factors associated with failure in Eastern and Southern Provinces, Zambia.

This was a retrospective cohort study using data extracted from hospital records of obstetric fistula repairs between January 2010 to December 2016 at St. Francis and Monze Mission Hospitals which are among the four major fistula repair hospitals in Zambia. All women who underwent repair for obstetric fistula between 2010 and 2016 were included while non obstetric fistulas and lack of dye test results at discharge were excluded from the study. The outcome of interest was failure of fistula repair at hospital discharge confirmed by a dye test. Descriptive statistics were calculated and STATA version 13 used to conduct multivariable logistic regression to determine factors associated with failure of fistula repair.

A total of 453 obstetric fistula repairs were included in the analysis. Of these, 56 (12.4%) had failure of fistula repair at hospital discharge. The median age at fistula development was 23 years; at fistula repair was 27 years; and years with fistula was 1 (IQR: 0–5). In multivariable logistic regression, factors associated with increased odds of failure included having a fistula with urethral involvement (55.4 % versus 14.1%; AOR=6.0, 95% CI: 2.83—12.97; vaginal scarring (46.4% versus 18.6%; AOR=2.5, 95% CI: 1.17—5.35 ;) and experiencing post-operative complications (48.2% versus 2.3%; AOR=22.9, 95%CI: 9.33—55.97).

Women with vaginal scarring, urethral involvement and post-operative complications, had greater odds of repair failure. It is therefore recommended that quality of post-operative care be improved and caution be paid to the repair of women who present with urethral damage, vaginal scarring and post-operative complications. The evidence generated would help the Ministry of Health to restructure and improve fistula care programs in Zambia.

Key words: Obstetric fistula, Repair failure, Retrospective cohort, Zambia

ACKNOWLEDGEMENTS

I would like to thank the following without whose contributions, support and guidance my work would not have been successful:

Prof. Charles Michelo, my supervisor for the unwavering encouragement and support during the research;

Mr. Mumbi Chola, my co-supervisor for encouragement, support and guidance in the research process.

I wish also to acknowledge the support and encouragement of my mentors; namely Dr. Nathan Kapata, Dr. Ellen Yard, Dr. Nyambe Sinyange, Dr. Stephen Mupeta, Dr. Idongesit Essiet-Gibson and Ms. Sylvia Chibuye.

Further, I would like to thank the dedicated health staff and Managers at St. Francis and Monze Mission Hospitals, the Ministry of Health and the University of Zambia School Of Public Health for all their support.

Finally, I would like to thank ERES Converge for ethical approval and my classmates for peer review.

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CERTIFICATE OF COMPLETION OF DISSERTATION

I, **Fred Kapaya** hereby certify that this dissertation is the product of my own work and, in submitting it for the Degree of Master of Public Health by Research programme, further attest that it has not been submitted to another University in part or whole for the award of any programme.

Signature……Date……

DEDICATION

This dissertation is dedicated to my son Mapalo and my wife Maureen for their unwavering support and encouragement during the whole period of the programme. To my mother, father, brothers and sisters for their moral and spiritual support during my studies, I am truly grateful. The successful completion of this dissertation is due to your support.

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LIST OF ABREVIATIONS

AD	After Death
AIDS	Acquired Immune Deficiency Syndrome
AOR	Adjusted Odds Ratio
BC	Before Christ
CI	Confidence Interval
CS	Caesarean Section
CSO	Central Statistics Office
DHIS	District Health Information System
ERES	Excellency in Research Ethics and Science
HIV	Human Immunodeficiency Virus
IQR	Inter Quartile Range
MMR	Maternal Mortality Rate
MS	Microsoft
NHRA	National Health Research Authority
OR	Odds Ratio
RVF	Rectovaginal Fistula
STATA	Statistical software package
SVD	Spontaneous Vaginal Delivery
UNFPA	United Nations Population Fund
USA	United States of America
VVF	Vesicovaginal Fistula
WHO	World Health Organization
ZDHS	Zambia Demographic and Health Survey

DEFINITION OF KEY WORDS

Comorbidities: The simultaneous presence of two or more disease conditions in the same patient which may complicate the patient response to treatment (Karp et al., 2019)

Incidence: The number of people who are newly diagnosed with a condition (Kempker and Martin, 2016)

Obstetric Fistula: It is an abnormal opening between a woman's vagina and bladder and/or rectum through which her urine and/or feces continually leak (WHO, 2006)

Obstructed Labour: It is the arrest of vaginal delivery of the foetus due to mechanical obstruction. It causes complications such as rupture of uterus, Necrotic vesico-vaginal fistula, birth injuries and infections (Arrowsmith et al., 1996)

Prevalence: Means newly diagnosed people, plus people who were diagnosed in the past, and, if the information is obtainable, people who haven't been diagnosed (Kempker and Martin, 2016)

Primiparous: Giving or having given birth for the first time (Dahl and Kjolhede, 2006)

Rectovaginal Fistula: An abnormal opening between a woman's vagina and rectum through which her feces continually leak(WHO, 2006)

Still born: Born dead (the child is born dead)(Jolly, 2016)

Vesicovaginal Fistula: Abnormal opening between a woman's vagina and bladder through which her urine continually leak (WHO, 2006)

CHAPTER ONE

1.1 **Introduction**

Obstetric fistula is an abnormal opening between a woman's vagina and bladder and/or rectum through which her urine and/or feces continually leak (WHO, 2006). This complication is usually caused by prolonged or obstructed labor which causes tissue necrosis and results in a hole to form between the vagina and bladder or rectum or both. Any woman suffering from prolonged or obstructed labor without timely access to an emergency caesarean section is at risk of developing an obstetric fistula. It is a severe maternal morbidity with devastating consequences for a woman's life and an indicator of inequity in health service provision (United Nations General Assembly, 2016).

The existence of obstetric fistula is said to have been known to physicians of ancient Egypt before 2,000 years BC (Stamatakos et al., 2014) and it is estimated that 5% of all pregnant women worldwide will experience obstructed labour. The likelihood of fistula formation is high when obstructed labour is prolonged (Tayler-Smith et al., 2013)

The condition results in uncontrolled leakage of urine from the bladder through the vagina, in the case of vesico-vaginal fistula (VVF) and leakage of feces from the vagina, in the case of recto-vaginal fistula (RVF) (Delamou et al., 2016). In rare cases, it can also be caused iatrogenically and by sexual violence. It is one among the most distressing complications of gynecologic and obstetric procedures(Adler et al., 2013). Evidence shows that approximately 90% of women who develop fistula deliver a still born (Ahmed and Holtz, 2007).

A woman with fistula may also experience neurological disorders, orthopedic injury, bladder infections, painful sores, kidney failure or infertility. They are exposed to untold social problems such as shame, stigma, depression and poverty. Many women with fistula are abandoned by their husbands and families. This isolation may affect their mental health resulting in depression, low self-esteem and suicide (WHO, 2013).

Obstetric fistula is a debilitating condition that affects mostly women in sub-Saharan Africa and Asia. Globally, the exact prevalence is not known although in 2006, the WHO estimated that more than 2 million young women throughout the world live with untreated fistula and between 50,000 and 100,000 new women are affected each year (Nielsen et al., 2009).The Global Fistula Map reports that between the years 2010 and 2013, only 60,280 women received

fistula repair surgery; about 15,000 per year, on average. For every woman that gets treatment, at least 50 go without (Miller et al., 2005).

The incidence of fistula is highest in sub-Saharan Africa and parts of Southeast Asia. A study about the prevalence of symptoms of vaginal fistula in 19 sub-Saharan countries estimated a lifetime prevalence of obstetric fistula in sub-Saharan Africa to be 1.60 to 3.0 cases per 1000 women of reproductive age (Maheu-Giroux et al., 2015). Obstetric fistulae occur in settings where access to emergency obstetric care is limited and as such affects women in rural areas more than in urban areas. According to the United Nations Population Fund (UNFPA), there are three phases of delay that contribute to the development of a fistula: delay in seeking medical attention; delay in reaching a medical facility; and delay in receiving medical care once arriving at a health care facility (Thaddeus and Maine, 1994).

In Zambia, maternal health indicators have been steadily improving. The 2013—2014 Zambia Demographic Health Survey (ZDHS) reported that the maternal mortality had improved from 591/100,000 in 2007 to 398/100,000 live births in 2013-2014 and 64% of deliveries were assisted by skilled health personnel in 2013-2014 as compared to 47% in 2007. Antenatal coverage improved from 34% in 2001-2002 to over 96% in 2013-2014. However, this improvement in Antenatal care has not helped to resolve the problem of phase one delay. Many women still delay to seek care until complications arise mainly due to individual behavior, attitude, knowledge and family dynamics. A study conducted at the University Teaching Hospital, Lusaka by Nkata and Skinner (Nkata, 2015) showed that there is limited information on the patient's perspectives and knowledge about fistula and that knowledge on fistula is not understood by majority of women. This is similar to the 2013-2014 Zambia Demographic Health Survey report which showed that only one in three women aged 15-49 years had heard about fistula in Zambia. Women in rural areas had more knowledge than those in urban probably because this condition is more prevalent in rural areas where access to health facilities is limited.

Evidence shows that fistula has been eliminated in many developed countries but it continues to afflict many poor women in low- and middle-income countries (Osotimehin, 2013). In Zambia, women have to cover long distances to access medical facilities leading to the travel delays (phase two delays). This is made worse by poor road network, ineffective communication system and inadequate ambulance services especially in rural areas. In

addition, phase three delays (delays in the delivery of competent emergency obstetric care) also exists in Zambia. This is due to inadequate competent human resource in public health facilities, shortages of supplies and other logistics for optimal care.

No studies to determine the factors associated with failure of closure of fistula after surgical repairs have been done in Zambia. In order to eliminate fistula, it is necessary to scale up country capacity to provide access to comprehensive emergency obstetric care, treat fistula cases by surgery and address underlying health, socioeconomic, cultural and human rights determinants. This can be achieved by getting a deeper understanding of the factors that predictor failure of repair of fistula so that targeted measures are undertaken to address these factors.

1.2 Statement of the Problem

Obstetric fistula is a significant cause of maternal morbidity with a lot of social and economic implications. The most important factors contributing to the high incidence and prevalence of obstetric fistulae are socioeconomic which lead to increased cases of obstructed labour (Thaddeus and Maine, 1994). The unfortunate women who endure such obstructed labour and resulting incontinence are often young, undernourished, uneducated and married early (Wall, 2006). They are often from rural, poor areas, often with an early first pregnancy.

The 2013-2014 ZDHS reported improvement in literacy levels among women, aged 15-49 years, from 64% in 2007 to 68% in 2013-2014, this rate being higher in urban women (83%) than rural women (54%). However, it reported a high teenage pregnancy rate of 29% with rural areas affected more (36%) than urban area (20%). The country has also a high MMR of 398/100,000 live births, high HIV prevalence (13%), high unemployment rate (48%) and limited access to emergency obstetric care services (CSO, 2015). A study in Kapiri Mposhi found that 73% of women in rural areas in need of lifesaving intervention did not receive one and probably died or had severe morbidity (Selia et al., 2016). The 2013-2014 ZDHS reported that 0.53% of women said they had signs and symptoms of fistula and 60% of these occurred in rural areas where access to emergency obstetric care is limited. Further, some of the traditions especially in remote areas believed that giving birth at home was safe and only proceeded to the hospital in an event were home delivery failed (Sialubanje et al., 2015). Many

pregnant women and significant others fail to appreciate the importance of seeking care early and thus delay until a complication of child birth arises.

Surgery is the main stay of treatment of obstetric fistula and numerous studies have reported successful closure rates to be as high as 90% (Nardos et al., 2009, ayondo et al., 2011, Tayler-Smith et al., 2013, Landry et al., 2013, Delamou et al., 2016). However, failure of closure is also common and is attributed to several factors such as socio-demographic characteristics, fistula characteristics, skill of the surgeon, repair hospital and post-operative nursing management (Mark A. Barone et al., 2012, Vera Frajzyngier, 2012, Ruminjo et al., 2014)

In Zambia, a study by Holme et al (2007) found a success rate of 72.9% with a failure of as high as 27.1%. However, factors that predict the risk of failure of obstetric fistula repair have not been studied and this forms a major bottleneck in the successful treatment of fistula patients.

