THE CHARACTERISTICS AND CLINICAL OUTCOMES OF PATIENTS UNDERGOING REPEAT REPAIR FOR OBSTETRIC FISTULA AT KENYATTA NATIONAL HOSPITAL

A Dissertation Submitted in Partial Fulfillment of the Requirements for the Degree of Master of Medicine in Obstetrics and Gynaecology,
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STUDENT'S DECLARATION

I hereby declare that this dissertation is my original work. It was developed by me, with the guidance of my supervisors, senior members of the Department of Obstetrics and Gynaecology, University of Nairobi. It has not been submitted to any other University for a degree award.

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CERTIFICATE OF AUTHENTICITY

This is to certify that this dissertation is the original work of Dr Naomi Nabachenja Sitati, an M.Med student in the Department of Obstetrics and Gynaecology, College of Health Sciences, University of Nairobi, under the guidance and supervision of Dr Anne Kihara, Dr Kizito Lubano and Dr Weston Khisa. This dissertation has not been presented in any other university for award of a degree.

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DEDICATION

I dedicate my dissertation to God, for giving me life and opportunity. To my husband, Juma Mwangi, for his unwavering support and encouragement. To my beloved daughter, Olivia Wacera, for the miracle that she is. I also dedicate this work to my parents, Mr. and Mrs. Sitati for their constant prayers and for going above and beyond. To my siblings, Matthew, Peter, Moses, Francis, Elizabeth and Florence, thank you for walking with me.

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TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

ABBREVIATIONS

FGM: Female Genital Mutilation

KG: Kilograms

KNH: Kenyatta National Hospital

MDG: Millennium Development Goals

OF: Obstetric Fistula

RVF: Rectovaginal Fistula

SPSS: Statistical Package for Social Sciences

SSA: Sub Saharan Africa

TBA: Traditional Birth Attendant

UTI: Urinary Tract Infection

VVF: Vesicovaginal Fistula

WHO: World Health Organization

OPERATIONAL DEFINITIONS

Repeat repair of fistula	To perform a surgery on a fistula that had previously been surgically closed before

ABSTRACT

Introduction: The mainstay of managing obstetric fistula (OF) is surgical. Primary closure of an OF is usually successful but in some women this may persist necessitating secondary closure or repeat repair. Women who undergo repeat repair have certain characteristics majorly as a result of the type of fistula, extent of injury or unsuccessful closure of the primary fistula. Most studies include patients that are undergoing both primary and secondary repair This study aims at describing the clinical characteristics and clinical outcomes associated with repeat OF repairs, with the aim to improve their management.

Objective: To describe the socio-demographic and clinical characteristics of patients undergoing repeat repair for obstetric fistulae at the KNH between 1st May 2010 and 30th June 2015 and the clinical outcomes following repeat repair.

Methodology: Out of a total of 723 patients with obstetric fistula operated during the period, 249 (34%) underwent repeat repairs. Two hundred and three records (102 VVF and 101 RVF) of patients who underwent repeat repairs were consecutively selected. Descriptive data was presented in tables of means and medians; further analysis was done using the student t test for comparing means and chi square tests for association between patient characteristics and outcomes. A p value of < 0.05 was taken to be statistically significant.

Results: Overall, 60% of the study participants were married and just about two thirds had attained some basic level of education. The most common type of VVF was type IIAa at 44% while type IIb was the commonest type of RVF at 89.9%. The mean age for VVF development was 22.3 years while for the RVF was 25.5 years. This was statistically significant with a p value <001. Delivery via caesarean section was higher in those with VVF (55.9%) as compared to those with RVF (7.9%). Most of the VVF were small at 55.7% and had at least one prior repair at 59.8%. For the RVF patients, 70.6% were medium in size while 40.2% had one prior repair. Residual incontinence was at 36.6% of patients with VVF. Patients with RVF had 100% recovery.

Conclusion: Specific policy guidelines by stakeholders of obstetric fistula should be developed into prevention and management of associated complications.

CHAPTER ONE: INTRODUCTION

1.1 Background of the Study

An Obstetric fistula (OF) is an opening between the vagina and the bladder (Vesico-vaginal fistula: VVF) and/or the vagina and the rectum (Recto-Vaginal fistula: RVF) resulting from prolonged and obstructed labour. It leaves the women with leakage of urine or feaces or both and has been observed since women first began delivering children (1). The mainstay of treatment is surgical. Unsuccessful primary closure may then warrant or require a repeat repair. Most studies include those undergoing both first time and secondary repair. Little is known about the outcome of obstetric fistula surgery following subsequent surgery (2).

Currently, the global estimates for OF is at 2- 3.5 million cases, with an incidence of 50,000 – 130,000 yearly (3). It is most common in SSA with a high prevalence in Nigeria, Chad as well as Ethiopia. In Northern Nigeria, there are approximately 1000 patients awaiting treatment at any one time. A further review of admissions at the Addis Ababa Fistula Hospital in 1974- 2006, showed a prevalence of RVF at 13.5% amongst a population of 14,928 Ethiopian women (1).

In Kenya, there are an estimated 3000 cases annually. Only 7.5% of these women are able to access care for the condition (4). The KDHS 2014 showed that 1% of women had ever experienced fistula (5). During the VVF camps held at KNH and Embu level V hospital in the same year, more than 1400 women presented with complaints of urinary leakage, feacal incontinence or both. Among those with symptoms, 32% had unrepaired 3rd and 4th degree tears while 58% had fistula of obstetric origin (2). The proportion of women represented by these figures may be underestimated. Khisa et al presented the fact that women may suffer from unrepaired 3rd and 4th degree tears hence possibly alleviate a sizeable portion of the local/global fistula burden (4).

Sustained pressure exerted by the presenting part of the foetus during labour results in obstetric fistula. The process of labour may even last for several days. The level at which foetal descent is arrested determines the site of injury in the lower uterine tract. As pressure increases, the blood supply to the soft tissues of the pelvis reduces. This results in extensive vascular injury hence tissue necrosis thus the formation of large fistula, with scarring and reduced vascularity in the tissues surrounding the defect (6,7).

As a result, most women with obstetric fistulas may have injuries involving multiple organ systems. These injuries have been characterized as part of a syndrome called "obstetric labour injury complex" which can involve the urologic, gynaecologic, gastrointestinal, neurologic and the musculoskeletal system (7–9). The level of injury, usually in the lower uterine tract is determined by the point at which the descent of the presenting foetal part is obstructed during the process of labour. This may involve the urethra, the bladder, one or both ureters and the rectum (1,10,11).

