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Towards a fistula free generation

Lessons learned from long-term follow-up of
women after obstetric fistula repair in Guinea

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In memory of my beloved father P  p  

For my mother Nowai CAMARA

*You thought me the quest for excellence and humility that does not exclude
ambition*

For Seni Fulbert KOLIE, for all your sacrifices

In memory of my friend and brother Celestin MILLIMOUNO

For Dominique DUBOURG, who opened the doors

To God, my Parents and my Masters

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ACRONYMS AND ABBREVIATIONS

AGFO	Association guinéenne de lutte contre la fistule obstétricale (Guinean Association to Fight Obstetric Fistula)
Amref	African Medical and Research Foundation
ANC	Antenatal care
BC	Before Christ
BMC	BioMed Central
CHWs	Community Health Workers
CI	Confidence Interval
CNERS	Comité National d'Ethique pour la Recherche en Santé (National ethics committee for health research)
CS	Cesarean Section
C-section	Cesarean Section
DHS	Demographic and Health Survey
EmONC	Emergency Obstetric and Neonatal Care
EVD	Ebola Virus Disease
FGDs	Focus Group Discussions
FIGO	International Federation of Gynecology and Obstetrics
FO	Fistule obstétricale (Obstetric fistula)
FP	Family Planning
GMER	Geneva Foundation for Medical Education and Research
HCW	Healthcare Workers
HIV/AIDS	Human Immunodeficiency Virus/ Acquired Immunodeficiency Syndrome
IBD	Islamic Development Bank
IC	Intervalle de confiance (Confidence interval)
IDI	In-depth interview
IQR	Interquartile range
IRB	Institutional Review Board
ITM	Institute of Tropical Medicine

JHPIEGO	Johns Hopkins Program for International Education in Gynecology and Obstetrics
Lancet Glob. Health	Lancet Global Health
LTFU	Lost to follow-up
MoH	Ministry of Health
MSF	Médecins Sans Frontière
NGO	Non-Governmental Organization
OF	Obstetric Fistula
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analysis
Ref.	Reference
Reprod. Health.	Reproductive Health
RVF	Recto-Vaginal Fistula
TB	Tuberculosis
Trop. Med. Int. Health	Tropical Medicine and International Health
UGANC	University Gamal Abdel Nasser of Conakry
UK	United Kingdom
ULB	Université Libre de Bruxelles
UN	United Nations
UNFPA	United Nations Fund for Population Activities
UON	Unmet Obstetric Need
US	United States
USA	United States of America
USAID	United States Agency for International Development
VVF	Vesico-Vaginal Fistula
WAHA	Women and Health Alliance International
WHO	World Health Organization

GLOSSARY

Bias	The inclusion of subjects or methods such that the results obtained are not truly representative of the population from which it is drawn
Childbirth	Synonymous with delivery
Cohort	A component of a population identified so that one or more characteristics can be studied as it ages through time.
Confounding variable	A variable that is associated with both the exposure and outcome of interest that is not the variable being studied.
Context	Environment or setting where the research was conducted or where an intervention is implemented.
Continent (dry)	This is when a woman has her fistula closed and does not experience any leakage of urine or feces.
Coverage	Represents the proportion of a population which receives a given health service (e.g., first antenatal care)
Delivery	The process of giving birth
Determinant	A factor which affects a health outcome such surgical failure, or an outcome such as loss to follow-up
External validity (Generalizability)	The extent to which the findings of a study apply to other populations or settings.
Female genital fistula	A fistula that can result not only from prolonged labor but also from other causes that include genital cutting such as yankan gishiri, sexual violence, iatrogenic reasons (from C-section, hysterectomy or poorly performed abortions), pelvic fractures, and malignancy or radiation.
Fistula repair	Fistula surgery
Repaired fistula (successful repair)	This concept can be interpreted differently according to the perspective of health care workers (closure of the fistula) or that of women suffering from fistula (continent and dry).
Health care workers	Professionals trained to provide health care, such as doctors, state nurses, state midwives and assistants nurses/midwives.

Health facility	A physical structure where health services are offered. It can be public or private. In Guinea, depending on its level of importance, a health facility can be a health post, health center or hospital (district, regional or national).
Incidence	The number of new cases that develop during a specified time interval.
Incontinent	Either the woman has uncontrolled and continuous leakage (surgical failure) or her fistula was closed but there remains some incontinence (residual incontinence).
Internal validity	The extent to which the findings of a study can be relied upon
Intervention	A purposeful action or actions to achieve a change. For instance, an intervention to reduce fistula recurrence.
Loss to follow-up	When a woman fails to attend the follow-up appointment at the hospital where she got surgery within 6 months of her discharge for any reason.
Maternal death	The death of a woman while pregnant or within 42 days of termination of pregnancy, irrespective of the duration and site of the pregnancy, from any cause related to or aggravated by the pregnancy or its management but not from accidental or incidental causes
Neonatal death	The death of a baby within the first 28 days of life
Observational study	A study in which no intervention is made (as opposed to experimental study).
Obstetric fistula	An abnormal communication that occurs either between most commonly bladder and vagina [vesicovaginal fistula (VVF)], between rectum and vagina [rectovaginal fistula (RVF)] or a combination of both because of prolonged labor.
Obstructed labor	Also known as labor dystocia, is when, even though the uterus is contracting normally, the baby does not exit the pelvis during childbirth due to being physically blocked. Obstructed labor covers a broad range of conditions, from prolonged labor to uterine rupture, feto-pelvic disproportion or abnormal fetal presentation.
Odds ratio	The ratio of the probability of an event occurring to the probability of non-occurrence.

Pregnancy	Condition of being pregnant or the period during which a woman is pregnant. Pregnancy can be documented by a positive pregnancy test or medical record
Prevalence	The number of cases (old and new) of a disease that exist in a defined population at a specified point in time.
Prolonged labor	Is the result of an obstructed labor, when the active phase of labor is longer than 12 hours
Quality of care	The extent to which health care services provided to individuals and patient populations improve desired health outcomes,
Recurrence of fistula	Breakdown of a repaired fistula or the occurrence of a new fistula from the day a woman is discharged from repair hospital.
Repair failure	Surgical failure
Repair breakdown	Surgical failure
Residual incontinence	When the woman still experiences some incontinence remaining after surgery despite fistula closure. This could be urge, stress or overflow incontinence.
Risk factor	A variable associated with a specific disease or outcome
Surgical failure	When the woman reports an uncontrolled and continuous leakage of urine or feces (or both) despite having had surgery.
Variable	A value or quality that can vary between subjects and/or over time. Eg. The variable "age".

EXECUTIVE SUMMARY

BACKGROUND: Obstetric fistula (OF) is described as a health and human rights tragedy due to its devastating consequences and debilitating sequelae. In sub-Saharan Africa, the lifetime prevalence of OF symptoms is estimated at 3.0 cases (95% CI 1.3-5.5) per 1000 women of reproductive age. In Guinea, this prevalence is 6.0 (95% CI 3.9–7.4) per 1000 women of reproductive age, a double that of sub-Saharan Africa. As maternal mortality reduction is accelerating in many countries due to better access to cesarean section and more women are benefiting treatment for OF worldwide, women who have a successful fistula repair need more attention to prevent fistula recurrence and adverse maternal and neonatal outcomes.

AIM: To analyze the long-term reproductive health outcomes in women who undergo fistula surgery in Guinea and contribute to closing the knowledge gap on the reproductive health of women after fistula surgery.

METHODS: The situational analysis of fistula management programs in Guinea included three retrospective cohort studies. **Study I** analyzed the clinical outcomes of fistula care programs in Guinea. **Study II** analyzed the trends and factors associated with loss to follow-up after surgical repair of obstetric fistula in Guinea. **Study III** estimated the overall proportions of surgical failure of fistula closure and incontinence among women undergoing repair for obstetric fistula in Guinea and identified factors associated with these outcomes. To analyze the health and reproductive outcomes in women after female genital fistula surgery in Guinea, two studies (IV and V) were conducted. **Study IV** critically reviewed the existing literature on pregnancy and childbirth post repair of obstetric fistula and **Study V** analyzed the incidence of fistula recurrence and pregnancy post repair along with the associated maternal and neonatal outcomes.

RESULTS: Routine programmatic repair of OF was found to achieve satisfactory short-term clinical outcomes with 85% of women having their fistula closed and 79% becoming continent after surgery (**Study I**). However, additional 18% recurrence and 10% residual urinary incontinence were recorded within 28 months median follow-up post-surgery (**Study V**). Reimbursement of transportation costs and the reduction of geographical barriers to care for women with OF were highly related to reduced loss to follow-up after hospital discharge (**Study II**). Women who present for surgery with a damaged urethra and those who delivered vaginally during the delivery leading to the fistula were more likely to experience surgical repair failure and residual urinary incontinence (**Study III**). Women who become pregnant and deliver after fistula repair in sub-Saharan Africa were identified as carrying high risk of adverse maternal and neonatal health outcomes (**Study IV**). In Guinea, only few women achieved pregnancy (28%) after surgery. Stillbirths (24%) and recurrence of fistula after delivery (14%) were common among women who delivered after fistula repair (**Study V**).

CONCLUSIONS: Improving the performance of fistula management programs in the context of decentralization of services in Guinea needs therefore to integrate long-term perspectives. This should include establishing a “level of care framework” into fistula surgery along with training for health providers, tracing of women after repair, and increased community awareness-raising that include men and target gender inequalities (**Studies I to III**). Increasing funding and support for fistula care from both local governments and international donors is needed in the current context of decentralization of fistula care to address service gaps for women suffering from fistula (**Studies III to V**). Achieving a fistula free generation should include interventions to address women’s vulnerability before fistula formation and after fistula repair (**Studies IV and V**).

RÉSUMÉ EXÉCUTIF

CONTEXTE : La fistule obstétricale (FO) est décrite comme une tragédie de santé et des droits de l'homme en raison de ses conséquences dévastatrices et de ses séquelles débilitantes. En Afrique subsaharienne, sa prévalence est estimée à 3,0 cas pour 1000 femmes en âge de reproduction (IC à 95% 1,3-5,5). En Guinée, cette prévalence est de 6,0 cas pour 1000 femmes en âge de reproduction (95% IC 3,9-7,4). Comme la réduction de la mortalité maternelle s'accélère dans de nombreux pays en raison d'un meilleur accès à la césarienne et que plus de femmes bénéficient d'un traitement pour la FO dans le monde, les femmes opérées ont besoin d'attention pour éviter la récurrence et les complications pour la mère et le nouveau-né.