1.3 Justification

Understanding the main predictors, associated predisposing factors and the rate of failure after obstetric fistula repair surgery is very critical in many ways. Firstly, Zambia has a high fertility rate, high teenage pregnancy rate (29%) and limited access to emergency obstetric care facilities especially in rural areas. This places Zambian women at an increased risk to develop fistula.

Secondly, Zambia working with partners like UNFPA has designed a catalytic intervention model aimed at improving fistula prevention and repair services. Through this intervention, 1846 fistula patients have been treated between 2006 and 2014 at the main repair hospitals and through several fistula repair camps conducted throughout the whole country. Thirdly, evidence suggest that successful surgical closure of obstetric fistula brings renewed hope and self-esteem in women with fistula but failure of repair causes increased stigma, social isolation, depression and increased suicidal tendencies. Worse still, it makes subsequent repairs in such women more difficult (Tayler-Smith et al., 2013, Tuncalp et al., 2015, Umoiyoho et al., 2011, Ouedraogo et al., 2018)

The fourth argument is that although numerous studies on factors associated with obstetric fistulae repair outcomes have been conducted in other countries and have identified factors such as vaginal scarring, patient comorbidities, fistula characteristics, repair technique and

expertise of the surgeon(Kapoor et al., 2007, Delamou et al., 2016), none has been done in Zambia. Therefore, this study was conducted to estimate the proportion of obstetric fistula repair failures and to identify the risk factors that are associated with repair failures so as to help inform and restructure our fistula care program, quantify the problem of obstetric fistula repair failures and highlight additional areas for research in Zambia.

1.4 Research Objectives

1.4.1 Research Question

What are the factors associated with repair failure among women who underwent obstetric fistula surgical repair at Monze and St. Francis Mission Hospitals between January, 2010 and December, 2016.

1.4.2 General Objective

To determine the factors associated with obstetric fistula repair failures among women who underwent repair at Monze and St. Francis Mission Hospitals between the years 2010 and 2016.

1.4.3 Specific Objectives

i. To estimate the prevalence of failure of obstetric fistula repair at Monze and St. Francis Mission Hospitals.
ii. To identify the socio-demographic characteristics of women undergoing obstetric fistula surgical repair at Monze and St. Francis Mission Hospitals.
iii. To determine the obstetric, clinical and fistula characteristics that are associated with failure of obstetric fistula repair at the two hospitals.

CHAPTER TWO

2.1 Literature Review

2.1.1 Global and Regional Situation of Obstetric fistula

Literature has provided a universally agreed definition of an obstetric fistula as a hole that develops between a woman's genital tracts and either the urinary or the intestinal tract and almost all studies have used this definition(ayondo et al., 2011). While it is almost always preventable, fistula is all too common in the developing world, where it is estimated to affect more than 2 million girls and women (UNFPA and Engender Health 2003). Studies have found that each year pregnancy related complications claim the lives of over 500,000 women worldwide with about 99% of these deaths occurring in developing countries(Polan et al., 2015).

Reliable data on the burden of obstetric fistula has been scarce. It was not until 1991 that the World Health Organization (WHO) produced a map to show the global picture of obstetric fistula (Figure 1). The map clearly indicates that this condition is concentrated in sub-Saharan Africa and Asia. This is the region which is also devastated by HIV/AIDS, malaria, famine, endemic poverty and years of political instability(Wall, 2006).

Figure 2 1: *World Health Organization map of obstetric fistula.*
Reproduced with permission from Wall LL, Arrowsmith SD, Briggs ND, and Lassey A. Urinary Incontinence in the Developing World: The Obstetric Fistula. *Geneva, Switzerland: World Health Organization; 1991. Available from http://www.fistulafoundation.org/pdf/UIDW. pdf.Accessed November 13, 2008.*

This condition has been with man from the time giving birth started although the first recorded reference of an obstetric fistula was in 1550 BC. The relationship between obstructed labor and fistula development was first recognized and described by the Persian physician, Avicenna, in 1037 AD (Zacharin, 2000). It has also been established that before the twentieth century, both urinary and rectal fistulas were a common result of deliveries throughout the world. This was a huge problem for women as they had to live with this debilitating condition with no hope of recovery. In 1845, a series of experimental operations on slaves was conducted in Montgomery, Alabama, USA and based on these experiments, James Marion Sims established the foundations of Obstetric fistula repair in 1852 (Symmonds,1976).

The 2010 UNFPA campaign to end fistula report indicated that for each woman who dies from pregnancy related complications, another 15 to 30 suffer serious morbidities including obstetric fistula and all these are preventable and treatable conditions. In spite of this, eradication of obstetric fistula remains a major challenge in developing countries, especially in sub-Saharan Africa, where health systems are weak and adequate emergency obstetric care services are lacking (Osotimehin, 2013, Miller et al., 2005). A review by (Adler et al., 2013) and a meta-analysis by (Maheu-Giroux et al., 2015) reported similar estimates of the lifetime prevalence of obstetric fistula in sub-Saharan Africa as being between 1.0 and 1.57 per 1000 in women aged 15–49 years. These studies also provided evidence that maternal morbidity and mortality are significantly increased by conditions that prevent access to safe obstetric surgery.

The consequences of fistula are life altering. The studies by (Polan et al., 2015) and (Siddle et al., 2013) found that women who develop obstetric fistulae, usually loose the baby during labour, and are left with chronic incontinence which often leads to other physical, psychological and social impediments such as isolation, divorce or rejection by relatives and community . Without surgical repair, a woman's prospects for work or family support are greatly diminished and she is often left to rely on charity. These problems become excessively difficult in cases of traumatic fistula, which is caused by rape or sexual violence in which stigma is said to be worse. In these cases women face greater psychological trauma and increased vulnerability to HIV or other sexually transmitted infections. According to Ahmed,

2007, women with obstetric fistulas may not die immediately but experience so much suffering with this disease such that they are occasionally referred to as the walking dead.

In the past decade, an increasing commitment to holistic care of fistula has occurred in sub-Saharan Africa (Delamou et al., 2016). After international funding of fistula care programmes worldwide (Report, 2014) and (Osotimehin, 2013) many countries have developed national plans for eliminating obstetric fistula, including a preventive component to strengthen emergency obstetric care but also the training and equipment of health facilities for the treatment of fistula. The surgical closure of an obstetric fistula is the most effective way to treat this condition. Evidence indicates that life improves dramatically for the majority of women after successful fistula repair. Women are able to return to their normal lives; interact freely with their families, friends, and communities; and play active roles in economic pursuits (Report:, 2014)

Surgical repair of obstetric fistula has given back hope to these women who usually suffer physical and social problems. Although this treatment shows closure rates as high as 95%, the repair outcome is affected by several factors. A study at the Jimma Teaching Hospital in Ethiopia which evaluated the association of fistula type, experience of operating surgeon, route of repair, post-operative care and type of anesthesia with the outcome of the surgical repair found that 6.6% repairs did not close while 8.9% of women still had urinary incontinence despite closure of the fistula (Sori et al., 2016). A similar study done in three (3) hospitals in Guinea by Delamou et al, 2016 looked at the socio-demographic, gynaecologic and clinical characteristics that are associated with failure of obstetric fistula following surgical repair. The overall proportion of the failure of fistula closure was found to be 14.5% and the failure was significantly associated with mode of delivery, status of the urethra and repair hospital. Other studies have also implicated vaginal scarring as a major predictor of failure of fistula closure (ayondo et al., 2011, Ruminjo et al., 2014, Nardos et al., 2009).

2.1.2 Obstetric fistula in Zambia

According to the World Fact Book, (WHO, World Bank, 2015), the Zambia Fistula Foundation report of 2015 and the Zambia Demographic and Health Survey 2013-2014, the country is characterized by high fertility rate of 5.7 children per woman, while attendance by skilled personnel at delivery stands at 64% and high maternal mortality rate of 398/100,000. The proportion of births delivered by caesarean section is 4% with Copper-belt and Lusaka being the highest at 7%. Out of the total deliveries in Zambia, 31% occur at home with long distances to health facilities and limited facilities with emergency obstetric care as the main reasons. This is a recipe for obstetric complications like fistula(CSO, 2015).

Zambia has an estimated lifetime prevalence of obstetric fistula of 0.53% among women aged 15-49 with regional variations ranging from 0 to 1.3 %. Muchinga province (1.3%) recorded the highest while Central province (0%) is the lowest. There is a high potential for underreporting as most of the affected women are isolated due to stigma and may not have been interviewed during the survey. These findings are similar to other regions in sub-Saharan Africa. Of the women with fistula, 75 % reported developing the fistula after delivery, 3 % were a result of sexual violence, and 2% said problems started after pelvic surgery while the remaining 20 % cited other unspecified causes or did not know what caused their symptoms. Forty-seven percent (47%) of women with obstetric fistula reported that the fistula developed after a very difficult labour that resulted in a live birth while 6% resulted in a stillbirth (CSO, 2015).

The study by Holme et al., 2007 at Monze Mission Hospital, Zambia; of the 259 cases of obstetric fistulae reported that 95.5% occurred following labour for more than 24 hours before the completion of delivery, 2.5% reported no antenatal care before delivery and only 9.6% reported delivery at home. These statistics are quite impressive compared to studies conducted in other regions of similar settings. A Study of 201fistula cases northern Ethiopia found that 92% of the cases reported not having any antenatal care (Gessessew and Mesfin, 2003).

It is important to have a better understanding and knowledge of the risk factors for obstetric fistula in order to educate the community, healthcare providers, policy makers, and program

managers to improve prevention of obstetric fistula at a regional and national level. UNFPA has been working with the Zambia's Ministry of Health in designing a catalytic intervention model. This model is aimed at improving the capacity of the national health system to routinely deliver a comprehensive package of fistula prevention and repair service at the four regional fistula repair sites as well as conducting fistula camps across the whole country (UNFPA, 2013) The main hospitals offering fistula repair on a continuous basis are University Teaching Hospital(UTH), Monze Mission Hospital, St. Francis Mission Hospital, Chilonga Mission Hospital and Kabwe General Hospital.

The report by UNFPA and Ministry of Health Zambia (2015), as well as other studies (Kirschner et al., 2010, Turan et al., 2007, Holme et al., 2007) have shown that obstetric fistula, usually affects first time mothers who have laboured for several days at home, with no access to emergency obstetric care including lifesaving procedures like caesarean section. Women who develop fistula are usually small and short which is an indication of pelvic immaturity. These women need surgery to close the fistula and improve their lives.

Success rate after repair of obstetric fistula varies from center to center and is determined by many factors like site of fistula, degree of scarring, previous repair attempts, repair technique and expertise of the surgeon, equipment and post-operative nursing care among others. Although no studies have been done in Zambia, studies done in other countries with similar socio-economic characteristics have shown success rates after repair as high as 87-93% (Polan et al., 2015, Browning, 2004). However, generally, 15-20% of closures fail. This is because the closure of fistula following surgery is affected by a lot of factors (Roenneburg et al., 2006, Nardos et al., 2009).

2.2 Conceptual Framework

Obstetric fistula remains the most common female genital fistulae in sub-Saharan Africa and Asia. For the purpose of this study, we have adapted the conceptual framework developed by Wall(Wall, 2006)and inspired by the McCarthy and Maine (McCarthy and Maine, 1992) framework proposed for analyzing maternal mortality (Figure 2.2).