Many classification systems have been employed in the past and most are based on the description of the size and anatomic location of the defect. These have been especially important in giving information on the appearance of a given fistula but give no information on the difficulty of repair or the prognosis for a successful outcome. Defects have been classified using the Sims, VVF score, Mahfouz, Lawson, Goh & Krause, Waaldijk amongst many others (12–15). At the KNH, the Waaldijk system is largely used. This system classifies fistulae as shown in table 1 below:

Table 1: Waaldijk system of fistula classification

a. VVF classification

I- Fistula not involving the closing mechanism
II- Fistula involving the closing mechanism
A Without total urethral involvement
a Without circumferential defect
b With circumferential defect
B With total urethral involvement
a Without circumferential defect
b With circumferential defect
III- Ureteric and other exceptional fistulas

b. RVF classification

Ia Without rectal stricture
Ib With rectal stricture
IIa Without sphincter involvement
IIb With sphincter involvement
IIc Circumferential involvement

The management of this condition may be conservative or surgical. One of the greatest challenges for the fistula surgeon has been to regain continence in patients suffering complex injuries. Even then, fistula repair has had the reputation of being difficult (8).Primary repair approaches are either trans-vaginal or through the abdominal route. At times, even after primary repair of the fistula, the woman may still have involuntary loss of urine (stress incontinence) due to damage to the closing mechanism. This has been shown to occur in up 24% of patients (16). Barone et al showed a residual incontinence in patients that varied between 9.9-47.1%.

Repeat fistula surgery is an added economic and social burden for both the woman and the fistula care programs. There is also a reduced likelihood for successful closure following repeated attempts.

CHAPTER TWO: LITERATURE REVIEW

Surgery remains the mainstay of treatment for OF. Unsuccessful fistula closure has been shown to occur in up to 10-15% of patients. It has been shown to be significantly associated with the size and type of fistula and also the extent of scarring of the surrounding tissue (2). In addition, the surgeons skill and method of closure may also influence the outcome(17). These patients may often have to undergo repeat surgical repair. However, the success rates have been shown to be lower with multiple attempts at repair (18,19).

In low resource countries, there is interplay of many factors contributing to poor maternal care. From the socio economic aspect, low levels of education, local birthing rites, early marriages, informal Traditional Birth Attendants (TBA) deliveries and cultural practices such as Female Genital Mutilation (FGM), poorly equipped and poor access to health facilities and poor management of emergency cases are some of the key issues contributing to OF. Biologically, immature development of the pelvis in teen pregnancies and malnutrition are also contributory (1,20,21).

The likelihood of obstructed labour has been linked to several factors and it reflects the deficiency in the general health status of women. Socio-economic factors such as early age at first marriage which is associated with short stature as the girls/young women are not physically well developed. Studies have shown that the average age at first marriage is between 14 - 17 years, with a mean range height of 146.2cm- 152.7cm. Immature pelvic development due to young age, small stature and malnutrition have all been associated with an increased risk of cephalo-pelvic disproportion, but none of these factors have adequate positive predictive value as screening tools for the development of OF (6,22,23).

Although the risk of obstructed labour is greatest in young nulliparous mothers, any woman can develop the condition if the right combinations of obstetric factors converge. Poverty and illiteracy also play a key role as major risk factors to developing fistula. In Sudan, 69% of women in 2008-2009, with OF were illiterate which is just as high as the 77.4% in Ethiopia. In Kenya, 43% of the female population in the reproductive age had attained some form of secondary education while 7% had no form of education at all (5).

A bimodal distribution of fistulae has often been reported, with the highest peak in primiparas and another peak in women who have had more than 4 deliveries- a reflection, perhaps, of the trend of increasing birth weights with subsequent gestations. Clinical studies in Africa show that a large proportion of OF's affect the women below 20 years. In Asia, most women are between 20-35 years, while in Pakistan, most women were often multiparas. In Nigeria, fistula developed most commonly in primipara at 45.8% and 20% in women of higher parity (> 4 pregnancies). In Uganda and Tanzania, 44% of women in both countries had a parity of two or higher while approximately 53% of them were primipara (23).

The rate of stillbirths related with OF is very high. In Nigeria, it stood at 91.7% and was mostly associated with male fetuses at 70.6% while 23.4% were female. Inadequate social and economic infrastructure poses a great challenge in accessing comprehensive and emergency obstetric care. Majority of the patients reside in the rural areas with poor road and communication networks. Ante natal care, delivery at health facilities and skilled attendants at delivery are all necessary in achieving MDGs. In Nigeria, 84% of fistula patients had less than 2 visits while 45% had more than 4 visits.(1)

Over the years, there has been an upward trend in Kenya. In 2003, 88% of women had ANC by a skilled provider as compared to 96% in 2014. For assistance at delivery by a skilled provider, this has improved from 42% to 62% while delivery at a health facility has increased from 40% to 61%. Utility of family planning methods has also greatly improved at 58 % (5).

As part of the urologic system injury, the flow of urine may be blocked due to injuries to the urethra. During voiding, the bladder empties through the urethra that is located at the lower end of the bladder. It is made up of smooth muscles and has sphincters that stay closed as the bladder fills up. In cases of extensive injuries, there is urine leakage. More complex fistulae involve the bladder neck, urethra and have severe scarring. Their repair usually has a lower success rate and even when successful, it is usually associated with significant residual stress incontinence. The incontinence may be corrected by standard surgical techniques such as the use of sub-urethral slings though some cases have been particularly resistant to these techniques (7,24–26).

As the leakage continues over a long duration of time (more than one 1 year), the tissue surrounding the fistula becomes more fibrotic making the defect more amenable to surgical repairs. Continence following repair greatly reduces the burden of suffering from the woman. Incontinence on the other hand, may worsen, if not always leading to social stigmatization, depression and isolation (25,26).

Most fistulae can be successfully closed at the time of surgical intervention with good success. The aim is to restore the functionality of the lower urinary tract and the surrounding pelvic structures (6,27,28). Primary repair of an OF has shown to have the highest probability of a good outcome. This however depends on the size, site and the amount of scarring in the surrounding tissues (18,28).

In 2003, the United Nations Fund for Population Activities (UNFPA) launched the "Global campaign to end fistula". During this time, 10-20% of patients had complex fistulae such that restoration of a continent bladder was near impossible. The choice of route of repair has been shown to be associated with the surgeons experience and the type of fistula. A transvaginal approach is used in most type I and II fistulae with a success rate of over 90%. The abdominal approach is used for high fistulae and those that have ureteric involvement (3,7).