OBJECTIF : Analyser les résultats à long terme de santé reproductive des femmes opérées de FO en Guinée et contribuer à combler le manque des connaissances sur la santé des femmes après une chirurgie réussie de la FO.

METHODES : L'analyse situationnelle des programmes de gestion de la fistule en Guinée incluait trois études de cohorte rétrospectives. **L'étude I** a analysé les résultats cliniques des programmes de prise en charge de la FO en Guinée. **L'étude II** a examiné les tendances et les facteurs associés aux pertes de vue après la réparation de la FO en Guinée. **L'étude III** a examiné l'échec de réparation de la FO et les facteurs qui y sont associés. Pour analyser les résultats en matière de santé et de santé de la reproduction chez les femmes après la chirurgie de la FO en Guinée, deux études (**IV et V**) ont été menées. **L'étude IV** a effectué une revue de la littérature existante sur la grossesse et l'accouchement après la réparation de la FO en Afrique sub-Saharienne et **l'étude V** a analysé l'incidence de la récurrence de fistule et la grossesse après réparation ainsi que les résultats maternels et néonataux associés.

RÉSULTATS : La réparation de la FO a donné des résultats cliniques satisfaisants à court terme en Guinée, avec 85% des femmes opérées qui ont eu une fistule fermée et 79% qui sont devenues continentales après la chirurgie (**Etude I**). Toutefois, des récurrences additionnelles de fistule (18%) et d'incontinence urinaire résiduelle (10%) étaient fréquentes chez les femmes après la réparation (**Etude V**). Le remboursement des frais de transport et la réduction des obstacles géographiques aux soins pour les femmes victimes de FO ont été essentiels pour éviter les pertes de vue après la sortie de l'hôpital (**Etude II**). Les femmes qui se présentent pour une chirurgie avec un urètre endommagé et celles qui ont accouché par voie vaginale pendant l'accouchement conduisant à la fistule étaient plus susceptibles d'avoir un échec de réparation et une incontinence urinaire résiduelle (**Etude III**). Les femmes qui deviennent enceintes et accouchent après la réparation de la fistule en Afrique sub-Saharienne ont été identifiées comme présentant un risque élevé de complications maternelles et néonatales (**Etude IV**). En Guinée, peu de femmes ont eu une grossesse après réparation (28%) et chez elles, les mort-nés (24%) et la récurrence de fistule après accouchement (14%) étaient courants (**Etude V**).

CONCLUSIONS : L'amélioration de la performance des programmes de prise en charge de la FO dans le contexte de la décentralisation des services en Guinée doit donc intégrer des perspectives à long terme. Cela devrait inclure l'introduction d'un « niveau de soins » dans la chirurgie de la fistule, la formation des prestataires de santé, le suivi des femmes après la réparation et une sensibilisation accrue de la communauté incluant les hommes et visant la réduction des inégalités de genre (**Études I à III**). L'augmentation du financement public et privé aux soins de la FO est nécessaire dans le contexte actuel de décentralisation des soins de la fistule pour combler les déficits de services pour les femmes souffrant de fistule (**Études III à V**). Réaliser une génération sans fistule exige des interventions pour atténuer la vulnérabilité des femmes avant la formation et après la réparation de la fistule (**Études IV et V**).

STRUCTURE OF THESIS DISSERTATION DOCUMENT

The present dissertation reflects the intellectual pathway of the 5 last years during which this PhD work has advanced and matured. The publication of the work occurred regularly and sequentially. This in effect implies that the most coherent presentation is to follow the timeline of the publication process as the conducting thread of the dissertation. This also is explained in §4.1. thesis framework.

LIST OF SCIENTIFIC PAPERS

In total seven papers constitute the core results of this thesis. Each study results are presented in a paper, except for study V where a study protocol was published prior to the study results paper.

Specific objective	Studies	Full citation
1) Conducting a situational analysis of fistula care in Guinea	I	1. Delamou Alexandre, Diallo Moustapha, Beavogui Abdoul Habib, Delvaux Thérèse, Millimono Sita, Kourouma Mamady, Beattie Karen, Barone Mark, Barry Thierno Hamidou, Khogali Mohamed, Edginton Mary, Hinderaker Sven Gudmund, Ruminjo Joseph, Zhang Wei-Hong, De Brouwere Vincent. Good clinical outcomes from a 7-year holistic programme of fistula repair in Guinea. <i>Trop Med Int Health</i>. 2015 ;20(6):813-9.
	II	2. Delamou Alexandre, Delvaux Thérèse, Utz Bettina, Camara Bienvenu Salim, Beavogui Abdoul Habib, Cole Bethany, Levin Karen, Diallo Moustapha, Millimono Sita, Barry Thierno Hamidou, El Ayadi Alison Marie, Zhang Wei-Hong, De Brouwere Vincent. Factors associated with loss to follow up in women undergoing repair for obstetric fistula in Guinea. <i>Trop Med Int Health</i>. 2015;20(11):1454-1461.
	III	3. Delamou Alexandre, Delvaux Thérèse, Beavogui Abdoul Habib, Toure Abdoulaye, Kolié Delphin, Sidibé Sidikiba, Camara Mandian, Diallo Kindy, Barry Thierno Hamidou, Diallo Moustapha, Leveque Alain, Zhang Wei-Hong, De Brouwere Vincent. Factors associated with the failure of obstetric fistula repair in Guinea: implications for practice. <i>Reprod Health</i>. 2016;13(1):135.

2) Assessing the reproductive health outcomes in women after female genital fistula surgery in Guinea	IV	4. Delamou Alexandre , Utz Bettina, Delvaux Thérèse, Beavogui Abdoul Habib, Shahabuddin Asm, Koivogui Akoi, Leveque Alain, Zhang Wei-Hong, De Brouwere Vincent. <i>Pregnancy and childbirth after repair of obstetric fistula in sub-Saharan Africa: Scoping Review.</i> <u>Trop Med Int Health.</u> 2016;21(11):1348-1365.
		5. Delamou Alexandre , Delvaux Thérèse, Beavogui Abdoul Habib, Leveque Alain, Zhang Wei-Hong, De Brouwere Vincent. A descriptive longitudinal study protocol: recurrence and pregnancy post-repair of obstetric fistula in Guinea. <u>BMC Pregnancy Childbirth.</u> 2016;16(1):299.
	V	6. Delamou Alexandre , Delvaux Thérèse, El Ayadi Alison Marie, Tripathi Vandana, Camara Bienvenu Salim, Beavogui Abdoul Habib, Romanzi Lauri, Cole Bethany, Bouedouno Patrice, Diallo Moustapha, Barry Thierno Hamidou, Camara Mandian, Diallo Kindy, Leveque Alain, Zhang Wei-Hong, De Brouwere Vincent. <i>Fistula recurrence, pregnancy, and childbirth following successful closure of female genital fistula in Guinea: a longitudinal study.</i> <u>Lancet Glob Health.</u> 2017;5(11):e11152-e11160.

CHAPTER 1. INTRODUCTION

1.1 Obstetric fistula

Female genital fistula is an abnormal opening between a woman's vagina and bladder (vesico-vaginal fistula, VVF), vagina and rectum (rectovaginal fistula, RVF) or vagina and both bladder and rectum (VVF + RVF) (1). It is a serious morbidity that primarily follows prolonged obstructed labor. More rarely, fistula may be caused by genital cutting such as *yankan gishiri*, sexual violence, iatrogenic reasons (from poorly performed caesarean section, hysterectomy or abortions), pelvic fractures, and malignancy or radiation (2;3). No matter the cause, the fistula results in continuous and uncontrolled leakage of urine, feces or both, among other sequelae (1). Obstetric fistula (OF) results from prolonged obstructed labor, where the two bony surfaces off the head of the unborn child and the maternal pelvis compresses the intervening tissue, ultimately causing tissue necrosis (4). The sloughing of this necrotic tissue forms the fistula, and the woman becomes completely incontinent of urine, feces, or both (4).

It is a preventable maternal condition which is no longer prevalent in the developed world but whose eradication remains a major challenge in developing countries, particularly in sub-Saharan Africa and South Asia, where health systems are weak and adequate emergency obstetric care services are lacking (5;6).

An Eleventh Dynasty mummy, Henhenit, appeared to have had a VVF in 2050 before Christ (BC) in Egypt, representing the earliest recorded example of OF (7). However, it is only in 1037 that the relationship between obstructed labor and OF development was described by the Persian physician Avicenna (7). In the late 1800s, early 1900s when fistula was still a concern in industrialized countries, there were fistula-specific hospitals in the US and Europe. However, this waned with increasing availability of emergency obstetric care (7). In the 1980, the global front of the Safe Motherhood Initiative accelerated the development of increasing international attention to maternal mortality and morbidities. The work by Wall (8) and others made OF widely known and of public health concern. In 2007 and 2008, the United Nations General Assembly adopted two consecutive resolutions supporting efforts to end OF worldwide (9). In 2012, a new resolution called upon the international community to designate 23 May as the International Day to End Obstetric Fistula (10), and henceforth use the International Day each year to significantly raise awareness and intensify actions towards ending obstetric fistula.

1.2 Importance of the problem

1.2.1 Gravity

Obstetric fistula (OF) is described as a health and human rights tragedy due to its devastating consequences and debilitating sequelae. It is often classified as a neglected tropical disease because it is both preventable and treatable but continues to be responsible for suffering, stigmatization, and lost productivity among poor women from the poorest countries (6;11).

OF results in continuous and uncontrolled leakage of urine and/or feces that prevents victims from participating in usual life activities (4). Incontinence is the primary presenting symptom of obstructed labor injury complex which includes physical and psychosocial co-morbidities including foot-drop, vaginal stenosis, infertility or chronic urinary-tract infections (4;12). The delivery leading to the formation of the fistula frequently results in stillbirth, depression and stigmatization (13).