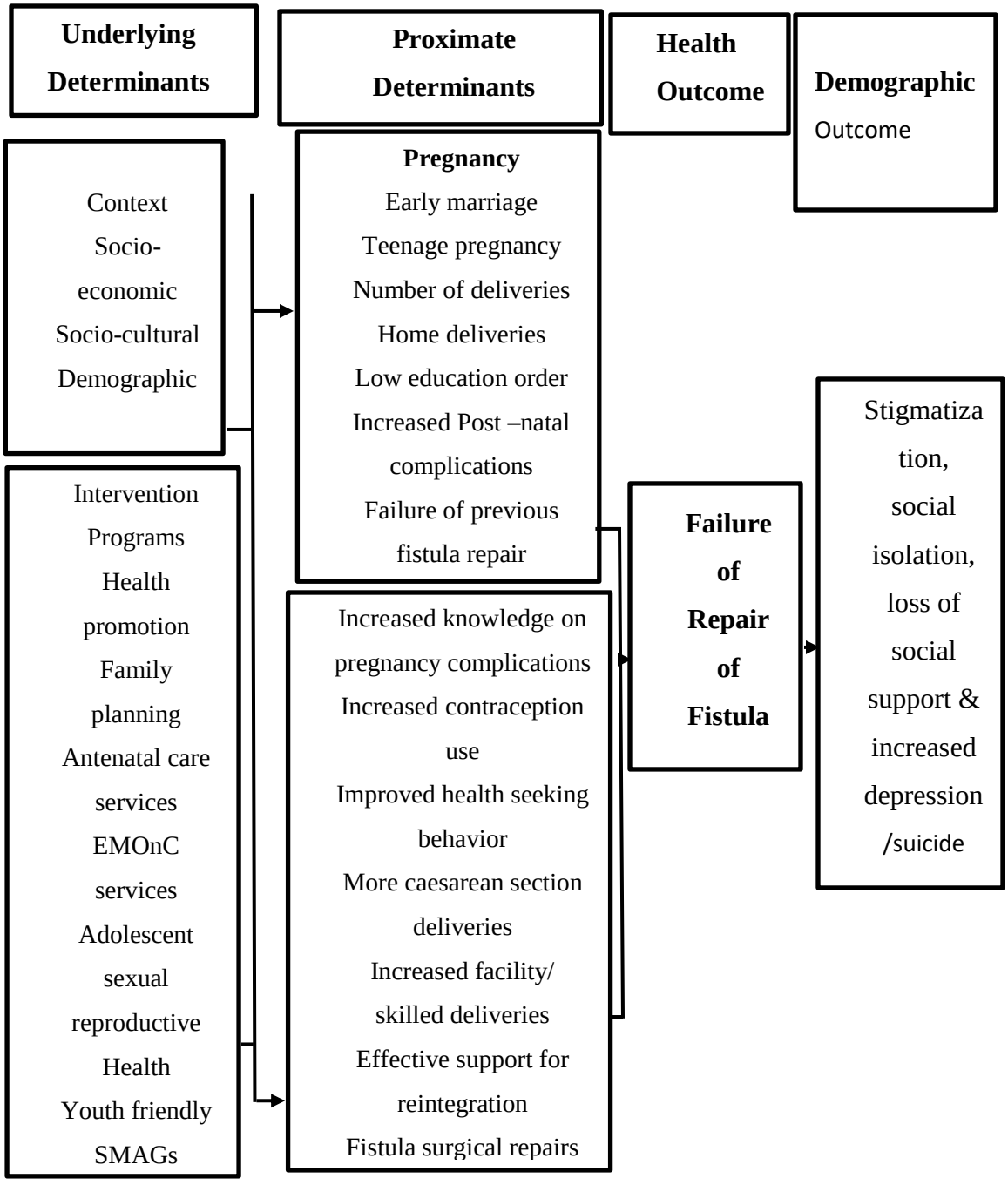


Figure 2 2*: Proximate-determinants conceptual framework for factors affecting failure of fistula repair (Osotimehin, 2013)*

Wall expresses the hypotheses underlying this framework as follows:

"*any factor that reduces the formation of obstetric fistula will work through one of these three mechanisms: (1) It will reduce the likelihood that a woman will become pregnant, (2) it will reduce the likelihood that a pregnant woman will develop obstructed labour, or (3) it will improve the outcome for women whose labour becomes obstructed*"

The conceptual framework for this study, looked at variables that influence fistula formation and fistula repair outcome. The variables included the social, cultural, economic, behavioural and biological factors all embedded in the three mechanisms proposed by Wall in his hypothesis(Wall, 2006).

The factors were categorized under three levels in order of influence on fistula repair outcome:

i. Determinants of pregnancy (exposure to pregnancy). These are factors that reduces the likelihood of a woman becoming pregnant. They include:
    - individual characteristics that influence behavior change such as the socio-demographic and physical factors(education and empowerment for women including community awareness of causes and prevention, delaying marriage and child bearing, birth preparedness)
    - Organizational and social institutions like reproductive health services and
    - Socio-cultural context characteristics

ii. Determinants of delivery (exposure to obstructed labour and fistula formation). Factors that will reduce the likelihood that a pregnant woman will develop obstructed labour including factors like early pregnancy, number of deliveries, home deliveries, maternal health status, illiteracy, knowledge on pregnancy complications, skilled attendance at every birth (EMOnC services) and post-natal complications.

iii. Determinants of fistula management (exposure to fistula repair). These are factors that will increase the likelihood of successful repair. Outcome can be improved for women who develop complications of labour and delivery through rapid assessment and competent treatment. This is the rational for reducing maternal morbidity and the factors to consider include:

- Individual characteristics such as improved health seeking behavior,
- Organizational factors like increased access to caesarean section deliveries, health facility deliveries and fistula surgical treatment services
- Healthy systems factors such as infrastructure, knowledge and skill gap

The framework acknowledges that health outcomes (fistula repair outcomes) are often influenced by factors that are within and beyond the individual (Feldacker et al., 2011). There is a dynamic interaction between the various factors whose equilibrium ultimately defines the overall health experiences (Elder et al., 2007), in this case failure of fistula repair. Failure of fistula repair is influence by several factors including previous repair attempts, vaginal scarring, comorbidities and urethral damage (Guimaraes, 2017, Lundblad, 2017, Delamou, 2016). Owing to technical difficulties associated with repair of obstetric fistula with these factors, the successful outcome relies on prevention of pregnancy (family planning and contraception use) careful management of pregnancy and delivery (healthy facility deliveries, skilled deliveries and caesarean section delivery), post care repair(infection prevention, fistula repair services)

CHAPTER THREE

3.1 Methodology

3.1.1 Study design

A hospital based retrospective cohort design was used in this study because it allowed an existing dependent variable(success or failure of surgical repair) within a defined group of people (women with obstetric fistula repaired at the two hospitals) to be examined following surgical repair of fistula. The available medical records of patients with obstetric fistula from St. Francis and Monze Mission Hospitals were analyzed to answer the research question. This design was the most suitable because women included in the study had already undergone fistula surgery at the two repair hospitals. Successful repair was defined as obstetric fistula patients who after surgical repair had no leakage of urine while unsuccessful repair (failed repair) was those women after repair still had leaking fistula at the end of hospitalization of approximately 14 days.

3.1.2 Study Setting

The specific study settings were the two obstetric fistula repair centres in Zambia namely; St. Francis Mission Hospital in Katete district of the Eastern province and Monze Mission Hospital in Monze District of Southern province. The two sites were chosen because they are among the major obstetric fistula repair centres in Zambia where highest number of repairs are done. On average both hospitals repair approximately 50- 100 cases a year.

3.1.2.1 St. Francis Mission Hospital

St. Francis Mission Hospital is situated in Katete, a rural district in Eastern province with a catchment population of about 200,000(CSO, 2013) and receives specialist referrals from the whole province. The hospital has a bed capacity of 350 divided into adult medical, paediatric, maternity and surgical wards. The hospital has a two operating theatres and offers a wide range of surgical operations, among them, surgical obstetric fistula repair. However, the hospital does not have a resident fistula surgeon; it depends largely on visiting fistula surgeons who always visit the hospital to conduct fistula repair at least once every year. Women are booked in advance and given specific dates when to come for the repair. Healthcare services at this facility is fully integrated into the Zambian Health System. It is partly funded by the Zambian

Government while the Anglican and Catholic Churches and overseas support from groups in the Netherlands and the United Kingdom provides the other part of funding.

3.1.2.2 Monze Mission Hospital

Monze Mission Hospital is situated in Monze, another rural district in Southern province. It has catchment population of over 215,000(CSO, 2013) and a hospital bed capacity of 276. The hospital has a male and female surgical and medical wards, paediatric and maternity wards. It has three operating theatres, two for major surgery and one for minor surgery.

Monze District has no district hospital and so Monze Mission Hospital provides both District and General Hospital levels of care. This means that other districts refer patients to Monze Mission Hospital because of its General Hospital status thereby further increasing the catchment population of more than 800,000. Other provinces in Zambia also refer to Monze Mission Hospital for specialized care. In addition, it is the longest primary referral centre for fistula in the country. It serves clients from around the country especially for more difficult fistulas. The hospital has a resident fistula surgeon assisted by a visiting fistula surgeon every year. The hospital is supported by the Zambian government and receives scattered donations including a bit from the Catholic Holy Spirit Sisters, the local Zambian order.

3.1.3 **Study Population**

The study population were women with obstetric fistula who met the inclusion criteria. The target population in this study were all women diagnosed with obstetric fistula admitted to St. Francis and Monze Mission Hospitals for repair between 2010 and 2016. We first examined differences in individual characteristics between those with failed fistula closure (failure of repair) recorded on the medical records versus those with successful fistula closure (Fistula healed). For each maternal covariate, we calculated the proportion of those with failed fistula repair. We also calculated, for each group, the proportion distribution of each maternal covariate, and then assessed the differences in proportion between the two groups.

3.1.3.1 Inclusion and exclusion criteria

All women with obstetric fistula diagnosed by a gynaecologist through a thorough physical examination or using a dye test repaired at St. Francis and Monze Mission Hospitals from

January1, 2010 to December 31, 2016 were included in the study. In contrast, all those women whose dye test at discharge was missing from the medical records, all those who were repaired elsewhere but visited the two hospitals for evaluation, all those who were repaired outside the stated study period and all those who had non obstetric fistula (eg. congenital fistula) were excluded from the analysis.

3.1.4 Sample selection

3.1.4.1 Hospitals

The Hospitals were purposefully sampled because they are among the well-established fistula repair centres in the country.

3.1.4.2 Sample size and Power Calculation

All medical records of women who underwent obstetric fistula repair at the two hospitals between January 1, 2010 and December 31, 2016 were eligible in this study. It was a complete enumeration. Despite this, a priori power analysis was calculated to determine the minimum sample size needed to detect fistula repair outcome differences for women who underwent fistula repair at St. Francis and Monze Mission Hospitals. By convention, a Cohen's medium effect size of 0.5, alpha of 0.05 and a power of 0.80 were used for the power calculation(Hickey et al., 2018). Based on the G*Power results (Table 4.1), a 1-tail *t*-test for difference of two independent means requires 51 patients per group, giving a total sample of 102.

Table 4 1: Power Analysis using G* Power (Version 3.1.9.2)

Statistical Test	**t tests** **Means: Difference between two independent means**
Analysis Input	A priori: Compute required sample size Tail(s)=one Effect size d = 0.3 A err prob = 0.05 Power (1-β err prob) = 0.80 Allocation ratio N2/N1= 1 Noncentrality parameter $^{\delta}$= 2.5248762 Critical t = 1.6602343 Df = 100
Output	Sample size group 1= 51 Sample size group 2 =51 Total sample size = 102 Actual power = 0.8058986

3.1.5 Data management and variable definitions

A list of all women who underwent surgical repair for obstetric fistula was obtained from the Hospital Health Information System and compared with what was in the theatre register. Patient records were then retrieved according to the year of repair. Data was extracted from the patients records using a structured data collection tool, verified and stored in MS excel. Data collection was done during the months October and November 2017.

The data extraction tool/check list included data about:

i. Socio-demographic characteristics
   - Age of patient at presentation/repair(in years)
   - Residence(rural/urban)
   - Marital status(married/union or other-single, divorced or widow)
   - Woman's occupation(none, formal, informal)
   - Level of education(non, primary, secondary, tertiary)

ii. Gynecological and clinical characteristics
   - Parity at fistula development/fistula repair(number of deliveries)
   - Duration of labour (in days) which resulted in fistula formation
   - Mode of delivery(vaginal or caesarean section or instrumental
   - Perinatal outcome(alive or stillborn)
   - Post-natal complications(Yes/No)
   - Presence of comorbidities(Yes/No)—presence of other diseases
   - HIV status(Negative, positive or unknown)
   - Pre, intra and post-operative antibiotic use

iii. Fistula Characteristics
   - Type of fistula(vesicovaginal, rectovaginal, combined)
   - Vaginal scarring(yes/no)
   - Number of previous repairs and year of repair
   - Previous repair attempts(Yes/No)
   - Urethra involvement(Yes/No)

iv. General examination at admission for fistula surgery

v. Review of post-operative surgical and anaesthesia notes to identify complications during operation

vi. The treatment outcome will be classified as:

- Fistula closed (yes or no)
- Fistula continent(yes or no)

Note: Failure of repair of fistula will be determined using a dye test (Delamou et al., 2016) and defined as:

- A woman with a positive dye test indicating continuous leakage of urine. This is assessed by the surgeon prior to hospital discharge or woman whose dye test at discharge was negative but the woman reported a leakage of urine.