Despite the high success rate following primary repair of OF, urinary incontinence is still a significant, debilitating problem that is not well understood. A repair is described to have failed if there is evidence of continued leakage of urine at 6-12 weeks post surgery (29). In some of the cases, the surgery may have anatomically closed the defect but remains functionally inadequate. Some factors related to the outcome include pre operative bladder size, extent of vaginal scarring, involvement of the urethra, location of the fistula and history of previous attempts at repair (18,28).

Many patients in SSA and other resource poor areas of the world have complex fistulas that require expert skills for management and evaluation. These include those that involve the continent mechanisms and are larger than 4 cm in association with moderate to severe scarring of the bladder trigone or the urethrovesical junction and with multiple openings. They become more complicated if more than 6 cm in their largest dimension with the absence of the urethra or when combined with a RVF (30).

The success of fistula repair largely depends on good surgical skills, excellent post operative care and the prevention of complications. The aim is to restore normal functioning of the lower urinary tract and other pelvic structures. The surgical procedure must always exploit the basic surgical principles. A good outcome is also achieved by accurate and timely repair (31).

Immediate repair of fistula can be done with retaining a catheter for a period of 10-14 days. Traditionally, repair was undertaken after three months to allow for fibrotic tissue to form hence allow for mobility during the surgery (9,18). Studies in Nigeria have shown 10-15% of patients to have a residual fistula or residual pelvic floor disorder for instance, stress incontinence following primary repair (8). This remains as a perplexing problem for the patient.

Different authors may report outcomes using varied definitions. Some present the rates of closure, others clearly distinguish fistula closure and continence following surgical repair. A comparison of the true outcomes and performance from different settings may somewhat be ambiguous. Success is also considered if a woman is dry 14-21 days following surgery when performing the dye test before discharge (32). The duration for follow up varies among different centers. Three months may be used as a way to ensure that enough scar tissue has formed and the patient has abstained from sexual practices that may influence outcome. Patients with RVF only usually have shorter periods of follow up.

Studies have shown successful closure being achieved in up to 90% of patients (33). Lower rates of success were reported in women that gave a history of prolonged labour of more than three days, more than one prior attempt at repair and having the fistula for over one year duration. Of the unsuccessful repairs, 34.2% had VVF while 17.6% had RVF (32).

Browning et al also showed that women that had prior surgery were more likely to develop residual incontinence than those who were undergoing surgery for the first time. At the 3 month follow up, he noted that various predictors can be used to determine the outcome. Those that had a small bladder size, prior bladder repair, severe vaginal scarring, partial urethral involvement, circumferential involvement or complete destruction of the urethra had failed closure (18). Additional factors that were significantly associated with residual incontinence included the age at presentation and the mode of delivery (25,33).

Further literature has shown a growing body of evidence that the patient characteristics and co morbidities may not independently predict the outcome following surgery. In Cameroon, Tebru et al found that the characteristics were not significantly different among patients that were undergoing first time repair and those undergoing repeat repair. In their study series, 37% of patients were undergoing repeat repair (34).

The higher the number of previous attempts, the lower the success rates. After first repair, the success rate is between 70-90%, 50-60% after the second repair and less than 40% after the third repair. Findings by Pierre et al showed similar decline in closure rates with 88.2% after the first attempt, 76.9% and 64.7% after second and third attempts respectively. Most patients that presented for repeat repair has fistulae with rigid edges, localized close to the urethra and were big in size (>4 cm in diameter) (2,32).

During repair, fibrosis of tissue may cause contraction of the urethra and the bladder making them stiff thus losing the ability to be a compliant organ. The bladder then fails to act as a reservoir while the urethra functions almost in a "hose pipe" manner due to loss of the sphincter mechanisms (32).

RVFs have good repair outcomes of up to 100% while VVFs have failure rates of about 20.3%. Circumferential fistulae have been shown to have a poor success rate of up to 10 fold. In the VVF classification, type IIB has been shown to be six times more likely to result in stress urinary incontinence. VVF type IIB and having a prior unsuccessful repair were shown to be the only factors independently associated with successful anatomical closure with residual stress incontinence (35).

In VVF type IIB, the urine continent mechanism is usually damaged during the process of fistula formation by ischaemia and may explain the higher rate of incontinence. The use of urethral plugs, slings and vaginal colposuspension may be applied to reduce the incontinence. Just like any other surgical procedure, they are associated with complications that may result in reopening of the fistula (2,35).

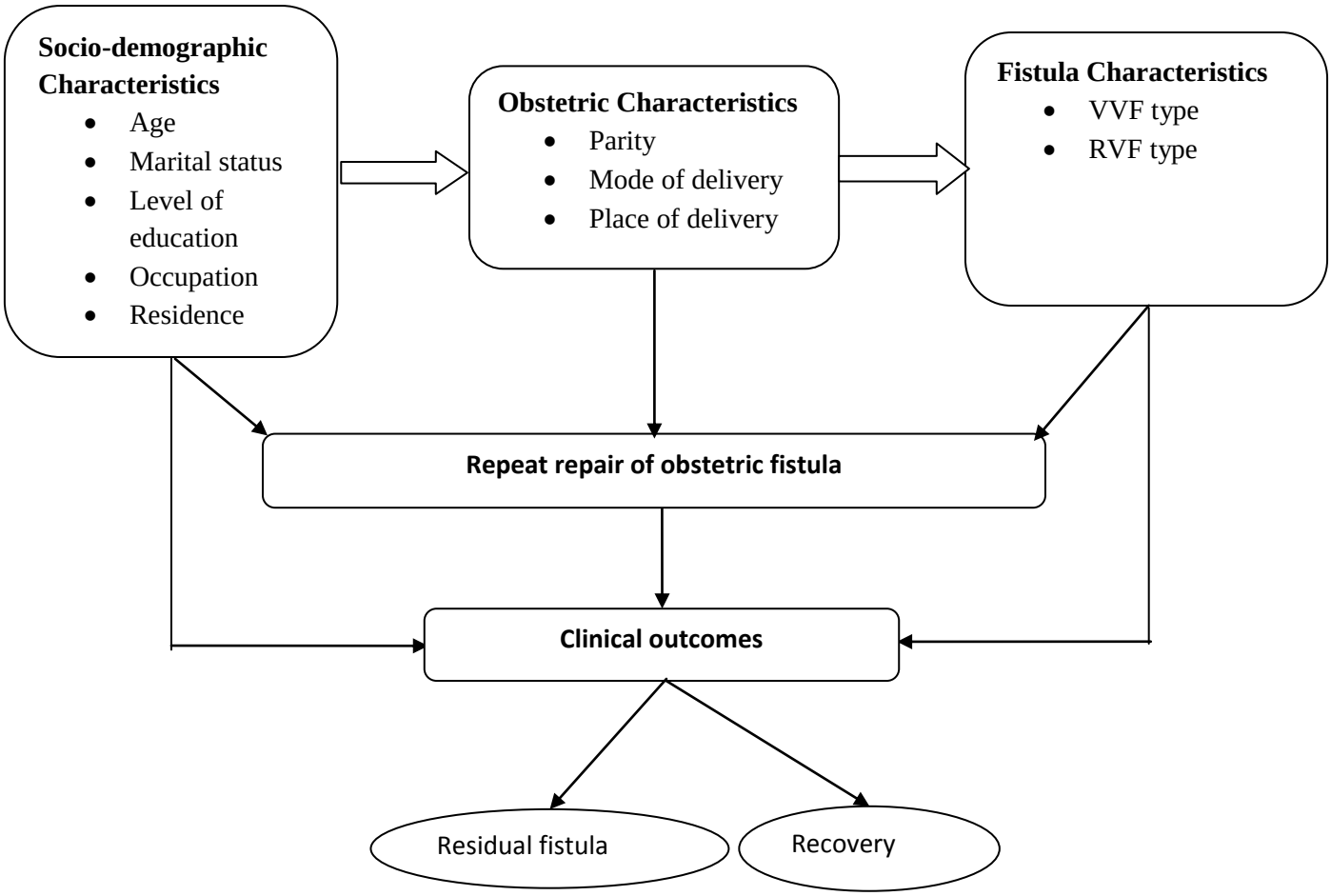
Once obstetric fistula has occurred, the difficulty the patients go through is enormous, although the tragedy is neglected and still remains high. Many patients suffer for years with a condition that could easily be cured by low technology surgical operations.