1.2.2 Epidemiology of Obstetric Fistula

Vangeenderhuysen et al. (14) in 2001, Wall (8) in 2006 and de Bernis et al (1) in 2007 have estimated the prevalence of OF ranging from 2 to about 3.5 million women in sub-Saharan Africa and South Asia, with an annual incidence of about 100,000 to 130,000. Other authors provided estimates of obstetric fistula prevalence ranging from one to two million worldwide according to a review by Stanton, Holtz and Ahmed (15;16). More recent estimates of the prevalence of fistula were proposed by Adler *et al.* (17) and Maheu-Girou *et al.* (18). In a systematic review and meta-analysis of the exiting literature, Adler et al (17) used 19 studies to determine the prevalence and incidence of fistula in low and middle-income countries. They found a pooled prevalence in population-based studies of 0.29 (95% CI 0.00, 1.07) fistulae per 1000 women of reproductive age in all regions. The combined prevalence for sub-Saharan Africa and South Asia was 1.57 (95% CI 1.16, 2.06). By region, the prevalence was 1.60 (95% CI 1.16, 2.10) per 1000 women of reproductive age in sub-Saharan Africa and 1.20 (95% CI 0.10, 3.54) per 1000 in South Asia. Adler et al. found a pooled incidence of 0.09 (95% CI 0.01, 0.25) per 1000 recently pregnant women globally (17). Maheu-Giroux et al (18)'s a meta-analysis of national household survey data from 19 sub-Saharan Africa countries estimated the lifetime and point prevalence of symptoms of vaginal fistula based on women's self-report of symptoms. They found a lifetime prevalence of 3.0 cases (95% confidence interval (CI)

1.3-5.5) per 1000 women of reproductive age and point prevalence of 1.0 case (95% CI 0.3-2.4) per 1000 women of reproductive age.

In Guinea, where maternal mortality is still high at 724 maternal deaths per 100 000 livebirths (19), the lifetime prevalence of self-reported obstetric fistula symptoms is double the combined lifetime prevalence for sub-Saharan Africa as a whole at 6.0 (95% CI 3.9–7.4) per 1000 women of reproductive age (19). There are no good and precise estimates of the burden of fistula because of the variability of data sources, contexts and measurement. This is regrettable and challenging as good estimates are needed for advocacy, policy making and programming.

1.2.1 Physical, Psychosocial and Economic Consequences of Fistula

In addition to suffering from uncontrolled urine and/or fecal incontinence, women living with fistula may suffer from physical impediments caused by the obstructed labor or resulting from it but also psychological and social consequences (20-22). Physically, women with fistula usually develop the “obstructed labor injury complex” (12) which includes several co-morbidities (4;12;23;24) such as:

- ✓ Chronic pyelonephritis, hydro-nephrosis and bladder stones
- ✓ Renal failure
- ✓ Vaginal stenosis (scarring) and dyspareunia (pain during intercourse)
- ✓ Pelvic inflammatory disease, amenorrhea and infertility
- ✓ Osteitis pubis (infection of the pubic bone and pubic symphysis)
- ✓ Lumbar plexus and/or peroneal nerve damage resulting in foot drop, loss of control of rectal muscles and numbness/weakness of pelvic area and lower extremities (leading sometimes to contractures of the legs)
- ✓ Urea dermatitis which is a chronic irritation and excoriation of skin (labia, perineum, groin) from contact with urine and stool
- ✓ Malnutrition which is often a result of neglect, depression and poverty

Apart from physical issues, many women suffer persistent psychological complications. Because of the smell of urine that results, women suffering from fistula are often abandoned by their spouses and relatives, keeping victims in poverty, anxiety, social isolation and depression (8;24). In Kenya (25), depression was found in 51 of 70 patients (72.9%), with 18 (25.7%) meeting criteria for severe depression. Authors found that women older than 20 years of age, those unemployed or lacking social support

following fistula and those living with fistula for over 3 months were more at risk of experiencing depression (25). In Tanzania (26), Wilson et al reported that obstetric fistula patients had more symptoms of depression, post-traumatic stress disorder, somatic complaints, and maladaptive coping than gynecology outpatients. In Ethiopia for instance, Muleta et al (20) reported that some health, social, and sexual problems remained in women after surgery. They found that half (54%) of the 48 women with feelings of depression had suicidal ideation (20).

Many women experience sexual dysfunction after repair and the sexuality of some is hindered by the fear of fistula recurrence despite childbirth expectations (27-30). In Nigeria for instance, a study with 102 women post-repair found that 63 women (61.7%) had reduced sexual desire as compared with the pre-fistula period and 48 (47.1%) reported dyspareunia (30). Wilson et al (31) have reported that women repaired for genital fistula frequently complained of infertility. In addition, biological and physiological dysfunctions are frequent after fistula surgery, such as amenorrhea (30;32;33).

It has also been reported that most women experience stillbirth during the delivery leading to the formation of the fistula (13). Furthermore, adverse maternal and neonatal outcomes after fistula surgery have been reported to be common including recurrence of fistula, stillbirth and abortion (32;34-37).

All these health issues coupled with divorce and the social abandonment women who develop fistula experience from husbands, families, and communities (24) makes fistula a “social calamity” (38).

1.3 Framework for analyzing the determinants of obstetric fistula

Despite recent studies highlighting important concerns about the increasing number of iatrogenic fistulae (39), obstetric fistula remains the most prevalent and incident type of female genital fistula encountered in sub-Saharan Africa and South Asia (6). The present framework (Figure 1) for analyzing the determinants of obstetric fistula formation was developed by Wall (4), inspired by the framework proposed for analyzing maternal mortality by McCarthy and Maine (40).

Wall expresses the hypothesis 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 labor, or (3) it will improve the outcomes for women whose labor becomes obstructed” (4). The framework divides influencing factors into three major stages or sets of components: acute clinical, intermediate and remote determinants. Wall defines how each of these categories of determinants affects the ultimate outcome of fistula.

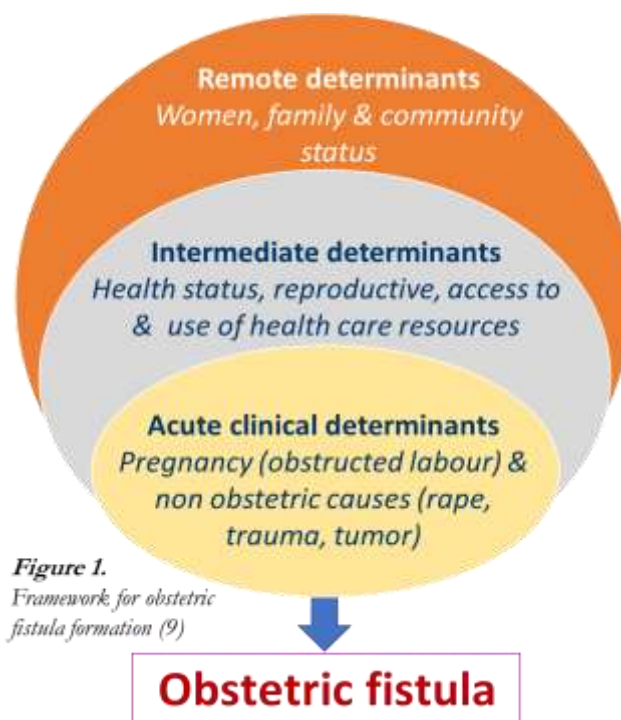


Figure 1.
Framework for obstetric
fistula formation (9)

1.4 Continuum of care for Obstetric Fistula: Achieving a Fistula-free Generation

In 2013, UNFPA and partners launched the Campaign to End Fistula with the goal of reducing the number of OF patients in affected countries (41). The Campaign is currently working in more than 50 countries across Africa, Asia, the Caribbean, and the Arab region where it promotes a holistic care for OF (41). The holistic care of OF includes prevention, case management and reintegration after successful repair (4).

Primary prevention relies on several interventions that include:

- ✓ Adolescent and maternal nutrition
- ✓ Education and empowerment for women including increased community awareness of causes and prevention measures
- ✓ Delaying marriage and child bearing
- ✓ Birth preparedness, including transportation and family decision making
- ✓ Skilled attendance at every birth
- ✓ and provision of quality emergency obstetric and neonatal care
- ✓ Monitoring of every labor with the partograph for early recognition of obstructed labor

Secondary prevention of OF includes provision of urinary catheter to any woman in or after possible state of obstructed labor (42).

In many countries in sub-Saharan Africa, the provision of quality emergency obstetric care is still challenging (43). In addition, efforts are still needed to increase awareness about maternal health, provide quality modern family planning services to avoid unintended pregnancies and delay the age of first pregnancy, especially among younger women who are at greater perinatal risk (44).

When the fistula occurs, the diagnosis is done clinically through a pelvic exam verified by a dye test or cystoscopy and the treatment is mainly surgical through transvaginal or transabdominal techniques (45). Surgical closure rates are usually high (up to 90%) but vary according to the repair site and fistula characteristics: fistula surgeon skill level and availability of quality pre/post-surgery care, size of fistula, pre-operative bladder size, degree of vaginal scarring, degree of urethral involvement, number of previous repairs, and repair outcome definition (46;46-49;49-51).

Successful closure of fresh fistula (occurring less than 3 months prior) can be achieved through catheterization (Foley catheter 18 or 20) (52;53). In a study by Waaldjik in Nigeria among 170 women presenting with fresh fistula, closure was achieved through catheterization for 156 women (92%), and 146 of those with closed fistula (94%) became continent (53). Closure and continence rates were higher among women with less complicated fistula.

Because fistula repair after previous attempts to close the fistula is technically difficult for the surgeon and exhausting for the woman (54;55), the prevention of OF recurrence relies on avoiding heavy work, early sexual intercourse along with careful management of pregnancy and delivery post repair. It is common practice for providers to recommend an elective caesarean section for subsequent delivery of women repaired for fistula (34;36;56), but there is little evidence whether and to what extent this recommendation is followed and implemented due to lack of longitudinal follow-up following fistula repair. After repair, successful social and economic reintegration is key to helping women resume a social life, overcome the isolation and psychological trauma they experienced, and prevent the occurrence of adverse health outcomes (57-59). However, there is a lack of evidence around standardized services or interventions to best support women post-repair. Currently, most services offered are limited to hospital stay and include sexual

and reproductive health counseling at discharge, psychological counseling, and skill empowerment, literacy classes or psychological support groups (57;58;60-62).

Women who experience surgical failure are usually advised to wait three months before a new surgical attempt is done by a more specialized surgeon (63).

1.5 Fistula Care in Guinea

OF is a public health concern in Guinea where the determinants of fistula formation are numerous (low coverage and quality of obstetric care, poverty, gender-based violence, illiteracy, early marriage and early pregnancy, etc.) (4;19;64). Fistula care started on an “ad hoc” basis in the 1990’s in specific sites such as Donka national hospital in Conakry and NZerekore where Medecins Sans Frontieres (MSF) was doing surgical repairs and trained a few surgeons. However, the first OF situational analysis conducted in 2007 was facility-based and estimated the prevalence of OF at 184 per 100,000 women of reproductive age and the incidence at 124 new cases per 100,000 live births (65). In 2012, the Demographic and Health Survey (DHS) estimated the lifetime prevalence of obstetric fistula symptoms at 6‰ among women aged 15-49 with regional variations ranging from 2 to 12‰, although this figure is likely underestimated (19). This represents about 15,000 women who have experienced fistula-related symptoms in their lifetime and doubles the overall lifetime prevalence of sub-Saharan Africa at 3.0 cases per 1000 women of reproductive age (95% CI: 1.3-5.5) (18).