3.1.6 Study Terms

The major terms used in this study have been defined as shown below (Table 4.2)

Table 4.2: Definition of study terms used in this study

Criteria	Simple	Complex
Number of fistulas	Single	Multiple
Site of fistula	Vesico-vaginal fistula(VVF)	Recto-vaginal fistula(RVF), mixed VVF/RVF, all non VVF
Vaginal scarring	Absent	Present
Previous repair attempts	No	Yes
Post-operative complications	No	Yes
Urethral involvement	No	Yes
Presence of comorbidities	No	Yes

3.1.7 Data Entry/analysis

The predictor variables were checked for completeness and only those variables with complete information were included for analysis and entered on a data spreadsheet created on MS excel and then imported to STATA version 13(Stata Corporation, TX, USA). Some data variables were also recoded. Firstly descriptive statistics were used to determine the frequencies of failure of obstetric fistula repair failures. For continuous variables (age at fistula development, catheterization period, years with fistula, duration of labour, number of previous repairs) was assessed by use of box-plots or histogram and Shapiro-Wilk test to determine whether data were normally distributed to help make a decision on whether to use parametric or non-parametric tests to use.

Cross tabulation to determine the overall distribution of predictor variables of failure of repair was then done. This was followed by unadjusted logistic regression. Significance at unadjusted logistic regression was set at a p-value of 0.1.and a 95 percent confidence interval. Variables that were found to be significant at unadjusted logistic regression were then fitted into the multiple logistic regression to control for confounding and to come up with the final model of predictor variables. For multiple logistic regression, significance was set at a p-value of 0.05 and 95 percent confidence interval. Variables with the largest p-values were then removed one at a time until only significant variables were left in the final model. The analyzed information was summarized using tables and graphs.

3.1.8 **Ethical considerations**

Ethics approval (Reference number 2017-July-028) was obtained from the Excellence in Research Ethics and Science (ERES) converge while permission to obtain and use data from St. Francis and Monze Mission Hospitals was obtained from the Ministry of Health, the National Health Research Authority (NHRA) (Reference number 2017-September-20). No information regarding names of participants was obtained. The data set was only used for purposes of this study and not given to any other person or organization. Since there was no direct contact with participants, as the study involved secondary data, no obvious physical injury to participants was observed. Instead, the study brought out maximum benefits as information obtained and analyzed can be used for decision making.

3.1.9 Study Limitations

Our study had some limitations. It being an observational type of study using secondary data, some key variables on patient and clinical characteristics, experience and skill of key health workers such as surgeons, nurses and support staff was not available and thus limited our ability to do a more comprehensive assessment of the risk factors associated with obstetric fistula repair failures. Some confounding factors could not be controlled for. In addition, patient records had some missing information as there is no agreed standard data collection or patient screening tool. This study was conducted in two mission hospitals with quite similar settings and thus only generalizable to such settings. Despite these limitations, the observed results were from a well representative hospital based sample of women in Zambia and hence point to significant difficulties associated with surgical repair of obstetric fistula. It is one of the few studies to examine the factors associated with failure of fistula repair in Zambia.

CHAPTER FOUR

4.1 Results

4.1.1 Descriptive Analysis

The findings presented here are based on a total of 591 surgical repair records screened of women who underwent repair for obstetric fistula at the two repair hospitals, Monze and St. Francis Mission Hospitals, from January 2010 to December 2016. However, only 453 records were included in the analysis after excluding 138 records (Figure 4.1).

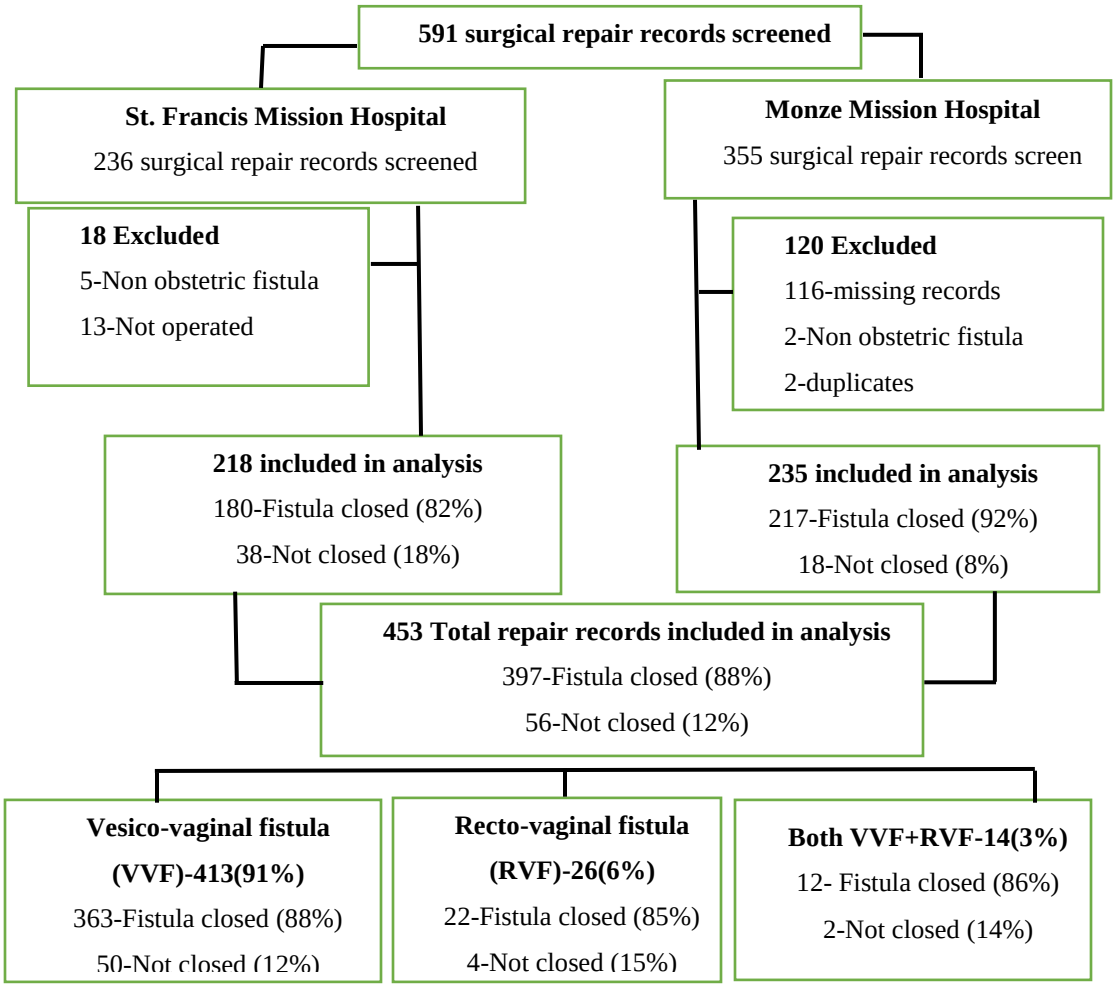


Figure 4. 1. ***Patient flow and surgical repair outcomes at hospital discharge in the two repair hospitals in Zambia, 2010 to 2016.***

Figure 4.1 shows the study flow and surgical repair outcomes at the time of hospital discharge. Overall there were 591 medical records of women with obstetric fistula seen at the two repair

hospitals, St. Francis Mission and Monze Mission, from January 2010 to December 2016. Out of these, 453 records were included in the analysis. A total of 138 records were excluded, 120 from Monze Mission Hospital and 18 from St. Francis Mission Hospital. At Monze Mission Hospital, 116 records were missing, two records were duplicates and two were non-obstetric fistula cases. At St. Francis Mission Hospital, five were non obstetric fistula cases while 13 fistula cases were not operated. The figure also shows that overall 56(12%; 95% CI: 9.6—15.7) repairs were not successful at discharge. This is further amplified in figure 4.2, which shows that the majority of women, 413(91%), in the study, had VVF. Of these 413 women, 50(12%; 95%CI: 9.1—15.6) had unsuccessful repairs. Out of the 26 women who had RVF (6% of the sample), 4(15%; 95%CI: 4.3—34.9) had unsuccessful repairs. For the 14 women who had both VVF and RVF (3% of the sample), 2(14%; 95%CI: 1.8—42.8) had unsuccessful surgical repair of obstetric fistula (Figure 4.2)

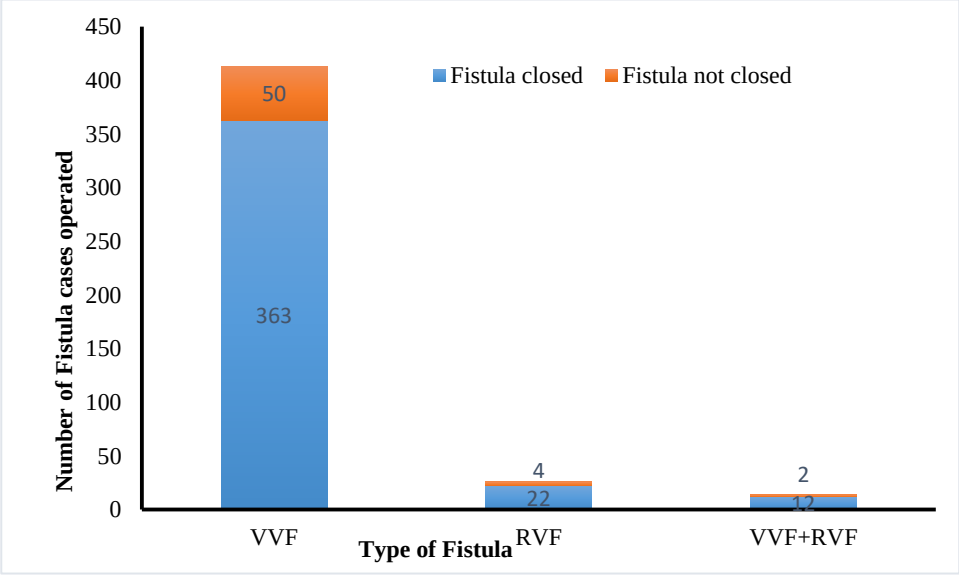


Figure 4. 2: Number of obstetric fistula cases by type and outcome operated at St. Francis and Monze Mission Hospitals between 2010 and 2016, Zambia

4.1.1.2 **Socio-Demographic Characteristics (A)**

The main socio-demographic characteristics of this study are summarized in table 4.1.

Table 4.1: Frequency distribution of predictor variables of failure of Repair for women operated at St. Francis and Monze Mission Hospitals 2010 – 2016 , Zambia.(N=453)

Variable	Overall n (%)	Repair Outcome		P-value (Chi2)
		Success n (%)	Failure n (%)	
Marital Status				
Married	303(66.9)	270(68.0)	33(58.9)	**0.03(8.7)**
Single	109(24.1)	97(24.4)	12(21.4)	
Divorced/Separated	30(6.6)	22(5.6)	8(14.3)	
Widow	11(2.4)	8(2.0)	3(5.4)	
Total	**453(100)**	**397(100)**	**56(100)**	
Education				
None	421(92.9)	367(92.4)	54(96.4)	**0.23(1.2)**
Other*	32(7.1)	30(7.6)	2(3.6)	
Total	**453(100)**	**397(100)**	**56(100)**	
Residence				
Rural	438(96.7)	383(96.5)	55(98.2)	**0.496(0.5)**
Urban	15(3.3)	14(3.5)	1(1.8)	
Total	**453(100)**	**397(100)**	**56(100)**	
Occupation				
None	453(100)	397(100)	56(100)	n.a
Works	0(0)	0(0)	0(0)	
Total	**453(100)**	**397(100)**	**56(100)**	

Age at Repair				
10—19	87(19.2)	83(20.9)	4(7.1)	**0.11(6.1)**
20—29	171(37.7)	146(36.8)	25(44.6)	
30—39	124(27.4)	107(26.9)	17(30.4)	
40+	71(15.7)	61(15.4)	10(17.9)	
Total	**453(100)**	**397(100)**	**56(100)**	

Other=Primary and above;* *Results interpreted using Pearson chi square test*

n.a = not applicable

Table 4.1 shows that the majority of women were married (n=303, 66.9%) with no formal education (n=421, 92.9%) and lived in rural areas (n=438, 96.7%). Women with successful surgery had higher prevalence of living in an urban area (n=14, 93%) than women with unsuccessful surgery (1, 7%). The majority of the women were aged between 20 and 39 years (n=293, 65.1%). None of the women operated at the two hospitals was involved in any formal employment.