OF has many social and economic consequences. The continuous dribbling of urine excoriates the adjacent areas, producing painful rashes and emits an offensive odor. These women are marginalized due to the offensive smell and live in isolation. This may lead to other morbidities like bladder calculi and infections. Some also experience secondary amenorrhoea, intrauterine scarring and vaginal stenosis. Urinary incontinence following repair of OF has been shown to be a source of depression (26,36,37).

Socially, most women are ostracized by their families and husbands. Most studies show that most are divorced, experience difficult sexual relations, have low libido, feel constantly ill and are generally embarrassed. This is besides the emotional burden of mourning the loss of their child. Their fight for their own survival, social position and value in society becomes a new challenge. Delays in seeking treatment following repair may be partly due to limitations in knowledge and access to fistula repair service (29). Research into management of obstetric fistula complications and improved methods of repair is necessary for those that don't have successful closure.

2.2 Conceptual Framework

The conceptual framework below shows the interplay between factors that influence repeat repair of obstetric fistula (dependent variable) and the independent variables. The independent variables include the socio-demographic, obstetric and the fistula characteristics. These patient characteristics do have an influence on those that undergo repeat repair of obstetric fistula. The clinical outcome following repeat repair are having a residual fistula or recovery.



2.3 Problem Statement

The characteristics and clinical outcomes of patients that undergo repeat repair for OF is still not well documented. It however still remains a significant problem in areas of low resource settings. The major limitation to providing appropriate surgical skills is the low number of specialized surgeons. Training of other medical cadres to help identify those that require repeat evaluation must also be put into consideration.

2.4 Study Justification

Fistula patients are living indicators of poor maternal health care and failed health systems, but are still largely ignored by the world. Obstetric fistula is still a major problem in Kenya and other low resource countries. The KNH statistics shows that about 600 patients are managed annually with fistula.

Although there is a high success rate of closure with first time repair, some patients do remain incontinent or have irreparable/complex fistulas. The true incidence of patients having repeat repair is little known. The added social and economic burden of repeat fistula is bore by the woman, the society and the health care programs. This study aims to show the clinical characteristics and outcomes of patients undergoing repeat fistula repair.

2.5 Research Question

What are the characteristics and clinical outcomes of women undergoing repeat repair for obstetric fistula at KNH between 1st May, 2010 and 30th June, 2015?

2.6 Objectives

2.6.1 Broad objective

To describe the socio-demographic and clinical characteristics of women undergoing repeat repair of obstetric fistula at KNH between 2010- 2015 and their clinical outcomes following repair.

2.8.2 Specific Objectives

a) To describe the socio-demographic characteristics of women undergoing repeat repair of obstetric fistula.

b) To describe the obstetric and fistula characteristics of women undergoing repeat repair of obstetric fistula.

c) To describe the clinical outcomes of women undergoing repeat repair of obstetric fistula.

d) To describe the associations between patient characteristics and clinical outcomes of patients undergoing repeat repair of obstetric fistula.

CHAPTER THREE: METHODOLOGY

3.1 Study Design

This was a cross sectional study conducted between September and November 2017: records for patients who underwent repeat surgery for OF at KNH were evaluated.

3.2 Study Site and Setting

The study was conducted at the KNH which is the country's largest public referral and teaching hospital. It is located in Upper hill, Nairobi. It has an ongoing fistula center located in clinic 66 which has been in operation since 1994. It still largely serves as the referral point for fistula management. There are three clinic days and two theatre days. There is a fistula specialist team that screens, manages and follows up patients. The patients' pertinent history is taken, after which they are carefully examined. The fistula is then classified, managed accordingly and follow up continues at the clinic.

It also hosts annual fistula camps in collaboration with donors and international fistula teams. The numbers seen at the camps are at 500 per year and have been steadily increasing.

3.3 Study Population

All patients with urinary or fecal incontinence following previous surgical repair were selected. Up to 10-15% of patients undergo repeat surgical repair. The success of the repeat repair is assessed at the time of discharge and at 3 months post repair for VVF and at 2 weeks for RVF. . Should the defect not be closed, a secondary repair may be undertaken. A patient is considered to have successfully recovered when they have a negative dye test done at three months post repair and/or have no residual urinary/feacal incontinence. The study population included all patients with OF that have presented to the fistula clinic at KNH and have had repeat surgical repair between the 1st May 2010 and 30th June, 2015. The patients may have had primary repair performed at another facility or at KNH.

3.4 Inclusion Criteria

a) Fistula caused by an obstetric event that underwent repeat repair during the study period.

3.5 Exclusion Criteria

a) Patients diagnosed with both VVF and RVF.