To address the burden of OF, the Ministry of Health (MoH) of Guinea developed and implemented two strategic plans for the prevention and management of obstetric fistula (2012-2016 and 2016-2020) (65;66). Both plans include prevention, treatment and reintegration activities and envision the integration of fistula management units into all eight regional hospitals across the country by 2020 (66). However, the achievement of the planned goals is still dependent on external funding. In Guinea, fistula prevention and management is supported by a small number of technical and financial partners (Table 1). USAID and UNFPA are the main funding bodies supporting the country. The end of the USAID-funded and EngenderHealth-led Fistula Care project in 2013 resulted in a drastic reduction in fistula repairs at all three supported hospitals until the resumption of USAID funding to fistula repair in 2016.

1.5.1 EngenderHealth funded activities

EngenderHealth led Fistula Care project lasted from 2006 to 2013 and aimed to improve prevention and treatment efforts for obstetric fistula, as well as support reintegration of fistula patients into the community (63). The project established a framework detailing the multiple levels of fistula care in order to optimally integrate fistula management activities in the Guinean health system and achieve the project's objectives (67). These activities resulted in the following achievements (63):

- ✓ About 3,000 fistula surgeries conducted at the following sites: Ignace Deen National Hospital in Conakry, Kissidougou Hospital, Labé Regional Hospital, and Jean Paul II Socio-Medical Center in Conakry;
- ✓ Training of 16 Guinean surgeons to repair simple and complex fistulas;
- ✓ Training of 384 providers in pre-, intra- and post-operative care, including psychological counseling, infection prevention and quality assurance;
- ✓ Training of 336 providers at the three repair sites on family planning (FP) counseling and key EmONC functions and fistula prevention interventions; and
- ✓ The establishment and training of 35 Village Motherhood Committees in the urban communes of Kissidougou and Labé.

In 2014/2015, EngenderHealth received additional funding from the Islamic Development Bank to support 50 surgical repairs in Labé and Kissidougou. In 2016, the new USAID-funded Health Services Delivery project (2016-2020) led by JHPIEGO was launched in Guinea, including a fistula management component implemented by EngenderHealth.

1.5.2 United Nations' Population Fund (UNFPA) funded activities

The United Nations Population Fund (UNFPA) has supported health programs in Guinea since 1972 with a focus on three components (reproductive health, population and development, and gender). The reproductive health component includes essential obstetric care, adolescent and youth health, family planning and health commodities. An evaluation of the 6th Cooperation Program between the UNFPA and Guinea (2007-2011) documented 110 fistula repairs at UNFPA supported site of Kankan Regional Hospital (68). As part of the current country program (2013-2017) in Guinea, the UNFPA aims to support national capacity for scaling-up emergency obstetric and neonatal care and

strengthen fistula treatment (69). The target number of women receiving surgical repair for OF under the 2013-2017 country program was 1,000 repairs. In 2012/2013, about 200 women had received surgical fistula repair at the UNFPA supported site in Kankan. The 2014/2016 Ebola virus disease (EVD) outbreak in Guinea might have jeopardized the achievement of the planned target given the decrease observed in the use of maternal health services in the country (70).

Table 1. Stakeholders involved in fistula prevention and management in Guinea, 2005-current

Organization	Period of intervention	Geographical coverage	Activities	Funding sources
EngenderHealth	2005-present	Three repair hospitals (Jean Paul 2 in Conakry, Labé and Kissidougou) Prevention only sites (Faranah, Mamou, Boke)	About 3,000 repairs, 16 surgeons trained, and mentored; 384 providers trained on pre/post-operative care as of 31 December 2013	USAID Islamic Development Bank (IBD)
UNFPA	2006 – present	Improve the prevention and treatment of women suffering from fistula in Guinea (Kankan and Nzerekore)	503 surgical repairs as of 31 December 2013	UN
Guinean Association against Obstetric Fistula (AGFO)		National	Provide local fistula surgeons to established project; training of health personnel	WAHA, UNFPA
WAHA International	2011 - present	Conakry (Ignace Deen National Hospital)	Support to AGFO: capacity development of the technical skills for local surgeons, providing technical documents	WAHA
Amref Health Africa	2015-2016	Supported fistula repair and reintegration in Conakry in 2014 and 2015	Provide support to fistula repairs at Jean Paul II Hospital	Private donors

1.5.3 Other actors

Other actors include Amref Health Africa, the Guinean Association against OF (AGFO) and WAHA International. Amref Health Africa is an African NGO that supported repairs in Conakry in 2014/2016. AGFO is a local professional NGO that provide expert surgeons to implementing partners, support training activities for surgeons and other health professionals and conduct surgical repairs at Ignace Deen National Hospital in Conakry. WAHA is an NGO periodically supporting capacity building and repairs at Ignace Deen National Hospital, in partnership with AGFO.

CHAPTER 2. THESIS RATIONALE

2.1 Rationale

As highlighted in the above introduction, fistula is a serious public health concern that threatens women's lives and well-being (2;6;17;18). In Guinea, where the majority (70%) of the population lives in rural areas and 55% live in poverty (less than \$300 per year in 2012), the prevalence of fistula is high (19;64). In 2012, the estimated number of deliveries was 435,000 while the delivery with skilled attendant rate was 45.3% at national level, and 83.9% and 31.6% in urban and rural areas, respectively (19).

In the past decades, thanks to the international mobilization against fistula, many countries in sub-Saharan Africa have improved care of OF including prevention, treatment and reintegration (6;71;72). As a result, more than 30,000 fistula repairs have been achieved in 15 countries since 2005 with support from the Fistula Care Project, a USAID-funded project managed by EngenderHealth, (63) and more than 57,000 repairs have been funded by the UNFPA (72). In addition, surgical outcomes are similar with shorter hospital stay which can reduce treatment-related costs, allowing more women to be treated (73). Furthermore, post-operative closure and continence rates after surgery are increasing, ranging between 60 and 90% (1;46;47;74).

In Guinea, the Fistula Care Project has supported about 3,000 fistulas repairs between 2007 and 2013 (63;65). Supported hospitals were in three different regions and the program was available over the country. This option was not that chosen by all countries nor has it been previously tested in Guinea; it was a political choice (see discussion section 6.2). However, despite the strengthening of research on fistula, including many studies reporting on fistula repair outcomes, and improvements in clinical outcomes, there remains a persistent evidence gap on interventions aimed at preventing recurrence of fistula and poor pregnancy outcome after fistula repair, both maternal and perinatal (75). To date, there is little data on follow-up after fistula repair as only few studies have estimated the recurrence of fistula after successful repair; they used various study designs and case definitions, and they had different lengths of follow-up (31;32;35). In Ethiopia, Nielsen observed 2.6% recurrence of fistula among 38 women during 21 months post-repair median follow-up (32) and Browning (35) recorded 4.3% fistula recurrence in 141 women successfully repaired through six months follow-up. Wilson

reported 3.85% of recurrence in 26 women in Malawi after 9 to 24 months follow-up post-repair (31).

Similarly, there is a paucity of data on fertility or pregnancy and childbirth after successful fistula repair, especially from robust studies that are able to provide a precise estimate of pregnancy and delivery outcomes (33;34;36;37;56;58).

Incidence proportions of pregnancy of respectively 13.2% (32) and 4.3% (35) have been reported in Ethiopia and 23.1% in Malawi (31). Delivery outcomes were poor with only one live birth out of four deliveries in both Ethiopia and Malawi (31;32).

Data currently available show that many women are relatively young at the time their fistula is repaired and although data are limited, most women return to their community after surgery with not only the desire to resume a normal social life, but also to become sexually active and have children (31;32;32;35;59;60). This return to sexual life exposes repaired woman to pregnancy and childbirth, which increases the risk of recurrence of a previously repaired fistula or the formation of a second, new fistula, especially if the woman does not benefit elective C-section which is a standard after successful OF repair (32;35). The repair of a previously repaired fistula is often difficult (54). Multiple surgeries are stressful and place an additional burden for fistula care programs and the community (28;55), especially given the high cost of fistula care (76).

As maternal mortality reduction is accelerating in many countries due to better access to cesarean section (71) while treatment for fistula continues (72), women who have a successful fistula repair need more attention to prevent fistula recurrence and adverse maternal and neonatal outcomes (28;54;55;77). This emphasizes the need to conduct quality research to address these knowledge gaps and guide policy making and management of women after fistula repair. Among current fistula research priorities there is the need to collect long-term follow-up data on fistula recurrence, and subsequent pregnancies and their outcomes (75). To fill this gap, the research reported on here was based on a cohort of women whose fistula was closed after surgery at three repair hospitals supported by EngenderHealth in Kissidougou, Labé and Conakry. It has generated new knowledge to guide and inspire reintegration programs and inform prevention of fistula in Guinea and possibly in countries with similar contexts in Africa.

2.2 Scientific, medical and societal relevance of the thesis

The global burden of OF is, like most severe maternal conditions, is mainly localized in low-income countries, most of which are in sub-Saharan Africa (13;78;79). OF usually affects the poorest women among the poor (11;24). Costs of care (transport, accommodation, surgery costs) and reintegration of women after successful repair of the fistula remain high and come primarily from development partners (76). Enhancing the quality of fistula care programs to make them cost-effective in the long-term requires a better understanding of the health of women after surgery. Among current research priorities there is the need to understand the long-term health outcomes in women after fistula repair (75). This research is likely to generate new scientific knowledge to guide fistula prevention and reintegration policies and programs.

Because most of the repaired women are of reproductive age, they are at-risk of fistula recurrence that can occur because of heavy work, sexual intercourse, wound infections or complication of a subsequent pregnancy (prolonged labor or poor management of vaginal delivery) (34;35). The research reported here will contribute to the evidence base on the health of women after repair and suggest strategies to improve their health after such a traumatic experience.

CHAPTER 3. AIM AND OBJECTIVES

3.1 Aim

To analyze the long-term reproductive health outcomes in women who undergo fistula surgery in Guinea and contribute to closing the knowledge gap on the health of women after fistula surgery.