4.1.1.3 **Social Demographic Characteristics (B)**

Table 4.2 gives a summary of this study's socio-demographic characteristics that were tested with the Shapiro-Wilk Test for normality. All of them did not assume a normal distribution.

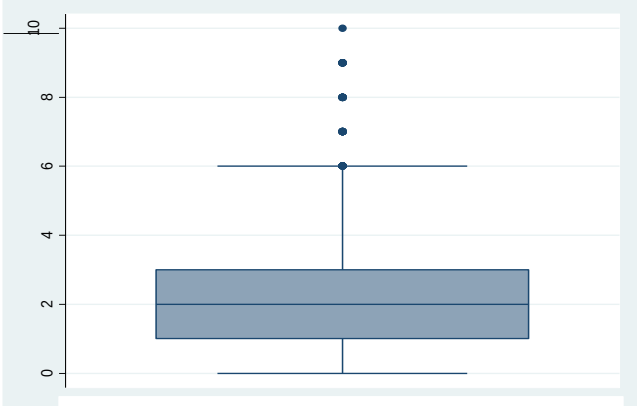
Table 4. 2: Frequency distribution of predictor variables of failure of Repair for women operated at St. Francis and Monze Mission Hospitals 2010—2016, Zambia. (N=453)

Variable	**Shapiro-Wilk Test for Normality(P-value)**	**Median(IQR)**	**Min**	**Max**
Age at Fistula repair	n=453 W=0.882(P<0.001)	27(21,35)	14	90
Age at Fistula Development	n=453 W=0.921(P<0.001)	23(19, 30)	14	60
Parity at Fistula Development	n=453 W=0.889(P<0.001)	2(1,3)	0	10

W=Shapiro-Wilk value, IOR=Inter-quartile Range.

Age at fistula repair and at fistula development were tested using the Shapiro-Wilk test and neither had data that assumed a normal distribution as shown in Table 5.2 above. Therefore, median and interquartile range were reported instead of the mean and standard deviation. Women developed fistula at a median age of 23 years and usually between their first and third pregnancy.

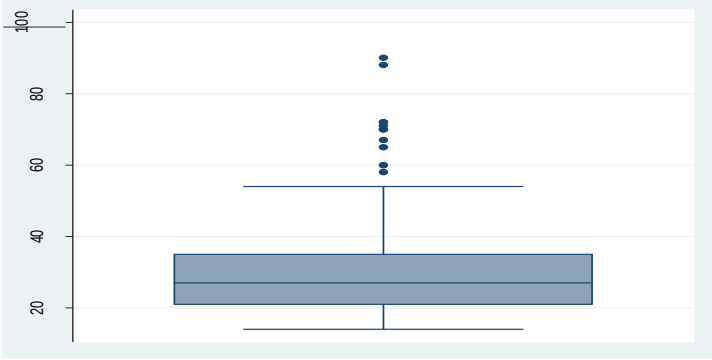
The median parity at fistula development was 2 but the parity was close to each other for the 1st, 2nd and 3rd quartiles **(Figure 4.3).**



Median=2(IQR 1, 3); mean=2.3(SD 2.2)

Figure 4. 3: Distribution of parity at fistula development

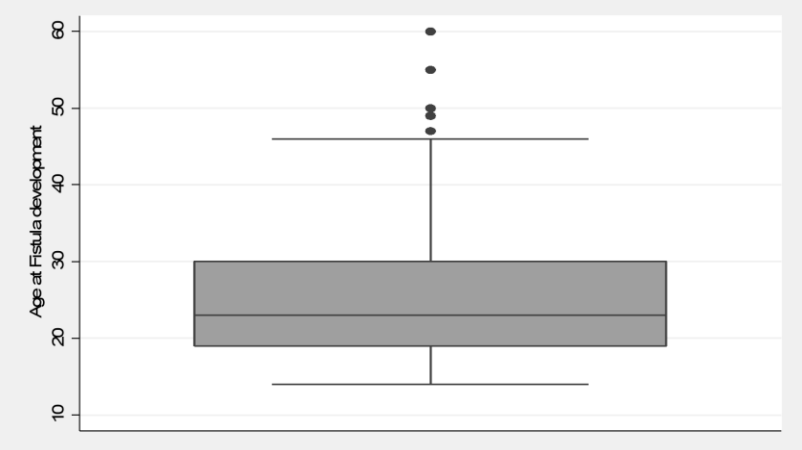
Figure 4.4 shows that the average age at fistula repair was 27 but much close for the 1st, 2nd and 3rd quartiles and fewer women above the age of 40 years**.**



Median=27(IQR 21, 35); Mean=29.3(SD

Figure 4. 4: Distribution of age (in years) at time of Fistula repair

The median age at fistula development was 23 years old much more close between 1st, 2nd and 3rd quartiles **(Figure 4.5)**



Median=23(IQR 19, 30); Mean= (25.14(SD 8.0)

Figure 4.5: Distribution of age (in years) at fistula development

4.1.1.4 **Obstetric, Fistula and Clinical Characteristics**

Table 4.3 shows obstetric, fistula and clinical characteristics associated with obstetric fistula repair failures.

Table 4.3: Frequency distribution of predictor variables of failure of Repair for women operated at St. Francis and Monze Mission Hospitals from 2010 and 2016, Zambia(N=453)

Variable	Overall n (%)	Repair Outcome		P-value Chi2
		Success n (%)	Failure n (%)	
Vaginal scarring				
No	353(77.9)	323(81.4)	30(53.6)	<0.001(22.0)
Yes	100(22.1)	74(18.6)	26(46.4)	
Total	453(100)	397(100)	56(100)	
HIV Status				
Negative	300(66.2)	256(64.5)	44(78.6)	0.010(9.2)
Positive	10(2.2)	7(1.8)	3(5.4)	
Unknown	143(31.6)	134(33.7)	9(16.0)	
Total	453(100)	397(100)	56(100)	
Comorbidities				
No	409(90.3)	364(91.7)	45(80.4)	**0.007(7.2)**
Yes	44(9.7)	33(8.3)	11(19.6)	
Total	453(100)	397(100)	56(100)	
Previous Repair attempts				
No	369(81.5)	328(82.6)	41(73.2)	0.09(2.9)
Yes	84(18.5)	69(17.4)	15(26.8)	
Total	453(100)	397(100)	56(100)	
Mode of delivery resulting in fistula				
SVD	155(34.2)	135(34.0)	20(35.7)	0.928(0.2)
C/S	278(61.4)	244(61.5)	34(60.7)	
Instrumental	20(4.4)	18(4.5)	2(3.6)	
Total	453(100)	397(100)	56(100)	
Urethral involvement				

No	366(80.8)	341(85.9)	25(44.6)	**<0.001(53.8)**
Yes	87(19.2)	56(14.1)	31(55.4)	
Total	453(100)	397(100)	56(100)	
Cause of Fistula				
Obstructed Labour	443(98.2)	387(98.0)	56(100)	0.283(1.2)
Other	8(1.8)	8(2.0)	0	
Total	451(100)	395(100)	56(100)	
Outcome of delivery				
Still born	360(79.5)	311(78.3)	49(87.5)	0.112(2.5)
Alive	93(20.5)	86(21.6)	7(12.5)	
Total	**453(100)**	**397(100)**	**56(100)**	
Pre-op-antibiotic use				
No	53(11.7)	50(12.6)	3(5.4)	0.115(2.5)
Yes	400(88.3)	347(87.4)	53(94.6)	
Total	**453(100)**	**397(100)**	**56(100)**	
Post-op-antibiotic use				
No	4(1.0)	4(1.0)	0(0)	0.451(0.6)
Yes	449(99.)	393(99.0)	56(100)	
Total	**453(100)**	**397(100)**	**56(100)**	
Post-op-Complications				
No	415(91.6)	386(97.2)	29(51.8)	<**0.001(131.9)**
Yes	38(8.4)	11(2.3)	27(48.2)	
Total	453(100)	397(100)	56(100)	
Repair Technique				
Transabdominal	58(12.8)	50(12.6)	8(14.3)	0.723(0.1)
Transvaginal	395(87.2)	347(87.4)	48(85.7)	
Total	453(100)	397(100)	56(100)	
Repair Hospital				
St. Francis	218(48)	180(45.3)	38(67.9)	**0.002(10.0)**
Monze	235(52)	217(54.7)	18(32.1)	
Total	453(100)	397(100)	56(100)	

SVD=Spontaneous Vaginal Delivery, C/S= Caesarean Section,

Results interpreted using Pearson chi square test

Most women delivered by caesarean section (n=278, 61%) with 360(79.5%) of deliveries resulting in stillbirths for the referent pregnancy with the majority of women developing obstetric fistula after obstructed labour (n=443, 98.2%) and 8(1.8%) were due to congenital, iatrogenic and trauma causes. The association between vaginal scarring and outcome of repair was statistically significant (X^2 =22.0, p<0.001) where the proportion of women with vaginal scarring was higher among failed repairs (46.4%) compared to successful repairs (18.6%). There is also a significant association between having a damaged urethral X^2 =53.8, p<0.001 where failure of repair was higher among women with damaged urethra (55.4%) than those with intact urethra (14.1%). Women with post-operative complication was statistically significant X^2 =131.9, p<0.001 with a higher proportion of failures among women who experienced post-operative complications (48.2%) compared to those with none (2.3%). In addition, comorbidities (X^2=7.2, p=0.007), HIV status (X^2=9.2, p=0.01) and repair hospital (X^2=10.0, p=0.002) were found to be statistically significant. Comorbidities included among others urinary tract infection, kidney stones, hypertension, Tuberculosis and Diabetes Mellitus.

Few women, 10(2.2%) were HIV positive at the time of fistula repair.

Post-operative antibiotics were used in 449(99.1%) women operated**.** Post-operative complications were proportionally high among cases (n=27, 71%) compared to 11(29%) among non-cases and transvaginal repair technique (n=394, 87%) was preferred by most surgeons. St. Francis Mission Hospital had more repair failures (n=38, 68%) than Monze Mission Hospital (n=18, 32%).

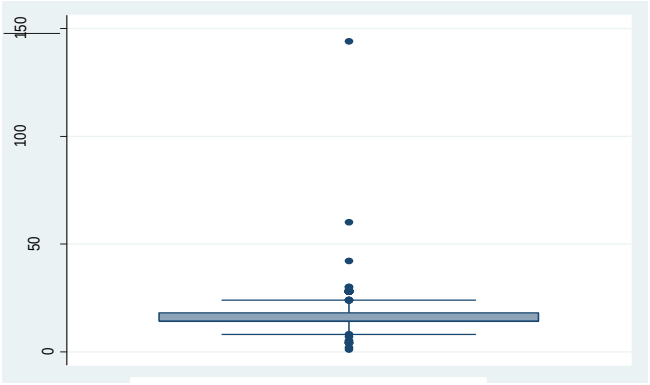
The distribution of the duration of labour in hours, duration of catheterization, years with fistula and number of previous repairs were tested using the Shapiro-Wilk test and none of them assumed a normal distribution (Table 4.4). Therefore median and Inter-quartile range were reported.