3.6 Sample Size Determination

The sample size will be calculated using Fishers Formula (Fishers et al 1998) as follows:

$$n=\frac{z^2_{1-\alpha/2} \text{ x } p\ (1-p)}{d^2}$$

n= minimum sample size

α=level of significance (0.05)

$Z_{1-\alpha/2}$= standard normal deviate at 95%, confidence interval (1.96)

P=proportion of women that undergo repeat repair of obstetric fistula (15.7%)(38)

d = absolute precision (error margin) (0.05)

Therefore:

$$n=\frac{1.96^2 \text{ x } 15.7 \text{ x } 84.3}{5 \text{ x } 5}$$

=203.29

=203

3.7 Sampling Procedure

Two complete lists of patients who underwent repeat repair for VVF and RVF were generated from the fistula clinic records between 1st May, 2010 and 30th June, 2015. Consecutive sampling was done until the required sample size was achieved.

3.8 Data Collection and Management

On completion of data collection, the principal investigator took custody of all the data tools and scrutinized them for authenticity and consistency. SPSS version 23 was used to detect any discrepancies from erroneous entries. The total data set consisted of 203 entries that were systemically serialized. The data was then cleaned, coded and analyzed.

The selected patients' files were retrieved from the Fistula clinic records department using their patient IDs. The files were screened following the inclusion/exclusion criteria. Any patient who did not meet the inclusion criteria was dropped from the sample and replaced. Data was collected from the files of the patients in the final sample using a structured data extraction tool. The following information was collected;

Dates of primary OF repair, OF repeat repair, recovery and/or onset of complication

a) The socio-demographic characteristics such as age, level of education, occupation, marital status and area of residence.
b) The obstetric characteristics are parity, mode of delivery, place of delivery and neonatal status at delivery.
c) Fistula characteristics include the type of fistula and the duration they have had it.
d) The clinical outcome following repeat surgical repair.

The data collected was entered and stored in Microsoft Excel sheet and exported into the Statistical Package for Social Sciences version 23 (SPSS) for analysis in a password protected computer. Descriptive data was presented in tables of means and medians. Further analysis was done using the student t test for comparing means and chi square tests for association between patient characteristics and outcomes. A p value of <0.05 was taken to be statistically significant.

3.9 Ethical Approval

Ethical approval was sought from the Kenyatta National Hospital/University of Nairobi (KNH/UoN) Ethics Review Committee (ERC). Consent to access the files was sought from the KNH management. No procedure was carried out hence no patient was harmed. The files were reviewed in a secluded place within the records department; accessible only by the principal investigator and research assistants hence confidentiality was maintained. Upon finishing with data collection, they were returned for filing.

CHAPTER FOUR: RESULTS

This chapter presents the results for 203 patients who underwent repeat repair for OF between 1st May, 2010 and 30th June 2015. Out of the 203, 102 (50.3%) underwent repeat repair for VVF while 101(49.7%) underwent repair for RVF.

Table 2: Mean maternal age of patients at causal delivery, primary repair and repeat repair

	Fistula Type	Mean age (years)	p value
Age at causal delivery	**VVF (n=102)**	22.28	0.001
	RVF (n=101)	25.53	
Age at primary repair	**VVF (n=99)**	24.48	0.409
	RVF (n=101)	26.41	
Age at secondary repair	**VVF (n=102)**	33.07	0.539
	RVF (n=101)	32.15	

As shown in Table 2 above, the mean age for VVF at fistula development, primary repair and repeat repair was 22.28, 24.48 and 33.07 years respectively. For the RVF group, it was 25.53, 26.41 and 32.15 years respectively. There is a statistically significant difference between the mean ages at causal delivery for VVF and RVF (p=0.001). However, no statistical significant difference exists for the mean difference in age at primary repair (p=0.409) and secondary repair (p = 0.539) between patients undergoing repeat repair for VVF and RVF.

Table 3: Socio-demographic characteristics of participants at repeat repair

Variable	Category	VVF (n (%)	RVF (n (%)	Chi square (df)	p value
Marital Status N=200	**Single (n=55)**	37 (67.3)	18(32.7)	16.59 (3)	0.0009
	Married (n=120)	46 (38.3)	74 (61.7)		
	Divorced (n=11)	7 (63.6)	4 (36.4)		
	Separated (n=14)	10 (71.4)	4 (28.6)		
Occupation N=203	**Farmer(n=55)**	37(72.4)	14 (27.6)	17.1 (4)	0.0018
	Businesswoman (n=63)	22(34.9)	41(65.1)		
	Office-work (n=10)	4 (40)	6 (60)		
	Other (n=50)	23(46)	27(54)		
	Casual (n=29)	16(55.2)	13(44.8)		
Education level N=179	**Primary(n=125)**	71(56.8)	54(43.2)	20.2 (2)	0.00004
	Secondary(n=36)	7 (19.4)	29(80.6)		
	Tertiary(n=18)	4 (22.2)	14(77.8)		
Residence N=202	**Rural (n=111)**	77(69.4)	34(30.6)	37 (2)	0.00001
	Urban (n=45)	12(26.7)	33(73.3)		
	Peri-urban (n=46)	12(26.1)	34(73.9)		

In Table 3 above, the relationship between repeat repair of the two types of OF and socio-demographic characteristics is shown. The study subjects who had repeat RVF repair were more likely to be married, own a small business, of a higher education status and lived in an urban or peri urban area(p =0.0009,0.0018,0.00004 and 0.00001 respectively). Women who underwent repeat VVF repair were more likely to be separated, farmers, of lower educational status and resided in rural areas.