3.2 Objectives

1. To conduct a situational analysis of fistula management programs in Guinea through:
 - a) Analyzing the clinical outcomes of fistula care programs in Guinea;
 - b) Determining the trends and factors associated with loss to follow-up after surgical repair of obstetric fistula in Guinea;
 - c) Estimating the overall proportions of surgical failure of fistula closure and incontinence among women undergoing repair for obstetric fistula in Guinea and identifying factors associated with these outcomes.
2. To analyze the reproductive health outcomes in women after female genital fistula surgery in Guinea through:
 - a) Critically reviewing the existing literature on pregnancy and childbirth post repair of obstetric fistula;
 - b) Analyzing the incidence of fistula recurrence and pregnancy post repair along with the associated maternal and neonatal outcomes in women after successful closure of their fistula.

CHAPTER 4. MATERIALS AND METHODS

4.1 Thesis framework

Through a literature review, I have developed a conceptual framework that illustrates the focus of this thesis within the context of multiple levels of health determinants (Figure 2).

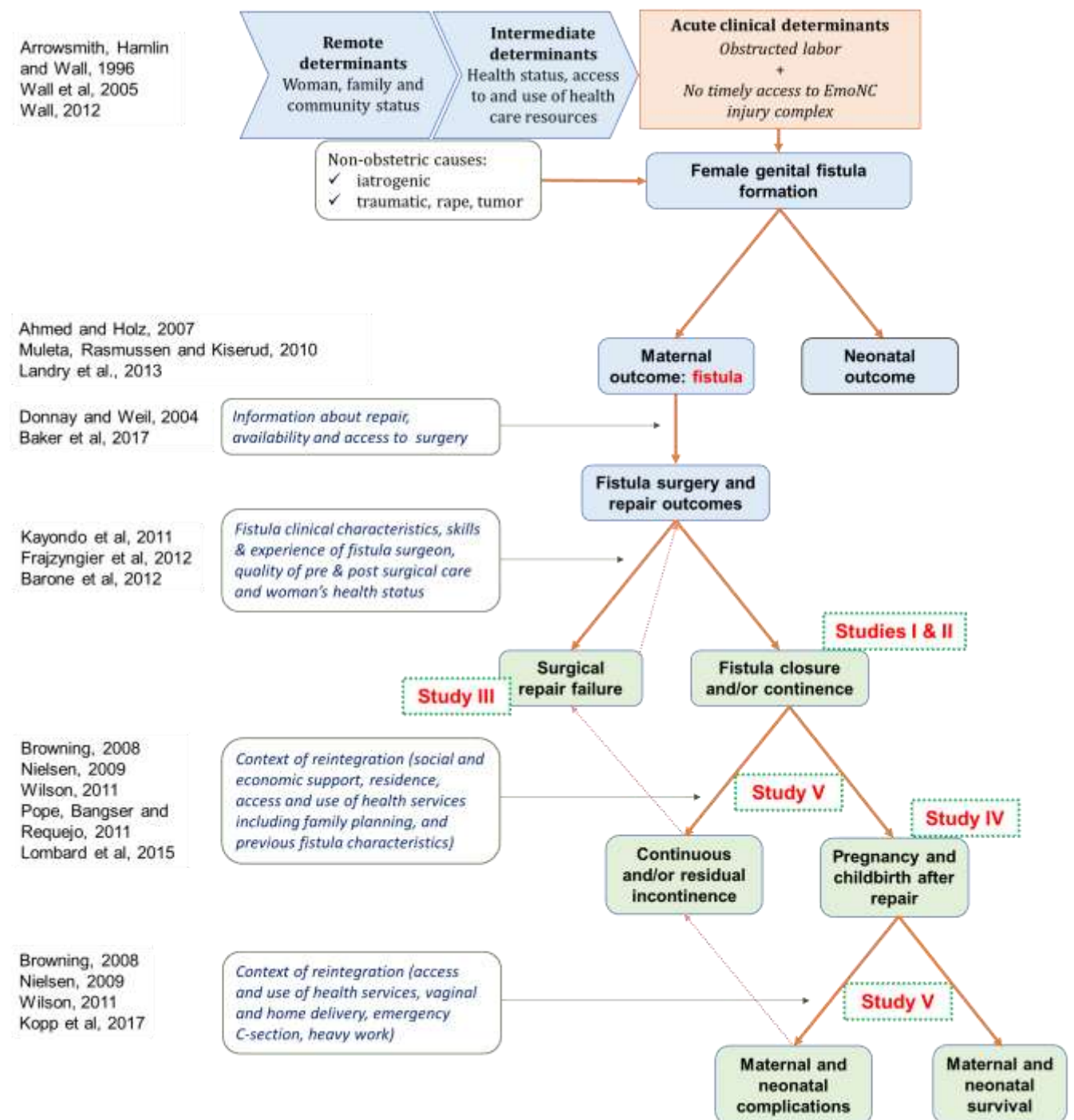


Figure 2. Thesis framework showing the areas of focus (green) and the individual studies included in this thesis (red)

The framework aligns with the continuum of care approach that is required for the holistic management of obstetric fistula, including prevention, treatment and reintegration (67;80;81). The framework is inspired by previous work on fistula formation (4), fistula repair outcomes (49-51;75;82), and post-repair life and health outcomes (31;32;35;57;58). It outlines different levels of outcomes in the continuum of care for the prevention and management of obstetric fistula including fistula occurrence, repair outcomes and post-repair outcomes. Each level of outcomes is the result of a set of determinants taken singly or in combination. Fistula occurrence is the result of remote, intermediate and acute determinants previously described by Wall (4). Fistula surgical repair outcomes are influenced by several determinants that include fistula clinical characteristics, and the context of repair such as the quality of intra and peri-operative care or the skills of the surgeon (46;49-51;83). Post-repair outcomes (fistula status, maternal and neonatal outcomes) depend on the context of reintegration (social and economic support, place of residence, access and use of health services, knowledge and use of family planning methods, and previous fistula characteristics (57;58;84). Finally, engagement in the continuum of care for women who develop fistula depends on the availability of information on fistula care services, availability and affordability of services provided along with access and use of these services (85).

4.2 Overview of thesis methods

Quantitative methods were used in this thesis; the overview of which is outlined in Table 2. Studies I, II and III included routine program data analysis while a scoping review was conducted for study IV. For study V primary field data collection was conducted.

Studies I to III form the situational analysis of fistula care programs in Guinea. This situational analysis along with the scoping review (Study IV) informed the development of the study protocol and guided the conduct of the longitudinal study (Study V). For example, the situational analysis helped understand the need for community follow-up instead of hospital-based follow-up, especially given the fact that the field work was conducted within the context of the 2014/2016 Ebola virus disease outbreak (86).

Table 2. Overview of thesis methods by study

Studies	Setting	Population, period and sample	Design, data source and collection tools	Analysis and outcome
Study I Good clinical outcomes from a 7-year holistic program of fistula repair in Guinea	Guinea: three fistula repair hospitals (Jean Paul II Hospital in Conakry, Labé Regional Hospital and Kissidougou District Hospital)	Women aged 15 years or more who underwent fistula repair between 1 January 2007 and 30 September 2013 (N=2116)	Retrospective cohort study using routine program data Individual medical records of repaired patients Standardized questionnaire	Frequencies, mean and/or median, comparisons using Pearson's chi-square test Assessment of treatment outcomes (fistula closure and residual incontinence) immediately after surgery, at the time of hospital discharge and at 3-month follow-up visit.
Study II Factors associated with loss to follow-up in women undergoing repair for obstetric fistula in Guinea	Same as Study I	Same as Study I, but sample restricted to women residing in Guinea (N=2080)	Retrospective cohort study using routine program data. Individual medical records of repaired patients Standardized questionnaire	Frequencies, mean and/or median, logistic regression Description of demographic and clinical characteristics. Assessment of loss to follow-up within 4 months after being discharged and identification of associated factors.
Study III Factors associated with the failure of obstetric fistula repair in Guinea: implications for practice.	Same as Study I	Women aged 15 years or more who underwent fistula repair at one of the study sites between 1 January 2012 and 31 October 2013 (N=754)	Retrospective cohort study using routine program data. Individual medical records of repaired patients Standardized questionnaire	Frequencies, mean and/or median, logistic regression Description of demographic and clinical characteristics. Assessment of fistula surgical repair failure and identification of associated factors.

Study IV Pregnancy and childbirth after repair of obstetric fistula in sub-Saharan Africa: Scoping Review	sub-Saharan Africa	Women who underwent obstetric fistula repair between 1 January 1970 to 31 March 2016 in sub-Saharan Africa	Scoping review Primary published studies Standardized questionnaire	Pregnancy and childbirth in women who underwent repair for obstetric fistula
Study V Fistula recurrence, pregnancy, and childbirth following successful closure of female genital fistula in Guinea: a longitudinal study	Guinea	Women discharged with a closed fistula between 1 January 2012 to 30 June 2015. (N=481)	Longitudinal cohort study Individual medical records of repaired patients & face to face interviews Standardized questionnaires	Cumulative incidence, incidence proportion, and incidence ratio using Kaplan-Meier methods. Assessment of fistula recurrence, residual incontinence, pregnancy and childbirth after successful fistula closure.

4.3 Study setting

4.3.1. The study country

The studies within this thesis were conducted in Guinea. Guinea is in West Africa and covers 245 857 square meters and had a population of 10.6 million inhabitants in 2014 (87). The country is composed of four natural regions (Lower Guinea, Middle Guinea, Upper Guinea and Forest Guinea) and divided into eight administrative regions (Figure 3).



Figure 3. Guinea administrative map (Source: Ministry of Health)

Most of this population live in rural areas (65%), 52% are women and 44% are aged below 15 years old (64). In 2012, 55% of the country's population was living below a poverty threshold daily income of \$1.25 and 65% lived in rural areas (19;64).

4.3.2 The Guinean Health System

“The Guinean health system is not performing, accessible and equitable, not capable of ensuring the right to health for all, especially for the most vulnerable” (88).

The Guinean health system is currently divided into public and private sectors which are organized as a pyramid from national to community levels (Figure 4).

The community level consists of community-based services delivered by community health workers (CHWs) and traditional birth attendants. Health centers and health posts deliver immunization services, primary curative care, antenatal care, family planning and delivery services. District hospitals (first referral level) offer an additional package that includes basic specialties such as internal medicine, surgery, pediatrics, gynecology-obstetrics and medico-technical services (e.g., laboratories). In addition to what district hospitals provide, regional hospitals offer specialized services such as cardiology, endocrinology, pneumology, neurology and urology. National hospitals provide all specialized services and are involved in training and research activities.

The private sector includes private for-profit and not-for-profit sectors. It is strongly dominated by informal facilities, mostly for-profit paramedics.