Table 4.4: Frequency distribution of predictor variables of failure of Repair for women operated at St. Francis and Monze Mission Hospitals from 2010 and 2016, Zambia

Variable	Shapiro-Wilk Test for Normality(P-value)	Median(IQR)	Min	Max
Number of days catheterized post-operatively	n=453 W= 0.520(P< 0.001)	14(4,18)	1	144
Duration of Labour in Hours	n=453 W=0.877(P<0.001)	0(0,29)	0	168
Years with Fistula	n=453 W=0.702(P<0.001)	1(0,5)	0	59
Number of Previous Repairs	n=451 W=0.906(P<0.001)	0(0, 0)	0	4

W=Shapiro-Wilk value, IQR=Inter-quartile range

The median duration of catheterization after repair was 14 days, however, some women had catheter in situ for as less as 1 day and as long as 144 days **(Figure 4.6).**



Median=14(IQR 14,

Figure 4.6: Distribution of Number of days catheterized post-operatively

Figure 4.7 below, shows that the proportion of failed repairs was highest among women who were HIV positive (30%)

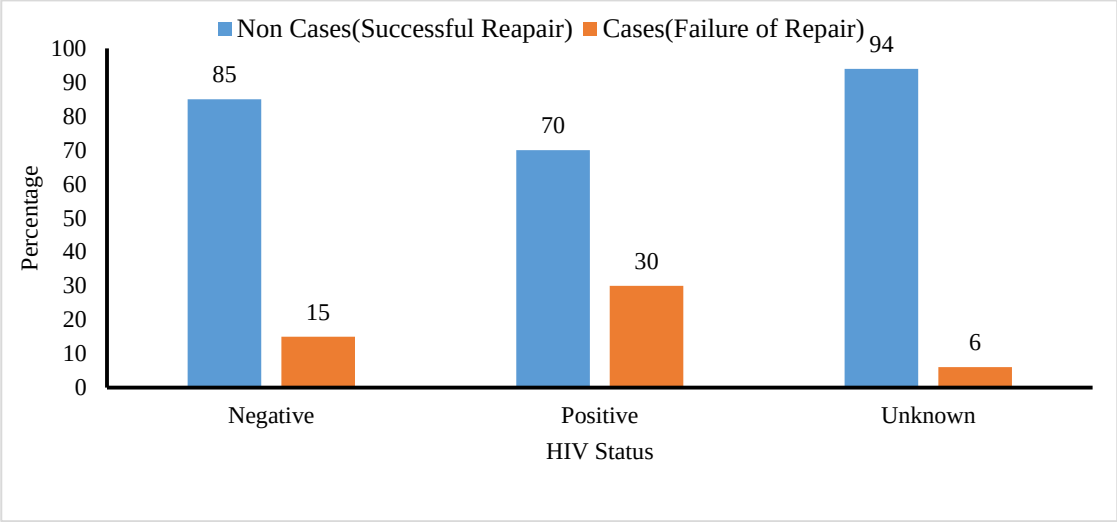


Figure 4.7: Distribution of HIV Status among cases and Non-cases at St. Francis and Monze Mission Hospitals, Zambia, 2010—2016.

The proportion of women with vaginal scarring was higher among cases than the non-cases (Figure 4.8)

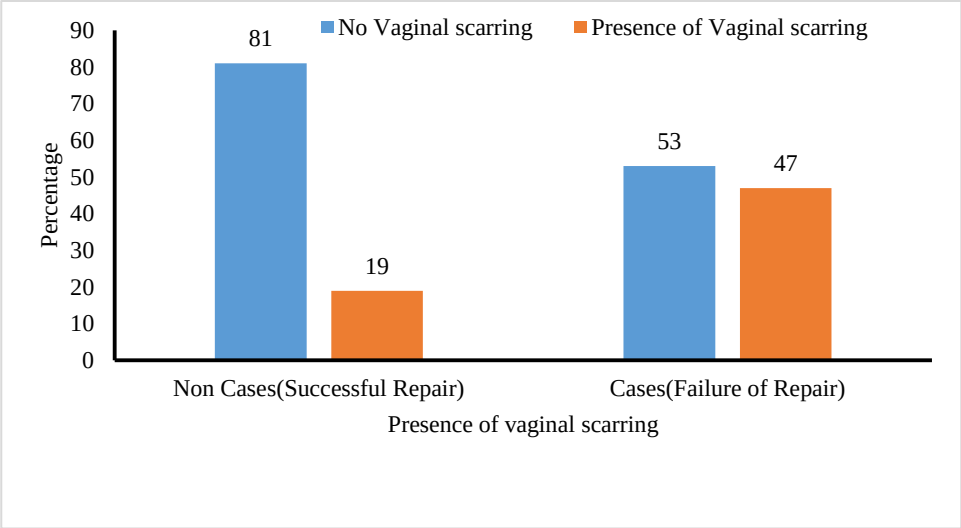


Figure 4.8: Distribution of presence of vaginal scarring among cases and Non-cases at St. Francis and Monze Mission Hospitals, Zambia, 2010—2016.

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Other comorbidities in the study population has been summarized in Figure 4.9 below. Presence of other comorbidities was proportionally higher among cases than non-cases.

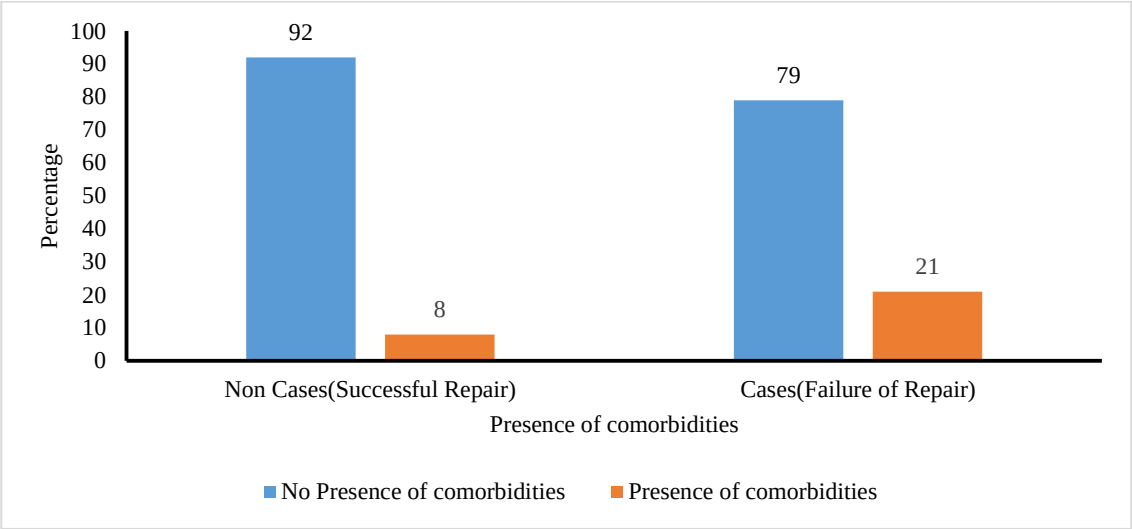

Figure 4.9: Distribution of presence of comorbidities among cases and Non-cases at St. Francis and Monze Mission Hospitals, Zambia, 2010—2016.

Figure 4.10 below shows the distribution of urethral involvement among cases and non-cases. Urethral involvement was higher among the cases than non-cases.

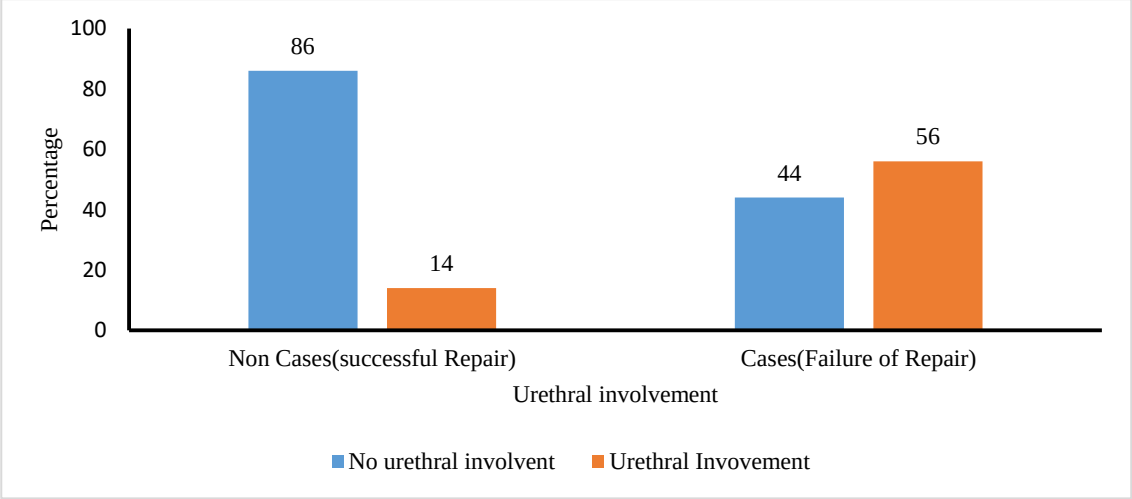

Figure 5.10: Distribution of Urethral involvement among cases and Non-cases at St. Francis and Monze Mission Hospitals, Zambia, 2010—2016.

Almost equal proportion of those who had post-operative complications and those who did not have among cases while among non-case, there were fewer women with post op complications (Figure 4.11)

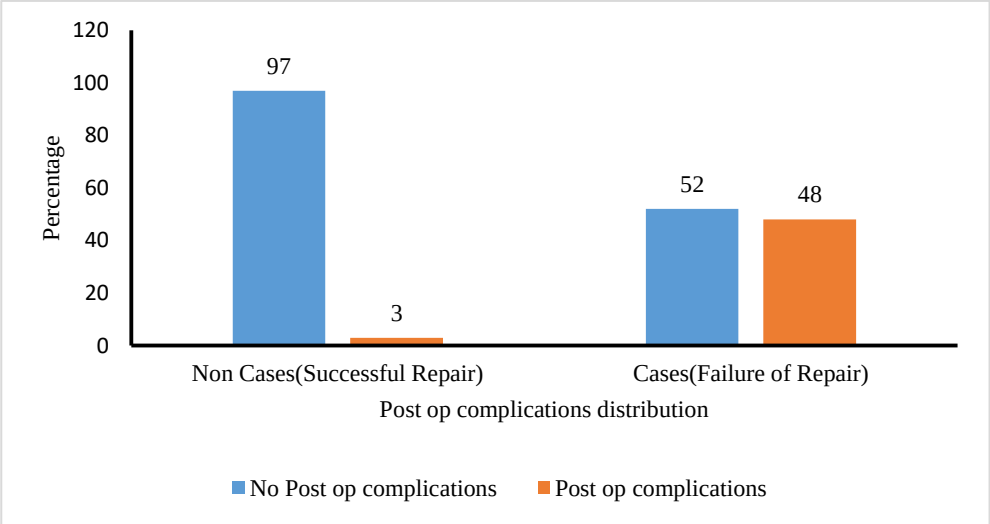

Figure 4.11: Distribution of Post op complications among cases and Non-cases at St. Francis and Monze Mission Hospitals, Zambia, 2010—2016.

Repair failures by repair hospitals was summarized in figure 4.12 below. Failures were higher at St. Francis (68%) than at Monze Mission Hospital (32%).

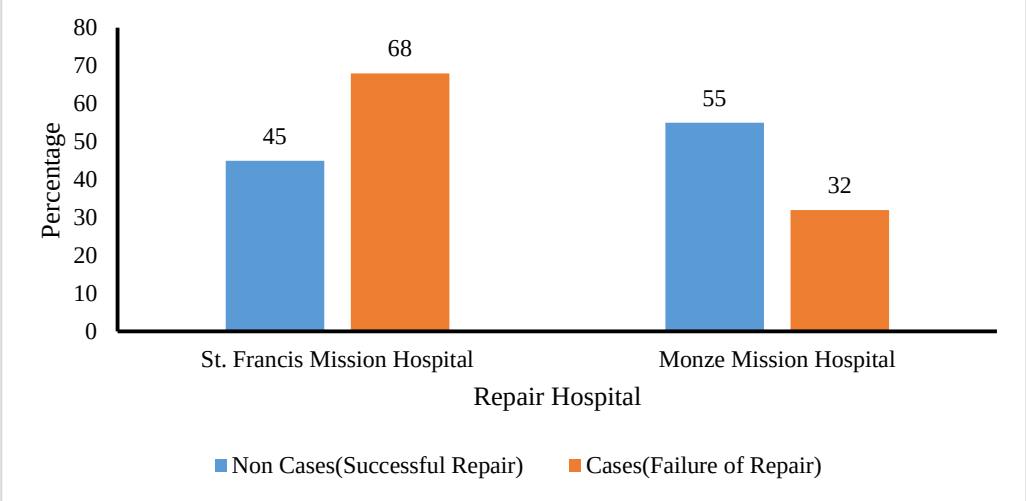

Figure 4.12: Distribution of failure of repair by repair hospital, Zambia, 2010—2016.

4.1.2 **Analytical Statistics**

The social demographic determinants associated with obstetric fistula repair failures at unadjusted logistic regression analysis in this study are summarized in Table 4.5.