Table 4: Obstetric characteristics of participants at repeat repair

Variable		VVF (n (%)	RVF (n (%)	Chi square (df)	p value	Odds Ratio (95% CI)
Parity at causal delivery (N=203)	**Primigravida(n=140)**	73(52.1)	67(47.9)	0.649	0.4204	1.3
	>1 delivery(n=63)	29(46)	34(54)	(1)		(0.7-2.3)
Mode of delivery (N=203)	**Caesarean section(n=65)**	57(87.7)	8(12.3)	53.63	0.0000	14.7
	Spontaneous Vertex Delivery(n=138)	45(32.6)	93(67.4)	(1)		(6.5-33.5)
Duration of labour (N=151)	**< 12 hours(n=73)**	19(26.0)	54(74)	9.16	0.0024	0.4
	> 12 hours(n=78)	39(50)	39(50)	(1)		(0.2-0.7)
Place of delivery (N=202)	**Medical facility(n=172)**	92(53.5)	80(46.5)	4.15	0.0416	2.3
	Home(n=30)	10(33.3)	20(66.7)	(1)		(1.02-5.2)
Causal baby's sex (N=156)	**Male(n=86)**	45(52.3)	41(47.7)	8.959	0.00027	2.74
	Female(n=70)	20(28.6)	50(71.4)	(1)		(1.4-5.4)
Neonatal outcome (N=202)	**Alive (n=121)**	28(23.1)	93(76.9)	90.326	0.00001	0.03
	Dead(n=81)	74(91.4)	7(8.6)	(1)		(0.01-0.07)

Table 4 above demonstrates the relationship between the obstetric characteristics of the participants at repeat repair women that delivered via caesarean section were about 15 times more likely to undergo repeat VVF repair compared to those that delivered via SVD(OR=14.7;95% CI= 6.5-33.5;p=0.0000). Having delivered a male infant at a medical facility was also strongly associated with an increased risk of having repeat repair of VVF.

Table 5: Mean of maternal and neonatal parameters at repeat repair

	Fistula type	Mean	p value
Maternal weight at repeat repair (kilograms)	**VVF (n=74)**	55.78	0.003
	RVF (n=87)	60.59	0.003
Birth weight of the causal delivery (kilograms)	**VVF (n=65)**	4020.00	0.001
	RVF (n=85)	3589.41	0.001
Time between primary and secondary repair (years)	**VVF (n=100)**	6.16	0.403
	RVF (n=101)	5.32	0.402

The table 5 above shows the association between the mean of maternal weight and neonatal birth weight at fistula repeat repair. The mean maternal weight for VVF was 55.78 kg (p=0.003) while that of RVF was 60.59 kg (p=0.003) which is statistically significant. As for the neonatal birth weights at causal delivery, those that developed VVF had a mean of 4020 gm (p=0.001) while those with RVF had a mean of 3589.41 (p=0.001) which shows a statistical difference. There is no statistical difference between the time taken between primary repair and repeat repair for VVF and RVF which was 6.16 years and 5.32 years respectively (p=0.403).

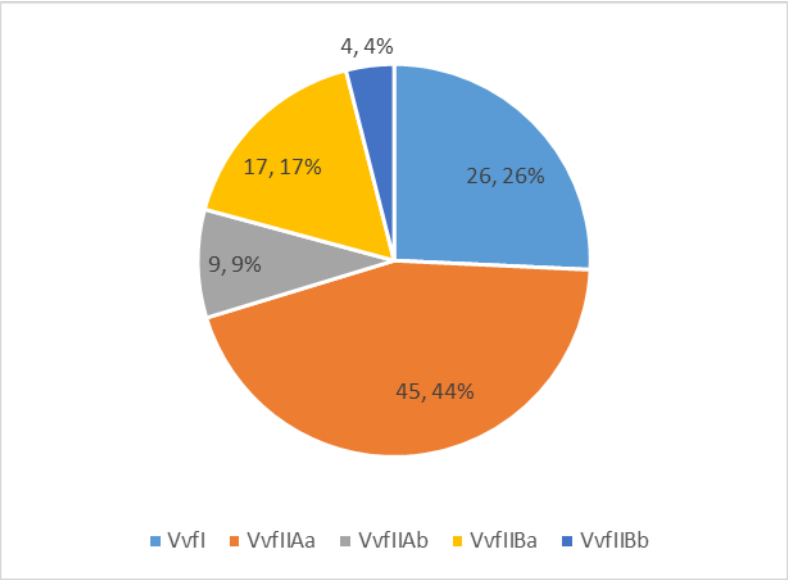


Figure 1: VVF Classification

Figure 1 above shows the most common type of VVF at repeat repair was type IIAa at 44% followed by type 1 at 25%. Type IIBa was the third most common at 17%.

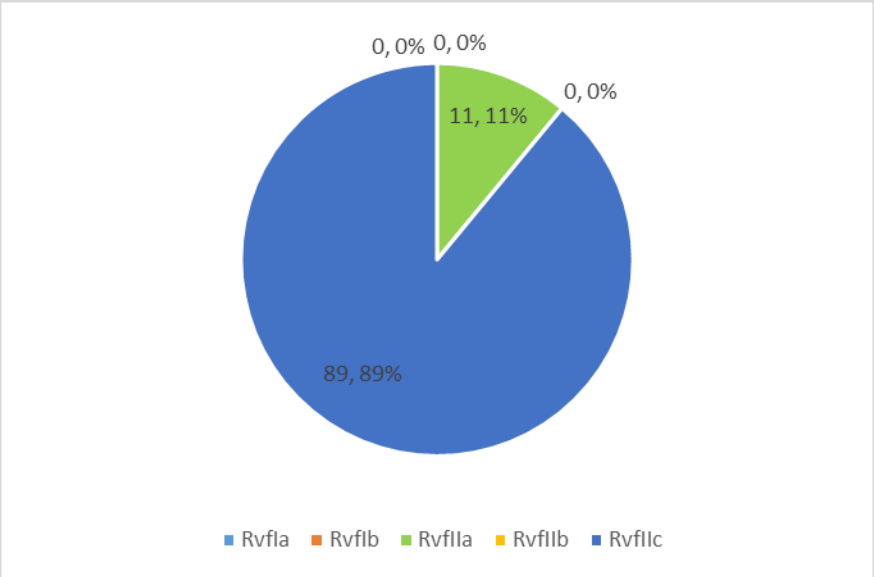


Figure 2: RVF Classification

As shown in figure 2, at repeat repair, RVF Type IIb was the most common at 90% followed by type IIa at 11%.

Table 6: Fistula characteristics of participants at repeat repair

		Fistula type			
		VVF (n(%)	**RVF (n(%)**	**Chi square (df)**	**P value**
Subclass N=182	**Small (n=76)**	54(71.1)	22(28.9)	21.27 (3)	0.0001
	Medium(n=96)	36(37.5)	60(62.5)		
	Large (n=8)	5(62.5)	3(37.5)		
	Extensive(n=2)	2(100)	0(0)		
Previous repairs N=203	**One repair(n=146)**	61(41.8)	85(58.2)	21.196 (1)	0.002
	More than one repair (n=57)	41(71.9)	16(28.1)		

In Table 6 above, the sub classification of the fistula shows that most of those with a medium sized fistula had a repeat repair of both VVF and RVF (p=0.0001) and so is the history of more than one previous repair significant (p=0.002).