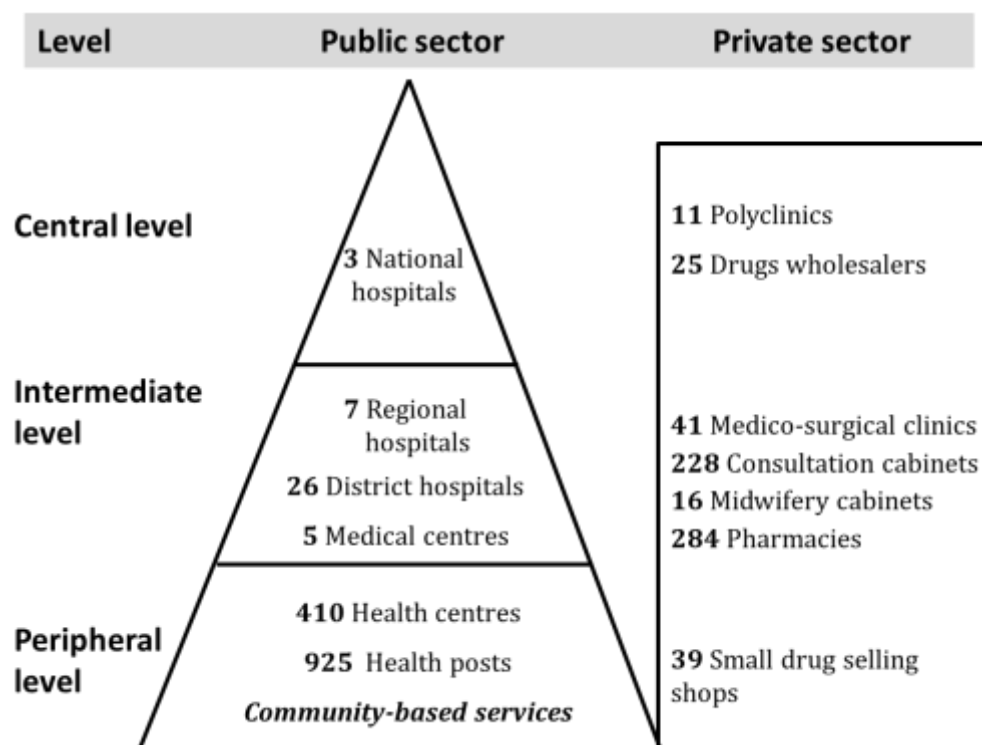


Figure 4. Public and private health provision in Guinea (Source: Ministry of Health, 2013)

4.3.3 Health financing in Guinea

Despite an accelerated increase of the country's total expenditures on health between 1995 and 2014, the general government expenditure on health, as a percentage of the country's total expenditure has remained low, between 7% and 9%, the difference being made up with funds from foreign assistance, (89). In the meantime, private expenditure on health has slightly decreased from 65% in 1995 to 52% in 2014. However, out-of-pocket expenditure, as a percentage of private expenditure, has remained about 88% of private expenditure on health during this period. This has negatively and durably affected the quality of health care provision resulting in worse health indicators for mothers and children (89).

4.3.4 Study country health indicators

Most health indicators in Guinea are of concern. Malaria is the leading cause of morbidity and mortality and TB (national prevalence of 60 cases per 100 000 persons) and HIV/AIDS (national prevalence of 1.5% in 15-49 years old) are considered as public health issues (90).

Table 3. Selected reproductive health indicators in Guinea

Towards a fistula free generation:
Lessons learned from long-term follow-up of women after obstetric fistula repair in Guinea

Indicators	Values
Annual population growth, %	2.4*
Life expectancy at birth (2012 DHS), years	56 **
Infant mortality rate (< 1 year), per 1000 live births	67 **
Under five mortality rate, per 1000 live births	123 **
Maternal mortality ratio, per 100,000 live births	679 [95% CI: 504 to 927] ***
Delivery with skilled birth attendant, %	45**
Annual cesarean section rate, %	1.5****
Coverage of first antenatal care consultation, %	85**
Coverage of fourth antenatal care consultation, %	57**
Coverage of postnatal care consultation within 48h, %	37**
Total fertility rate, children per woman	5.1
Contraceptive prevalence rate for modern methods, %	7.0
Prevalence of female genital mutilation, % of women >15 years	97

Sources: *National institute of statistics, 2014; ** Demographic and Health Survey, 2012; *** WHO, 2015; ****Annual report of health statistics, 2013.

Other infectious diseases such as cholera, measles and meningitis occur almost every year (90). Furthermore, the burden of chronic non-transmissible diseases such as diabetes and hypertension represented 14% of hospital-based deaths in 2013 (90).

As presented in Table 3, provision of the continuum of care for the mother and child is not ensured in Guinea. In 2012, modern contraceptive prevalence was low (6%) with concurrent high total fertility rate (5.1 children per woman) and high maternal mortality (724 deaths per 100,000 live births) (19). In 2015, the WHO estimated the maternal mortality ratio at 679 (95% CI: 504 – 927) per 100,000 live births (91). In addition, delivery with skilled birth attendants is still low in the country (45%) while first antenatal care visit achieves a high coverage (85%). Only 16% of health professionals (doctors, state midwives and state nurses) work in rural areas where they serve 65% of the population (19). Between 2007 and 2012, births in the country mainly occurred at home (59%) and were assisted by unskilled birth attendants (55%) (90). In 2011, the country introduced a free obstetric care policy into all public health facilities which included antenatal care and delivery (normal delivery and caesarean section, and child immunization. There is some evidence that the policy was working. For example, a study

conducted in 2014 found a significant decrease of unmet obstetric need (UON) between 2008 and 2012 in Kissidougou, especially in rural areas (92).

4.3.5 The 2014/2016 Ebola Virus Disease outbreak

In March 2014, the World Health Organization officially declared an EVD outbreak in Guinea (86), which rapidly spread to Sierra Leone and Liberia, becoming a global public health emergency (93). As of 14 February 2016, a total of 3,804 EVD cases from 26 of 34 country-wide health districts were reported in Guinea including 211 cases among healthcare workers (HCW). The case-fatality rates were 67% and 55% in the general population and in HCWs, respectively (94). In a context where maternal mortality and morbidity were already high and the health system weak (95), the occurrence of the EVD outbreak represented an additional risk for increased maternal mortality and morbidity including obstetric fistula. In fact, the disruption of health services that followed the EVD included non-use of facilities and mobility restriction. This prompted the Government of Guinea to create a new National Health Development Plan (2015 – 2024) with the aim to better implement the national health policy (90). The main outcomes of this plan for the mother and child include:

- ✓ Reduction of under-five mortality rate from 123 to 47 per 1,000 live births by 2024;
- ✓ Reduction of maternal mortality ratio from 724 to 349 per 100 000 live births by 2024; and
- ✓ Reduction of neonatal mortality rate from 33 per 1000 to 12.5 per 1,000 live births by 2024.

To operationalize this plan, a triennial Health System Recovery Plan (2015-2017) was developed with three priorities: 1) to eliminate EVD and other infectious diseases; 2) strengthen the district health system and; 3) improve health system governance (96). This resulted in the recruitment of 3802 new health care providers including 320 doctors, 950 nurses, 500 midwives, 1010 assistant nurses and 170 paramedics, the majority of whom were dispatched in rural areas to address the shortage of skilled health workforce (95). However, this recruitment happened while the data collection of the research reported here was already completed.

4.3.6 Study setting

The specific settings for Studies I to V were the following three fistula repair hospitals: Jean-Paul II Hospital in Conakry, the Regional Hospital of Labé and the Prefectural Hospital of Kissidougou. It is, however, worth mentioning that even though fistula repairs were conducted at the maternities of these three hospitals, women who underwent repairs originated from across the country.

Transportation, accommodation and surgery were free. Treatment in the repair hospitals included assessment and operation by a surgeon and counselling about exercises, family planning methods, resumption of sexual intercourse and heavy labor. For each woman, surgical outcomes (fistula closure and continence status) were assessed immediately after surgery, at hospital discharge and at 3 months using a dye test. Women who failed to achieve continence by the time of follow up visit were scheduled for an additional surgery. Continence was defined as the absence of leakage of urine or feces. Community awareness campaigns on fistula and the availability of fistula management services were conducted regularly through collaboration with rural radio, community leaders and community volunteers (village safe motherhood committees). As part of its capacity building component, the Fistula Care project supported the training of surgeons and nursing staff, provided counselling training, quality improvement, medical monitoring, equipment, and mentorship for continuous skills building (97). Surgeons from the Geneva Foundation for Medical Education and Research (GFMER) travelled to Guinea on a quarterly basis to lead training sessions along with a pool of Guinean surgeons and monitor progress of trainees. Sixteen Guinean local surgeons received training with support from EngenderHealth between 2006 and 2013. They attended an average of 22 training sessions, with 12 continuing to provide surgery after the Fistula Care Project ended in October 2013. Each center was staffed by two or three surgeons, an anesthetist, a counsellor and two to four nurses all trained in fistula prevention and management.

For Study VI, the city of Conakry and the health districts of Labé and Kissidougou constituted the specific setting.

4.4 Study designs

Based on the objective of each study, three study designs were used in this thesis. Studies I, II, and III applied retrospective cohort designs. Study IV used a scoping review and study V applied a prospective cohort design.

4.4.1 Retrospective cohorts using routine program data (Studies I to III)

In studies I to III, the objectives were to 1) analyze the outcomes of fistula surgery at three EngenderHealth supported fistula repair hospitals (paper one), 2) analyze the factors associated with loss-to-follow-up three months after hospital discharge among women who got fistula surgery and, 3) analyze the factors associated with surgical repair failure. We used a retrospective cohort design (98). This design was the most suitable because women included in the three studies that form this specific objective had already undergone fistula surgery at the study repair hospitals. Therefore, using a retrospective cohort design, which is usually less costly and quicker than a prospective cohort, allowed us to concurrently assess exposures and study outcomes (98;99). The design was relevant for assessing the performance of the fistula repair hospitals in terms of numbers of repairs and outcomes of surgery in a context where fistula services are integrated within the health system, i.e. within the maternity units (47;100).

4.4.2 Scoping review of the existing evidence on pregnancy post-repair (Study IV)

Study IV was a scoping review of the existing literature (101). The objective was to synthesize the evidence on pregnancy and childbirth after repair of obstetric fistula in sub-Saharan Africa and to identify the existing knowledge gaps. Scoping reviews are unique type of review used to map the key concepts of a given research area and identify knowledge gaps to inform research agenda setting and decision-making (101). In systematic reviews, the research question is highly focused, inclusion/exclusion criteria prespecified and the study types of interest defined, in scoping reviews, the research question is broadly defined, and all study types are included (102).