4.1.2.1 **Univariate Logistic Regression Analysis**

Table 5.5: Association between Social Demographic Characteristics and Failure of Repair of Fistula

Variable Characteristic	Unadjusted OR(95% CI)*	P-Value*
Marital Status		
Married	1	1
Single	1.012(0.503,2.039)	0.97
Divorced/separated	2.975(1.226,7.218)	**0.02**
Widow	3.068(0.776, 12.138)	0.11
Education Level		
None	1	1
Other	0.453(0.105,1.950)	0.29
Age at Repair		
10—19	1	1
20—29	3.55(1.195,10561)	**0.02**
30—39	3.297(1.069,10.168)	**0.04**
40+	3.402(1.019,11.359)	**0.05**
Age at Fistula Development		
10—19	1	1
20—29	2.038(1.006,4.127)	**0.05**
30—39	1.403(0.591,3.327)	0.44
40+	0.814(0.172,3.856)	0.79
Residence		
Rural	1	1
Urban	0.497(0.064,3.857)	0.50

OR=Odds Ratio ***CI= Confidence Interval*** ****Univariate logistic regression***

Being divorced or separated at time of fistula repair was associated with increased odds (P-value 0.016, CI 1.23-7.22, OR 2.9) of failure of fistula compared to being married. Age group

20-29 at fistula development was significantly associated with increased odds (P-value 0.048, CI 1.01-4.13, OR 2.04) of failure of repair compared to age group 10-19.

The obstetric, fistula and clinical characteristics associated with failure of repair of obstetric fistula at unadjusted odds ratios have been summarized below (Table 4.6)

Table 4.6: Association between Obstetric, Fistula and Clinical Characteristics and Repair Outcome

Variable Characteristic	Unadjusted OR(95% CI)	P-Value
HIV Status		
Negative	1	1
Positive	2.493(0.621, 10.009)	0.198
Unknown	0.391(0.185,0.825)	**0.014**
Mode of delivery resulting in fistula development		
SVD	1	1
CS	0.941(0.521,1.698)	0.839
Instrumental	0.750(0.162,3.479	0.713
Presence of Vaginal scarring		
No	1	1
Yes	3.783(2.112, 6.775)	**<0.001**
Presence of Comorbidities		
No	1	1
Yes	2.696(1.274, 5.704)	**0.009**
Parity at Fistula Development		
0—1	1	1
2—3	0.724(0 .355 1.475)	0.374
4+	1.139(0.582 2.230)	0.704
Parity at Fistula Repair		
0—1	1	1
2—3	1.656(0.841, 3.261)	0.144
4+	1.689(.8165, 3.495)	0.158

Previous Repair attempts		
No	1	1
Yes	1.739(0.912, 3.318)	0.093
Urethral Involvement		
No	1	1
Yes	7.551(4.153, 13.723)	**<0.001**
Outcome of Delivery		
Alive	1	1
SB	1.936(0.847, 4.427)	0.118
Pre-op antibiotics		
No	1	1
Yes	2.546(0.767, 8.455)	0.127
Post-op Complications		
No	1	1
Yes	32.671(14.736, 72.434)	**<0.001**
Repair Technique		
Transabdominal	1	1
Transvaginal	1.157(0.517, 2.587)	0.723
Repair Hospital		
Monze	1	1
St. Francis	2.545(1.404, 4.612)	**0.002**

OR=Odds Ratio ***CI= Confidence Interval*** ****Univariate logistic regression***

Women whose HIV status was unknown at the time of repair had 61 %(95% CI: 0.18-0.83, p-value 0.014; OR=0.39) increased odds of failure of repair compared to those who were HIV negative. Those women who had vaginal scarring (OR=3.8, 95%CI: 2.1—6.8; P-value <0.001) had four (4) times greater odds of failure of repair of fistula than those who had no scarring. Women who had other comorbidities (OR=2.7, 95%CI: 1.3—5.7; P-value<0.009) had three (3) times increased odds of failure compared to women who did not have. Women who had urethral involvement (urethral damage during fistula development) had eighty (8) times greater odds (OR=7.5, 95% CI: 4.2—13.7; P-value<0.001) than women who had an intact urethra.

Women who had post-operative complications had thirty-three (33) times increased odds of repair failure (OR=32.7, 95% CI: 14.7—72.4; P-value <0.001) compared to those who had none. Participants who had previous repair attempt had two (2) times increased odds (OR= 1.72; 95%CI: 0.912—3.318, P=0.093) of failure compared to women who had no previous repair. We also found that women who were repaired at St. Francis Mission Hospital had three (3) times greater odds of experiencing failure (OR=2.5, 95% CI: 1.4—4.6; P-value 0.002) than those repaired at Monze Mission Hospital.

4.1.2. 2 **Multiple Logistic Regression**

In multiple logistic regression analysis, after adjusting for the confounding effects of age at repair, marital status, age at fistula development and previous repair attempts, women with presence of vaginal scarring at repair had three(3) times increased odds of failure of (AOR=2.5, 95% CI: 1.17—5.35; P-value 0.002) compared to those who had none. Those who developed post-operative complications after repair had twenty-three (23) times greater odds of failure than those who did not (AOR=22.9, 95%CI: 9.33—55.97; P-value <0.001). Women who had damaged urethra had six (6) times increased odds of failure (AOR=6.0, 95% CI: 2.83—12.97; P-value <0.001) compared to those who had an intact urethra. Those women who were repaired at St. Francis Mission Hospital had two (2) times greater odds of failure (AOR=2.3, 95% CI: 0.95—5.61; P-value 0.06) than those repaired at Monze Mission Hospital (see Table 4.7)

Table 4.7: Final model for predictor variables for Obstetric Fistula Repair failures among women operated at St. Francis and Monze Mission Hospitals in Zambia between January 2010 and December 2016.

Predictors of Repair Failure	**Adjusted OR(95% CI)**	**P-Value**
Presence of Vaginal scarring		
No	1	1
Yes	2.5(1.17—5.35)	**0.02**
Post-op Complications		
No	1	1
Yes	22.9(9.33—55.97)	**<0.00**
Urethral Involvement		
No	1	1
Yes	6.0(2.83—12.97)	<**0.00**
Repair Hospital		
Monze	1	1
St. Francis	2.312(0.95—5.61	**0.064**
Presence of comorbidities		
No	1	1
Yes	2.0(0.69—5.99)	**0.20**
HIV Status		
Negative	1	1
Positive	1.1(0.11—8.65)	0.97
Unknown	0.4(0.17—1.02)	0.06

OR=Odds Ratio ***CI= Confidence Interval***

CHAPTER FIVE

5. 1 Discussion

In this thesis, we provide a detailed overview of the factors that were associated with failure of repair of obstetric fistula at two of Zambia's fistula repair hospitals. The discussion is structured under Obstetric fistula repair failure outcome, social demographic characteristics associated with failure of obstetric fistula repair, obstetric factors associated with failure of repair of fistula and Fistula and Clinical characteristics that affect fistula repair at the two hospitals among women who underwent repair at St. Francis and Monze Mission Hospitals

5.2 **Obstetric Fistula Repair Failure outcome**

The overall proportion of failure of repair of obstetric fistula at hospital discharge was found to be 12.4%. In a study done on a tertiary hospital in Rwanda(Tekle G. Egziabher, 2015), the failure rate was 13.7% while studies in the Democratic Republic of Congo(Nsambi et al., 2018),Guinea(Delamou et al., 2016) and South Africa(Naidoo et al., 2018), found failure rates of 14% ,14.5% and 14.9% respectively. The failure rates are similar because of probably similarities in context as well as fistula and clinical characteristics. In our study, the failure rate falls within the World Health Organization (WHO) proposed failure rate of less than 15% for first repairs (de Bernis, 2007). In addition, it was much lower than that reported of 27.1% (Holme et al., 2007) in 2007 at Zambia's Monze Mission Hospital and 22.1%(ayondo et al., 2011) in a Ugandan hospital. The difference mighty be explained by improvements in surgical and nursing skills for management of fistula clients in line with the "Campaign to End Fistula" launched in 2003(UNFPA., 2014) and adopted by many African countries. Following this vision, a number of countries have trained key medical staff to improve their surgical skills and also made improvements in medical infrastructure and equipment for the management of fistula patients.

5.3 **Socio-Demographic Characteristics of Obstetric Fistula Patients**

The majority of the women in our study were still married (66.9%) at the time of repair. This is similar to the 75.7% observed at Monze Mission Hospital in 2007 (Holme et al., 2007). The high proportion of women still married found in both these studies might be explained by increased sensitization and understanding about the cause of the obstetric fistula couple by positive religious beliefs in Zambia where divorce is considered unacceptable.

In the univariate logistic regression, we found that women with failure of repair had increased odds of being divorced or separated compared to women with successful repair and this is quite similar to what has been reported in previous studies which indicated that women with unsuccessful surgical repair face greater stigma and other challenges such as divorce or separation and rejection than those who are healed.(Muleta, 2004, Khisa and Nyamongo, 2012, Cook et al., 2004, Wall et al., 2004, Delamou et al., 2016). It also agrees with another study which reported that the woman with a persistent fistula either blames herself or is blamed by the community for the condition which is viewed as a mark of punishment for some wrongdoing (Johnson et al., 2010). She is abandoned by her husband and family to live as a social outcast without the ability to earn a living.

A high proportion (93%) of participants in our study had no formal education, no formal employment (100%) and came from rural areas (96.7%). These findings are consistent with that reported in other African studies in which the participants were undernourished, uneducated, poor and from rural areas (Raassen et al., 2008, Wall et al., 2004, Melah et al., 2007, Delamou et al., 2016). This could be due to an interaction between cultural and socio-economic factors like early marriages in rural poor areas complicated by long distances to health facilities for timely intervention during complications of obstructed and/or prolonged labour (Raassen, 2008, Nsambi, 2018).

5.4 **Obstetric Characteristics of Fistula Clients**

The median age of women at fistula development in this study was 23 during their second pregnancy and compares well with findings from a study in the Democratic Republic of Congo in which parity at fistula development was found to be between two and three. However, it differs from other previous studies where women with obstetric fistula were primiparous at fistula development (ayondo et al., 2011, Holme et al., 2007). This shows that fistula development can occur at any parity if quality obstetric care is not provided and agrees with the findings from a Tanzanian survey by the Women's Dignity Project and Engender Health (2006) which showed that fewer than half of the fistula resulted from a first birth while more than half occurred in subsequent pregnancies.

The majority of the participants in this study had delivered by caesarean section with a higher proportion of the deliveries resulting in perinatal mortalities. Similar findings were reported in Uganda, Rwanda, Nigeria and Guinea (ayondo et al., 2011, Barageine et al., 2015, Tekle G. Egziabher, 2015, Kirschner et al., 2010, Delamou et al., 2016). The high proportion of perinatal mortalities might be explained by inability of pregnant women to seek care at the health facility early probably due to long distances and lack finances for transport. In addition, delay by health workers to deliver the women by a caesarean section while at the health facility could also account for the high rate of perinatal mortalities. This is clinically important and calls for improvement in the quality of monitoring of women in labour using a partographs. To achieve this, medical staff handling fistula clients should be conducting regular standard clinic audits and reviews as well as mentorships and performance appraisals for midwives and doctors. It is also important to actively engage the community through the Safe Motherhood Action Groups (SMAGs) for early identification and referral of pregnant women for delivery at the health facility.

5.5 **Fistula and Clinical Characteristics**

In our study, majority of the participants had vesico-vaginal fistula while only a few had recto-vaginal fistula which compares well to a previous study at Monze Mission Hospital by Holme et al, in 2007. This is probably due to the mechanism of formation of fistula in cephalic presentation during labour and since it is the same country and context, the cause of fistula

could be similar. The findings also compares favourably with other studies in West and East Africa (ayondo et al., 2011, Barageine et al., 2015, Delamou et al., 2016). The median duration with obstetric fistula before surgical repair was one (1) year. This differs from studies done in Ethiopia (Goh et al., 2008, ayondo et al., 2011, Nardos et al., 2009) where the median duration was three to four years. This difference could be due to increased sensitizations and fistula repair camps that are conducted in Zambia in all the provincial general hospitals. Active identification of cases in the community and referring them for repair has helped to reduce the number of years that women stay with fistula.