Table 7: Association between socio-demographic characteristics and outcomes at repeat repair

		Outcomes				
		Incontinence (n (%)	**Recovered (n (%)**	**Relative Risk**	**p value**	**95%CI**
Marital Status N=199	**Married (n=55)**	15 (27)	40 (73)	2.08	0.520	0.985-4.390
	Not married (n=144)	22 (15)	122 (85)			
Residence N=201	**Rural (n=110)**	26 (24)	84 (76)	2.5	0.020	1.137-5.528
	Urban (n=91)	10 (11)	81 (89)			
Level of education N=178	**Primary (n=124)**	26 (21)	98 (79)	14	0.001	1.856-106.53
	Advanced (n=54)	01 (02)	53 (98)			

In Table 7 above, there was a statistically significant relationship between the level of education and the outcome at repeat repair of OF. Those with a lower level of education were 14 times more likely to develop incontinence following repair (RR=14; 95% CI=1.856-106.53; p=0.001). The rural residents were 3 times more likely to develop incontinence following repeat repair. The marital status did not have any bearing on the outcome of fistula repeat repair.

Table 8: Association between obstetric characteristics and fistula outcomes at repeat repair

		Outcomes			
Variable		**Recovery (n (%)**	**Incontinence (n (%)**	**Relative Risk (95% CI)**	**p value**
Parity N=202	**Primigravida(n=139)**	103(74.1)	36(25.9)	0.95	0.5748
	>1 delivery (n=63)	49(77.8)	14(22.3)	(0.81-1.1)	
Duration of labour N=150	**<12 hours (n=73)**	66(90.4)	7(9.6)	1.1	0.0572
	>12 hours (n=77)	61(79.2)	16(20.8)	(1.0-1.3)	
Place of delivery N=201	**Hosp (n=171)**	126(73.7)	45(26.3)	0.9	0.2594
	Home (n=30)	25(83.3)	5(16.7)	(0.7-1.1)	
Mode of delivery N=202	**CS (n=65)**	41(63.1)	24(36.9)	0.8	0.00576
	SVD (n=137)	111(82.2)`	26(17.8)	(0.6-0.9)	

As demonstrated in Table 8 above, women who were delivered by caesarean section were 0.8 times likely to recover after repeat OF repair compared to those delivered by SVD. That association was statistically significant (RR=0.8; 95% CI=0.6-0.9; p =0.006). Parity, duration of labour and place of delivery had no statistically significant association with the outcome.

Table 9: Fistula outcome of participants after repeat repair

		Outcomes			
		Recovered (n (%)	**Incontinence (n (%)**	**Relative risk 95% CI**	**p value**
Fistula type	**VVF (n=101)**	56(55.4)	45(44.6)	0.6	0.00001
	RVF(n=101)	96 (95.0)	5(5.0)	0.5-0.7	

As shown in table 9, women who underwent repeat VVF repair were statistically less likely to recover compared to women undergoing repeat RVF repair(RR=0.6;95%CI=0.5-0.7;p=0.00001).

CHAPTER FIVE: DISCUSSION

The findings from this study have demonstrated that there still persists prolonged morbidity associated with obstetric fistula. Despite having prior treatment for the fistula, there is still a long duration of time that lapses before patients seek intervention to restore continence.

The mean age at causal delivery for VVF was 22.28 years; at primary repair was 25.48 years while that at repeat repair was 33.07 years and that of RVF was 25.53 years, 26.41 years and 32.15 years respectively. OF has been shown to occur in those with a relatively young age, most patients being between the ages of 20-29 (39,40). This could possibly be due to the immaturity of the pelvis at quite a young age, hence predisposing the women to prolonged labour thus resulting in development of fistula. OF is also more common in mothers with babies of a higher neonatal weight (40).

On the social aspect, 60% of the patients in this study were married. Patients undergoing repeat repair for RVF were more likely to be married as compared to their VVF counterparts. Different findings across the continent have had different marital status profiles. These findings were similar to other studies where 89% of their study group was married (3) . In contrast, the findings in Ethiopia showed that most of the patients (69%) were divorced or had separated from their partners, especially amongst those with VVF (1).

A local study also showed that that most of the women were married at the onset of development of the fistula but up to 21% got separated or divorced and this was attributed to the fistula (41). Social stigma and alienation have been some of the psychological effects of living with this condition. The high rates of depression and suicidal ideation amongst women with obstetric fistula have also been well documented (26,42,43).

Obstetric fistula has often been defined as a disease of the poor. Overall, 31% and 25.1% owned small businesses and were farmers respectively. Those with RVF were more likely to have a higher education status and lived in an urban or peri urban area. Basic primary education had also been attained in 69.8% of the study group. It was more probable for a woman undergoing repeat repair for VVF to have lower educational status, be a farmer and reside in the rural area. Secondary education was at 20.1% while 10.1% had attained tertiary education. Majority of the population also resided in the rural areas. Of those with VVF, they were more likely to have delivered via caesarean section as compared to those with RVF.

Those with RVF had also a less duration of labour and were associated to having baby boys that were alive. The average time taken between primary and secondary repair for VVF was 6.16 years while that of RVF was 5.32 years. This is a prolonged duration of time bearing in mind that the patient has previously been seen at a medical facility or by medical specialists. Similar to other studies, there seems not to be much difference in the socio-demographic characteristics between those undergoing primary repair and those having subsequent surgery following prior unsuccessful closure.

Continued sensitization and mass campaigns must be advocated for so as to educate the patient on awareness of symptoms and follow up after primary OF repair. One local study showed the mean duration time of repair was 9 years (41) while one study in East Africa showed the mean duration of time between sustaining the fistula and primary repair was 36.4 months (44). In our study, the duration between primary and secondary repair was even longer. A plausible explanation being access to services, poor follow up and referral mechanisms.

The most common type of vesicovaginal fistula in this population was type IIAa at 44%. Type 1 was the second most common at 25% then followed by type IIBa at 17%. For the patients with RVF, type IIb was the most common at 89.9% followed by type IIa at 11.11%. VVF patients had higher rates of incontinenence at 36.6% while those with RVF that had none. 64.3% of VVF recovered with over 90% recovery of RVF. Literature has shown that patients with type IIBa had the highest incidence of stress urinary incontinence (45). This has been shown to occur despite successful closure of the fistula itself. This may be due to the involvement of the closing mechanism. A study by Tebeu et al showed that the success rate was 50% after a second repair and 33%after a third repair(2).