The Joanna Briggs Institute has published a reference document on how to conduct scoping reviews (103). In our context, conducting a scoping review was particularly useful as the existing body of literature had not previously been comprehensively reviewed. In addition, publications on pregnancy after OF repair were of heterogeneous

nature and therefore, not amenable to a more precise systematic review of the evidence (101).

4.4.3 Prospective cohort study with women post-repair (Study V)

In study V, I used a longitudinal cohort design. The study built on the results of the scoping review mentioned above. The objective was to determine the recurrence of fistula, outcomes of pregnancy and childbirth following successful fistula repair surgery. This design was chosen because women undergoing fistula repair surgery return home and therefore needed to be followed up at the community level to minimize loss to follow-up. Longitudinal cohort studies can establish the sequence of events and identify and relate these events to particular exposures (104). Prospectively, they also help exclude recall bias in study participants. To ensure transparency and credibility to my research, the study protocol was published and was registered on a public registry (ClinicalTrials.gov, Identifier: NCT02686957).

4.5 Data collection and analysis

4.5.1 Studies I, II and III

In Studies I to III, we collected routine program data using structured pre-tested questionnaires to extract data from medical records kept at the fistula repair hospitals. The three studies included women who underwent fistula surgery in the three repair hospitals between January 2007 and September 2013. However, the inclusion criteria varied between studies. Study I included all women irrespective of their place of residence at the time of surgery while Study II included only women residing in Guinea as those living out of Guinea were not asked to come back three months after hospital discharge for medical follow-up. The Study III was restricted to women who underwent surgery in the three repair hospitals between 1 January 2012 and 31 October 2013 (n=754) to better reflect the most recent clinical practices at repair hospitals (46;83). The sample size and outcomes for Studies I to III have already been summarized in Table 2. The fistula was considered not closed if the woman reported uncontrolled and continuous leakage of urine which was confirmed by a dye test performed at the repair hospital by a clinical staff (73). The woman was considered dry if the fistula was closed and there was no leakage of urine or feces while residual incontinence was declared if the woman still had some incontinence remaining despite fistula closure. Women were considered lost to follow-up if they failed to attend the follow-up appointment within 4 months of their discharge (100).

The first steps in the analyses were to summarize patients' characteristics and treatment outcomes using descriptive statistics (frequencies with confidence intervals, mean with standard deviations or median with interquartile ranges). The second steps were to compare treatment or study outcomes across independent variables using appropriate statistical tests (e.g. Pearson's Chi square (χ^2) for proportions, Student t-test for means when the distribution was normal). In Studies II and III, the third steps consisted of conducting bivariable and multivariable analyses using logistic regression models to analyze the factors associated with study outcomes and derive the unadjusted and adjusted odds ratios. In all studies, the level of significance was set at P=0.05 with 95% confidence intervals (CI).

EpiData Entry software (version 3.1, EpiData Association, Odense, Denmark) and STATA 13 software (STATA Corporation, College Station, TX, USA) were used for data management and data analysis, respectively.

4.5.2 Study IV

In study IV, we used the scoping review approach by searching relevant articles published between 1 January 1970 and 31 March 2016 in electronic databases (e.g. PubMed, Popline, Embase), general internet sources (e.g. Google Scholar) and grey literature without methodological or language restriction (101). Studies reporting on pregnancy and childbirth in women who underwent repair for obstetric fistula in sub-Saharan Africa were included. Two reviewers used a standardized tool to extract related data and generate evidence tables. A qualitative synthesis was applied to the data to describe and summarize the characteristics of included studies, analyze study outcomes and potential factors associated with study outcomes for the mother and the child (101).

4.5.3 Study V

In Study V, women were recruited both retrospectively (Jan 1, 2012, to Dec 31, 2014) and prospectively (Jan 1 to June 30, 2015), with follow-up ending on June 30, 2016 (Figure 5). We included women who resided in Guinea and who had a single genital fistula confirmed to be closed via dye test at the time of discharge from one of the three repair hospitals supported by EngenderHealth (105). This was challenging because participating women came from across the country and for most of them, the surgery had been performed more than a year before the study started. The minimum sample size was estimated at 364 women. Data were collected prospectively as follows: 1) medical records kept at fistula repair hospitals were reviewed to identify eligible participants and locate them within their community (retrospective inclusion; 348 women) to obtain informed consent or women were approached at the time of hospital discharge (prospective inclusion; 133 women) to obtain informed consent; 2) medical records were used to extract women's demographic and clinical data and; 3) women were visited within their community to collect follow-up data. The study team included nurses involved in the management of women at the fistula repair hospitals, doctors, and final year medical students.

Data were collected by trained data collectors using structured and pre-tested standardized questionnaires. We collected sociodemographic and clinical characteristics at enrolment while at follow-up we captured data on demographics (current residence, marital status and occupation), participants' health and reproductive characteristics (fistula status, pregnancy, childbirth, etc.).

The primary outcome was recurrence of fistula following discharge from the repair hospital, defined as the breakdown of a repaired fistula or the occurrence of a new fistula. Breakdown was defined as continuous and uncontrolled leakage of urine in a woman and was confirmed by a dye test (73). The secondary outcomes were time to pregnancy, pregnancy outcome, and maternal and neonatal outcomes at first delivery after repair, and occurrence of residual urinary incontinence among women continent at discharge. Pregnancy was documented by a positive pregnancy test or self-report, and time to pregnancy was calculated from the time of hospital discharge until the estimated date the woman became pregnant. Residual incontinence was confirmed by a dye test.

After summarizing patients' characteristics using descriptive statistics (frequencies with confidence intervals, mean with standard deviations or median with interquartile ranges), we estimated the study outcomes as cumulative incidence with Kaplan-Meier survival analysis methods or as proportions. We then derived incidence ratios of study outcomes and compared them for selected variables using Fisher's exact test after controlling for competing events (106). EpiData Entry software (version 3.1, EpiData Association, Odense, Denmark) and STATA 13 software (STATA Corporation, College

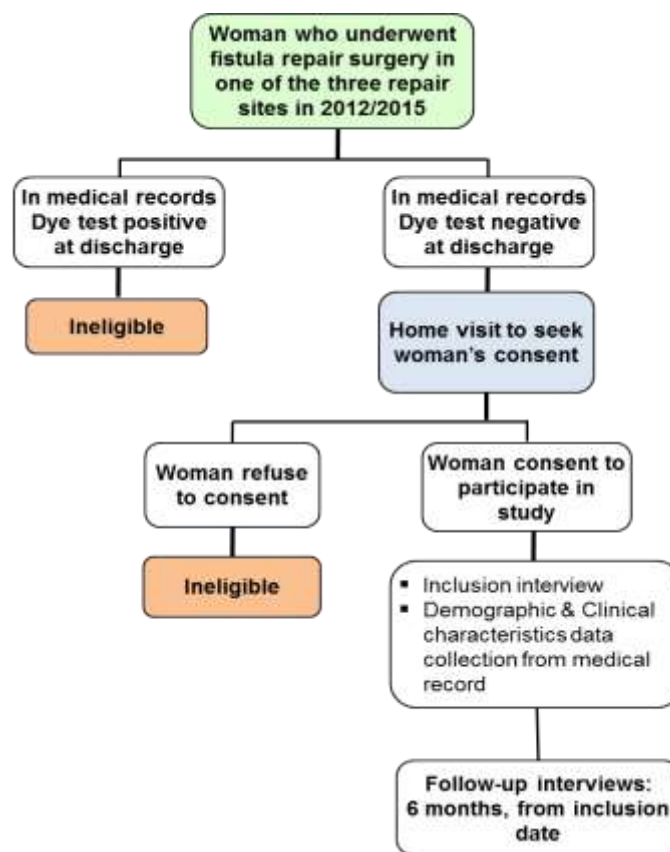


Figure 5. Longitudinal study flow chart

Station, TX, USA) were used for data management and data analysis respectively. For all statistical tests, the level of significance was set at $P=0.05$ with 95% confidence intervals.

4.6. Ethical considerations

4.6.1 Ethics approvals

Studies conducted as part of this research obtained ethics approvals from the appropriate bodies. Studies I and II obtained ethics approvals from the Comité national d'éthique pour la recherche en santé (CNER) of Guinea (Ref#26/CNER/14 and Ref#27/CNER/14), MSF Ethics Review Board (Switzerland) and the Ethics Advisory Group of the International Union Against Tuberculosis and Lung Disease (France). Study III was granted approval from the Institutional Review Board of the Institute of Tropical Medicine (ITM) of Antwerp, Belgium (IRB#968/14), and the CNER (Ref#22/CNER/14). Study IV did not require ethics approval. Study V obtained ethics approval from the ITM of Antwerp (IRB#948/14), the Ethics Committee of the University Hospital of Antwerp (Ref#14/22/238), and the CNER of Guinea (Ref#10/CNER/14).

4.6.2 Ethical challenges

Informed consent and data confidentiality for retrospective studies

Studies I to III used a retrospective cohort design. Therefore, informed consent could not be secured from participating women as only routine program data (patients' files) were reviewed. However, the names and identifying information of study participants were removed to preserve confidentiality and were not disclosed in any publication or presentation. In addition, the databases of these studies were only accessible to study investigators and were held in strict confidence.

Informed consent and confidentiality for vulnerable populations

Studies V and VI included women who have suffered female genital fistula. They are usually illiterate and often considered as vulnerable people because of the stigma and the social and economic exclusion that many of them face when they developed the fistula (11;24;79). Therefore, research that involve them raise ethical concerns (107;108). For instance, because they are vulnerable population, their privacy and confidentiality might be transgressed and/or violated, and these women might be exposed to more stigma into their communities when the research brings out a socially sensitive issue such as fistula

(109). In such a case, the study protocol needs to be appropriately reviewed by ethical authorities to ensure these vulnerable populations' rights are protected. Because most surgeries took place before the Study V starts, women were contacted within their community to seek their informed consent for participation in the research, as per the recommendations of the Guinean national ethics committee and the ITM IRB. For included women, receiving a visit at home by an unknown investigator could be hurting, especially if the woman does not want to recall her previous life with fistula. To address this issue, we involved Fistula Counsellors from repair hospitals (certified nurses or midwives) and Fistula Focal Points (women appointed by the Fistula Care Project at hospitals and health centers levels across the country) in making home visit. The responsibilities of Fistula counsellors included welcoming new fistula patients, supervising the provision of accommodation and food, providing counselling about surgery and hospital stay. At the time of hospital discharge, Fistula Counsellors would provide counselling about family planning methods, resuming of sexuality, pregnancy and childbirth post repair. They would also ensure each woman receives her transportation costs and small gift before leaving. Fistula Focal Points were trained to identify women with fistula symptoms and refer them to the dedicated repair hospitals. Because both Fistula Counsellors and Fistula Focal Points were involved at some point in the routine care of women who underwent fistula repair, their involvement in the home visits and the informed consent process was more acceptable for including women and their families. However, the risk of ethical breach in using these Fistula counsellors and focal points was related to the fact that women could place too much faith in the counsellors and consent to participate in the study even if they do not really understand it (108). For this reason, Fistula counsellors were oriented prior to taking part in the study. In addition, to maintain confidentiality and impartiality, Fistula counsellors and Fistula focal points were required to sign a confidentiality form.