5.6 **Factors Associated with Failure of Obstetric Fistula Repair**

In bivariate analysis, marital status, age at repair, age at fistula development, HIV status, vaginal scarring, comorbidities, urethral involvement, post complications and repair hospital were found to be statistically and significantly associated with failure of repair of obstetric fistula (Table 6). However, in multiple logistic regression, after adjusting for the confounding effects of marital status, age at repair, age at fistula development, repair hospital, previous repair attempts and comorbidities only vaginal scarring, post-operative complications and urethral involvement, were independently associated with failure of repair of obstetric fistula (**Table 4.7**).

In this study, women with vaginal scarring were found to have increased odds of failure of repair compared to those who had no vaginal scarring .This finding is similar to other observed studies. A study in Western Uganda on predictors and outcome of surgical repair of obstetric fistula found that women with moderate to severe vaginal scarring had twelve (12) times greater odds of unsuccessful repair than those with mild or none(ayondo et al., 2011). Several other studies have also reported strong associations between vaginal scarring and failure of repair of fistula (Mark A. Barone et al., 2012, Vera Frajzyngier, 2012, Goh et al., 2008, Browning, 2006). This is probably because of the formation of fibrotic or scar tissue which causes reduced amount of viable tissue to mobilize during repair coupled with reduced blood supply which is important for wound healing.

Women who had damaged urethra (urethral involvement) had greater odds to experience failure of repair of fistula than those who had an intact urethra. This is quite similar to what has been reported in other studies(Delamou et al., 2016, ayondo et al., 2011, Mark A. Barone et al., 2012, Vera Frajzyngier, 2012, Sjoveian et al., 2011, Nardos et al., 2009, Browning, 2006). A fistula that involves urethral damage is described as complex because of the associated great difficult surgeons face at repair. The damage might affect the sphincter mechanism and reduce the bladder size thereby making it more difficult to repair even by experienced surgeons.

We also found that women who had post-operative complications after repair had increased odds of failure of repair compared to those who did not and this contrasts findings from other studies in which researchers found that post-operative complications were not associated with failure of closure of fistula (Delamou et al., 2016). In our study, the post-operative complications were mainly post-operative infected wounds, blocked catheter and Urinary Tract Infection. This is probably linked to the low quality of post-operative care services of infection prevention and inadequate monitoring of catheter drainage. In addition, routine use of broad spectrum antibiotics which could be resistant to common causes of wound infection is a possibility. Conducting antibiotic sensitivity and susceptibility tests could help to identify highly effective antibiotics to prevent post-operative infected wounds.

We also found that failure of fistula repair varied between the two repair hospitals. Repairs that were done at St. Francis Mission Hospital were marginally significantly associated with greater odds of failure than those repaired at Monze Mission Hospital. The reasons might be because Monze Mission Hospital had a resident fistula surgeon for the period of the study while St. Francis Mission mainly depended on visiting fistula surgeons who had limited time to observe the patients repaired. In addition, Monze Mission Hospital has been the main primary fistula repair and training centre for a long time in Zambia. St. Francis Mission Hospital started just recently. Therefore, differences in uptake of interventions and skills might exist between the two hospitals. The fistula staff at Monze Mission Hospital might have had more experience and training that those at St. Francis Mission Hospital. However, it was difficult to adjust for this finding because the study did not assess the skills and experience of the surgeons and other

staff attending to fistula patients. A study in Guinea's three main fistula repair hospitals reported similar findings (Delamou et al., 2016).

Among factors associated with obstetric fistula repair failure, it was expected that previous repair attempt would be significant, but contrary to that previous repair attempt was insignificant in multiple logistics regression. This is quite in contrast to findings in other studies and could be because in our study, the proportion of those who had previous repair attempt in our study was quite low compared to those with no previous repair attempt. Findings from other studies(Tekle G. Egziabher, 2015, Delamou et al., 2016, Munoz et al., 2011, Goh et al., 2008, Nardos et al., 2009, Browning, 2006) have reported otherwise. A study at a regional referral hospital in western Uganda, researchers reported that women who had had previous unsuccessful repair had five(5) times greater odds of failure than those who had no previous repair (ayondo et al., 2011).This could be explained by the fact that each additional repair attempt leads to more tissue damage and scarring. Therefore, it is important to ensure high quality pre, peri and post-operative care of fistula patients at first attempt.

CHAPTER SIX

6.1 Conclusion

In this study, we found that obstetric fistula was more common among married women with no education, poor and coming from rural areas. The majority of the fistula were caused by obstructed labour with a high proportion of vesico-vaginal fistula as compared to the other types.

The obstetric fistula repair failure rate following surgery was 12.4% and the factors identified to be associated with failure were post-operative complications, urethral involvement/damage and vaginal scarring.

6.2 Recommendations

Based on the findings from this study, we would like to recommend the following:

i. Improve the care of women presenting with obstructed labour by performing quality caesarean section and urinary catheterization expeditiously.

ii. Improve post-operative management of women operated for obstetric fistula at the two hospitals. Good nursing care is essential to prevent post-operative complications such as wound infections. Both new and old doctors, nurses and physiotherapists at both St. Francis and Monze Mission hospitals should receive specialized training in pre and post-operative care of fistula patients including psychological and counseling skills.

iii. Women who present with complex fistulas (urethral involvement/damage, vaginal scarring, and previous repair attempt) should be identified early through detailed screening and physical examination and referred to experienced surgeons for fistula repair. In addition, these experienced doctors should identify other doctors who they can train to handle complex fistulas through mentorship, on the job training and exchange programs with hospitals that handle complex fistulas on a large scale such as the Addis Ababa Fistula Hospital in Ethiopia. This is critical in that it ensures transfer of skills to upcoming medical staff for continued provision of fistula services to the nation.

iv. Both hospitals need to improve fistula data management by adopting standardized tools that should capture important fistula indicators and thus avoid missing key information on fistula. This can be done in consultation with major stakeholders like UNFPA, the community, fistula surgeons/nurses/counselors, researchers and the Ministry of Health. What is also key is to develop a secure electronic data base for fistula which can be merged/ captured in the District Health Information System (DHIS).

v. In addition, there is need to conduct more studies especially prospectively to provide more insights into the other factors that may predict failure of repair and probably over consider longer follow-up periods.

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APPENDICES

Appendix 1: Data extraction form

PREDICTORS OF OBSTETRIC FISTULA REPAIR FAILURES

CHECK LIST

Study Number…….. Name of Repair Hospital…….

Socio-Demographic characteristics

1. Age (years) ☐

2. Religion of Client:

◯ Christian ◯ Muslim ◯ Other If other Specify :……

3. Marital status of client

◯ Married/union ◯ Divorced/separated ◯ Single ◯ Widow ◯ Other

If Divorced/separated, given reason ……..

4. Residence:

◯ Rural ◯ Urban

5. Province where residing……

6. What is the occupation of the client

◯ Does not work

◯ Formal employment

◯ Informal employment

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P/BAG 125, LUSAKA

7. Education Level of client:

◯ None ◯ Secondary

◯ Primary ◯ Tertiary

Gynecologic and Clinic characteristics

8. What is the parity (number of deliveries) of client? ☐

9. Did fistula develop after delivery? ◯ Yes ◯ No

   If "No" describe how fistula develop.....

10. Which delivery resulted in fistula development (Delivery number)? ☐

11. Where did the delivery take place? ◯ Home ◯ Health facility

    If health facility delivery, how long after labour pains began did client take to go the facility ☐

12. Mode of delivery
    ◯ Vaginal delivery ◯ Caesarean Section ◯ Instrumental delivery

13. Outcome of delivery
    ◯ Alive ◯ Stillborn

14. How long after delivery did fistula develop? ☐

15. Did the woman develop any infection of the female reproductive system before development of fistula? ◯ Yes ◯ No

    If "Yes" what type of infection?.....

Fistula Characteristics

16. Type of fistula
    ◯ Vesico-vaginal ◯ Recto-vaginal

    ◯ Combined vesico-vaginal and rectovaginal fistulae ◯ Other (specify).....

17. Presence of vaginal scarring ◯ Yes ◯ No

18. Any history of previous fistula repair? ◯ Yes ◯ No

    If "Yes" how many fistula repairs ☐ and when was last repair?.....

19. Number of fistulas: ◯ Multiple ◯ Single

Pre, Intra- and Post-operative Information

20. Pre-operative administration of antibiotics ◯ Yes ◯ No

21. How long did the surgical operation take? [ ]

22. Significant findings during the operation:

◯ Vaginal scarring ◯ Multiple Fistulas ◯ Other

If "Other" describe.....

23. Number of days catheterized post-operatively [ ]

24. How long was client admitted post-operatively? [ ]

25. Any post-operative complications? ◯ Yes ◯ No

If "Yes" describe complication.....

26. Dye test result at discharge

◯ Positive ◯ Negative ◯ No result indicated

If "Negative" is the woman still leaking urine and/or feces

◯ Yes ◯ No

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Appendix 2: Ethics approval letter

ERES CONVERGE

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I.R.B. No. 00005948
F.W.A. No. 00011697

8th September, 2017

Ref. No. 2017-July-028

Principal Investigator
Dr. Fred Kapaya
The University of Zambia
School of Public Health
P.O. Box 50110,
LUSAKA.

Dear Dr. Kapaya,

RE: PREDICTORS OF OBSTETRIC FISTULA REPAIR FAILURES AT MONZE AND ST. FRANCIS MISSION HOSPITALS: A RETROSPECTIVE COHORT STUDY.

Reference is made to your corrections dated 28th August, 2017. The IRB resolved to approve this study and your participation as Principal Investigator for a period of one year.

Review Type	**Ordinary**	Approval No. **2017-July-028**
Approval and Expiry Date	Approval Date: 8th September, 2017	Expiry Date: 7th September, 2018
Protocol Version and Date	Version-Nil	7th September, 2018
Information Sheet, Consent Forms and Dates	• N/A	7th September, 2018
Consent form ID and Date	Version -Nil	7th September, 2018
Recruitment Materials	Nil	7th September, 2018
Other Study Documents	Checklist.	7th September, 2018
Number of participants approved for study	-	7th September, 2018

Specific conditions will apply to this approval. As Principal Investigator it is your responsibility to ensure that the contents of this letter are adhered to. If these are not adhered to, the approval may be suspended. Should the study be suspended, study sponsors and other regulatory authorities will be informed.

Conditions of Approval

- No participant may be involved in any study procedure prior to the study approval or after the expiration date.
- All unanticipated or Serious Adverse Events (SAEs) must be reported to the IRB within 5 days.
- All protocol modifications must be IRB approved prior to implementation unless they are intended to reduce risk (but must still be reported for approval). Modifications will include any change of investigator/s or site address.
- All protocol deviations must be reported to the IRB within 5 working days.
- All recruitment materials must be approved by the IRB prior to being used.
- Principal investigators are responsible for initiating Continuing Review proceedings. Documents must be received by the IRB at least 30 days before the expiry date. This is for the purpose of facilitating the review process. Any documents received less than 30 days before expiry will be labelled "late submissions" and will incur a penalty.
- Every 6 (six) months a progress report form supplied by ERES IRB must be filled in and submitted to us.
- ERES Converge IRB does not "stamp" approval letters, consent forms or study documents unless requested for in writing. This is because the approval letter clearly indicates the documents approved by the IRB as well as other elements and conditions of approval.

Should you have any questions regarding anything indicated in this letter, please do not hesitate to get in touch with us at the above indicated address.

On behalf of ERES Converge IRB, we would like to wish you all the success as you carry out your study.

Yours faithfully,
ERES CONVERGE IRB

Prof. E. Munalula-Nkandu
BSc (Hons), MSc, MA Bioethics, PgD R/Ethics, PhD
CHAIRPERSON

Appendix 3: Authority letter to conduct Research

THE NATIONAL HEALTH RESEARCH AUTHORITY
C/O Ministry of Health
Haile Selaisse Avenue,
Ndeke House
P.O. Box 30205
LUSAKA

MH/101/23/10/1

20 September 2017

Dr. Fred Kapaya
The University of Zambia
School of Public Health
P.O Box 50110
LUSAKA

Re: Request for Authority to Conduct Research

The National Health Research Authority is in receipt of your request for authority to conduct research titled **"Predictors of Obstetric Fistula Repair Failures: A Retrospective Facility Based Cohort Study".**

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, and all key respondents.

Yours sincerely,

Sandra Chilengi-Sakala
For/Director
National Health Research Authority