Those with type one fistula also had incontinence presenting as patulous urethra. In type II VVF, the damage caused by ischaemia at the urethral vesical junction impair the continence mechanism. The high recovery rate of RVF may be a reflection of the fact that most had third and fourth degree tears that had given way as shown in some studies (4). RVF may be more prevalent with SVD due to lack of perineal support and not recognizing the need for episiotomy at the appropriate time.

5.1 Study Limitations

Some of the weaknesses of this study included incomplete data from the patients' records and the use of other people's notes assuming that the data collected was correct. Some records were also missing hence reducing the total sample size. Its strengths include the fact that it provided a track record of patients up to 3 months post repair.

5.2 Conclusions

Morbidity from OF remains a persistent problem in our setting. The prolonged duration between primary and secondary repair of OF is a gap that requires further investigation as it reflects failure of our health systems. Risk assessment of mothers and vigilant intrapartum monitoring and care must be emphasized to help avert development of OF. More information is needed on the outcomes of those that undergo subsequent surgery. This greatly helps to reduce the additional social and economic burden for fistula care programs.

5.3 Recommendations

Direct guidance on organization of fistula treatment and training in facilities is of utmost importance. Further research into prevention and management of associated complications for those with unsuccessful closure should be explored.

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APPENDIX I: ERC APPROVAL LETTER

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6th September , 2017

Dr. Naomi N. Sitati
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Dept. of Obs/Gynae
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Dear Dr. Sitati

REVISED RESEARCH PROPOSAL – THE CHARACTERISTICS AND OUTCOMES OF PATIENTS UNDERGOING REPEAT REPAIR FOR OBSTETRIC FISTULA AT KENYATTA NATIONAL HOSPITAL (P253/05/2017)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and **approved** your above proposal. The approval period is from 6th September, 2017 – 5th September 2018.

This approval is subject to compliance with the following requirements:

a) Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b) All changes (amendments, deviations, violations etc) are submitted for review and approval by KNH-UoN ERC before implementation.
c) Death and life threatening problems and serious adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH-UoN ERC within 72 hours of notification.
d) Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH- UoN ERC within 72 hours.
e) Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*).
f) Submission of an *executive summary* report within 90 days upon completion of the study. This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/ or plagiarism.

For more details consult the KNH- UoN ERC website**http://www.erc.uonbi.ac.ke**

Yours sincerely,

PROF M.L. CHINDIA
SECRETARY, KNH-UoN ERC

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APPENDIX II: DATA ABSTRACTION TOOL

SOCIO DEMOGRAPHIC CHARACTERISTICS:

1) Age of patient
    a) At time of causal delivery……..
    b) At primary repair……
    c) At repeat repair……
    d) Not indicated…….
2) Marital Status
    a) Single …….
    b) Married……
    c) Divorced……
    d) Separated……
    e) Not known……..
3) Education level
    a) Primary……
    b) Secondary……..
    c) College/university…….
    d) None…….
4) Area of residence
    a) Urban…
    b) Rural….
    c) Peri urban…
    d) Not indicated……
5) Occupation
    e) Casual….
    f) Farmer…..
    g) Small business…..
    h) Office work…….
    i) Others…….
6) Weight of patient in kilograms…….
7) Height of patient in centimeters……..

Obstetric Characteristics:

1. Parity at fistula development……
2. Sex of the baby.
    a) Male……..
    b) Female…….
    c) Not indicated…….
3. Birth weight (in grams).
    a) Not indicated……
    b) Don't know…….
4. Neonatal outcome.
    a) Alive…….
    b) Dead…….

5. Duration of labour
    a) Hours……
    b) Days……
6. Place of delivery
    a) Hospital……..
    b) Health center……..
    c) Home……
    d) Other…….

    If delivery was at hospital, was it a referral.

    Yes……..

    No……..

    Immediate level of facility……..

    Time interval to facility……..
7. Assistance in labour
    a) Midwife…..
    b) TBA……
    c) Doctor……
    d) Other……

8. Other deliveries
    a) Number……..
    b) Place…….
        - Hospital…….
        - Health center……
        - Home……..
        - Other……..
    c) Type of delivery
        - Normal…….
        - Caesarean section…….
        - Assisted vaginal……
    d) Baby's sex
        - Male…….
        - Female…..
    e) Neonatal outcome
        - Dead……
        - Alive…….
    f) No of children alive……

9. Ante natal clinic attendance….
    a) Yes…….

       If yes, number of times……
    b) No…….
    c) Not indicated……

Fistula Characteristics:

10. Leakage of
    a) Urine……..
    b) Feaces…….
    c) Both…….
11. Appearance of symptoms after delivery…….days.
12. Classification of fistula: Waaldijk classification (circle appropriately)

    I- Fistula not involving the closing mechanism

    IIAa- without total urethral involvement, without circumferential defect

    IIAb- without total urethral involvement, with circumferential defect

    IIBa- with total urethral involvement, without circumferential defect

    IIBb- with total urethral involvement, with circumferential defect

    Misc- other fistula

    Not assessed……

    Sub Classification:

    - Small <2cm……..
    - Medium 2-3cm……
    - Large 4-5cm……..
    - Extensive >6cm……..
    - Not assessed…….
13. Is a rectal fistula present
    - Y….
    - N…….
    - Not assessed……

If yes, type:

Ia- without rectal stricture…..

Ib- with rectal stricture…….

IIa- without sphincter involvement…

IIb- with sphincter involvement….

IIc- circumferential involvement…..

Not assessed….

If yes, size:

- Small <2cm…..
- Medium (2-3cm)…
- Large (4-5cm)…..
- Extensive >6cm…….
- Not assessed…..

14. How many times have you repaired the fistula?.....
15. Any residual incontinence?
    - Yes……
    - No……
16. Date (in months):
    - Date of primary repair……..
    - Date of repeat repair……
    - Recovery……
    - Diagnosis of repeat repair complications……..
17. Nature of repeat repair complication……..

APPENDIX III: BUDGET

ITEM:	COST (ksh):
Statistician -1	25,000
2 research assistants @5000 each	10,000
Stationary (4 reams@500), pens (8@25)	2,200
Printing (1 copy + 2 photocopy)	1,200
Binding (3 proposal copies @150) +3 final books @500)	1,950
Contingency	3,000
Ethical approval	2,000
TOTAL	42,500

APPENDIX IV: GANNT CHART

	MAY 2017	SEPTEMBER 2017	NOVEMBER 2017	DECEMBER 2017	FEBRUARY 2018
PROPOSAL SUBMISSION					
DATA COLLECTION					
DATA ANALYSIS					
PROJECT SUBMISSION					