4.6.3 The use of health professionals other than fistula counselors to trace women

As the longitudinal study was conducted while the EVD outbreak was ongoing, it became obvious that only fistula counselors and focal points would not permit the timely tracing of study eligible women. Sometimes, they were not available to travel to a remote and hard to reach area or no phone number was available to establish the contact with women. We therefore involved 20 final year medical students based in health districts

and conducted part of the home visits. This raises ethical concerns as these people were not directly involved in the management of the women at the fistula repair hospital. To address this issue, we first submitted an amendment to the study protocol to the Guinean national ethics committee for health research (Ref#10/CNERS/14 bis dated 28 December 2015) and the Ethics Committee of the University of Antwerp (Ref#14/22/238 bis dated 18 December 2015). In addition, we provided a five-day protocol training to the medical student before they depart to their respective health districts.

During the informed consent process in Study V, local languages were needed (e.g. for illiterate women) and an impartial witness was required when a participant was less than 18. The consent form was either signed or thumb print affixed by each the participant.

4.7 Methodological considerations

Studies within this doctoral research have used quantitative methods with different designs that brought some methodological concerns.

4.7.1 Retrospective cohorts

There are several limitations to retrospective cohort studies that include the poor quality of data if the record keeping was deteriorated in some ways, the absence of data on potential confounding factors due to retrospective recording of data, and differential losses to follow (99). In retrospective cohort studies, because the data has already been collected prior to the study conduct, it might be incomplete, inaccurate, or inconsistently measured between study participants (98). In Studies I, II and III, we could not explore the reasons for loss to follow. Fistula status (closure or continence) was unknown for women who did not return for follow-up. In the three studies, we could not evaluate some qualitative aspects of women's life such as their mental health status and their reproductive health intentions along with their health seeking behaviors.

Finally, even though data were extracted using standardized forms and trained data collectors, most of whom were unaffiliated with the facilities, there was the possibility of data collection errors because due to the use of routine data. In addition, some limitations related to the statistical analyses performed and the risks of bias such as selection bias and information bias (misclassification of outcomes or exposures) cannot be excluded (see section 6.8 on strengths and weaknesses of the study designs). However,

these limitations were attenuated using large sample sizes at repair hospitals were capacity building in data recording and review along with regular monitoring and supervision were routinely carried out. In addition, we reported our results using the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines (110).

4.7.2 Longitudinal studies

Among limitations to prospective cohort studies are loss-to-follow-up (attrition bias) and the inability to control for all confounding factors (99). Attrition bias might reduce the internal validity of the study (98). Added to these limitations are the need for a large sample size and a long follow-up period and the risks of selection bias (98). In Study V, follow-up time was short for some women who got in 2015 and part of the sample was included retrospectively which could have introduced recall bias. In addition, the circumstances of fistula recurrence relied on women self-reporting the date of onset of severe urinary or fecal incontinence symptoms and preceding activity. Furthermore, we could not collect qualitative data that could provide useful information on behaviors and experiences of women post-repair, and the possibility of data collection errors cannot be excluded. Finally, as mentioned above, the risks of bias such as selection bias and information bias (misclassification of outcomes or exposures) are associated with the epidemiological nature of the design (see section 6.8 on strengths and weaknesses of the study designs).

However, apart from women who died during follow-up (eight women), all women who consented to participate in the study were followed-up.

4.7.3 Lack of qualitative data to capture women and stakeholders' perspectives

One limitation of this thesis is the lack of qualitative data that would have provided a better understanding of the complex issue of the health and care of women after during and after repair of their fistula. It was initially planned to have a qualitative component of a mixed-methods study that would explore the mental health and the quality of life of women before and after fistula surgery as part of this thesis. However, as the work progressed, we understood that this component would be part of post-doctoral research. In effect, we have conducted a first qualitative study with key fistula stakeholders in Guinea to develop an intervention to address women's vulnerability after fistula repair.

Unfortunately, we could not include the findings in this thesis as the data analysis was still underway when we completed the thesis. Qualitative information from the perspective women and other key fistula stakeholders might have contributed to derive more holistic and context specific recommendations (111) useful to develop appropriate strategies (112). In fact, qualitative studies allow in-depth investigation of complex phenomena with a limited number of participants and triangulation with quantitative data. They provide a detailed insight into contextual factors and can generate findings that were not anticipated by the researcher (112;113). The iterative approach used in qualitative research allows flexibility in the research process and can be adapted to setting and participants as the study is conducted and information is generated (111-113). Even though the findings of qualitative research are not usually generalizable to other settings or participants, they can be transferrable to other settings through careful consideration of the contextual information that they provide (113).

4.7.4 Generalizability and transferability

Most studies within this thesis were conducted in Guinea. However, they used large sample sizes. Thus, since the findings might be applicable to other fistula care and management programs in developing countries, the lessons learnt might be applicable in other settings (99). The external validity of Study IV is strengthened because of its focus on sub-Saharan Africa.

4.7.5 Role of the doctoral candidate in the conduct of the research

I personally developed the initial thesis proposal while working with EngenderHealth between 2012 and 2013 as Regional Study Coordinator in the Fistula Care Project for Guinea, Niger, DR Congo and Sierra Leone. I initiated the protocols of all thesis related studies and followed-up to secure ethics approvals in Belgium and Guinea. I was responsible for the overall planning and conduct of the field work including data collection. I analyzed the data for all the thesis related papers and drafted the papers and the abstracts that were submitted to conferences. I followed-up with thesis promoters to finalize the papers and oversaw the publication process including submission to journals, dealing with reviewers' comments and correcting the proofs.

CHAPTER 5. RESULTS

5.1 Overview of thesis findings

The results section is composed of five papers published in peer-reviewed journals, one published protocol and one research manuscript. The first three papers analyzed the outcomes of current fistula management programs in Guinea. The following two papers and the published protocol explored the long-term health outcomes in women fistula repair, including fistula recurrence, pregnancy and childbirth status and outcomes. The last manuscript (research report) developed strategies to improve the health of women after fistula surgery in Guinea (Table 4).

Table 4. Overview of thesis findings in relation to study objective

Thesis specific objective	Study	Study objective	Study findings
To conduct a situational analysis of fistula management programs in Guinea	I	To analyze the clinical outcomes of fistula care programs in Guinea	Analyzing routine program data can provide estimate of fistula care programs' performance. Integrating fistula repair services into maternities in Guinea yielded good outcomes. Fistula closure was high after surgery, at hospital discharge and at 3 months follow-up visit (ranging from 83% to 85%). Continence status varied from 79% to 80% between surgery and 3 months follow-up visit. Residual incontinence despite fistula closure remained low at 5%.
	II	To analyze the trend and factors associated with loss to follow-up after surgical repair of obstetric fistula in Guinea	Almost one out five women was lost to follow-up at 3 months post-repair. Loss to follow-up varied across repair hospitals and over time with an increase from 2% in 2009 to 52% in 2013. Reimbursement of transportation costs and reduction of geographical barriers to care were the main factors influencing loss to follow-up at 3 months post-repair.
	III	To estimate the overall proportions of failure of fistula closure and incontinence among women undergoing repair for obstetric fistula in Guinea and	14.5 % of repairs were unsuccessful and 17.5 % of women were not continent at the time of hospital discharge. Women who delivered vaginally, had a partially or totally damaged urethra or who got surgery at Jean Paul II Hospital were more likely to experience the failure of fistula closure. Post-repair urinary incontinence was more likely to occur in women who had a partially or a totally

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		identify its associated factors	damaged urethra. These women should benefit more caution during repair.
To analyze the reproductive health outcomes in women after female genital fistula surgery in Guinea	IV	To synthesize the evidence on pregnancy and childbirth after repair of obstetric fistula in sub-Saharan Africa and to identify the existing knowledge gaps.	Women who get pregnant after repair of obstetric fistula in sub-Saharan Africa were found to carry a high risk of maternal and neonatal health outcomes. for pregnancy complications. Despite the existing desire to become pregnant, the overall proportion of pregnancies was only 17.4%. More than half of women who delivered (55%) did it by emergency CS or vaginally with greater risks of fistula recurrence and stillbirth. The existing evidence was insufficient to provide precise estimates of the outcomes.
	V	To analyze the incidence of fistula recurrence, residual urinary incontinence, and pregnancy after successful fistula closure in Guinea, and describe the delivery-associated maternal and child health outcomes.	In 481 women eligible, 73 recurrent fistulas occurred (18.4%) and 24 cases of post-repair residual urinary incontinence were recorded (10.3%). In 305 women at risk of pregnancy, 28.4% became pregnant and of them, 50 delivered mostly by emergency C-section or vaginally (82%), resulting in 12 stillbirths (24%), seven delivery-related fistula recurrences (14%), and one maternal death. Women were still at high risk of fistula recurrence and adverse pregnancy-related maternal and child health outcomes after fistula repair in Guinea.

5.2 Situational analysis of Fistula Care Programs in Guinea

5.2.1 Clinical outcomes in routine programmatic repair

5.2.1.1 Profile of women undergoing fistula repair

Overall 2116 women who got fistula repair between 2007 and 2013 in the three study repair hospitals were included in the analyses. Most women were of reproductive age (median age at presentation of 32 years, interquartile range (IQR) 25-40) had a vesico-vaginal fistula (n=2045, 97%) and their pregnancy leading to fistula formation often ended in stillbirth (n=1978, 93%).

5.2.1.2 Fistula treatment outcomes

Surgery achieved good clinical outcomes across years at the time of hospital discharge (Figure 6) and at three months follow-up visit (Figure 7). The proportion of overall fistula closure was 85% among 2116 women at the time of hospital discharge and that of fistula continence was 79%, leaving only 6% of women with residual incontinence despite fistula closure. At three months post-repair follow up, 84.5% of the 1663 women who returned had a closed fistula and 80% were continent (dry).

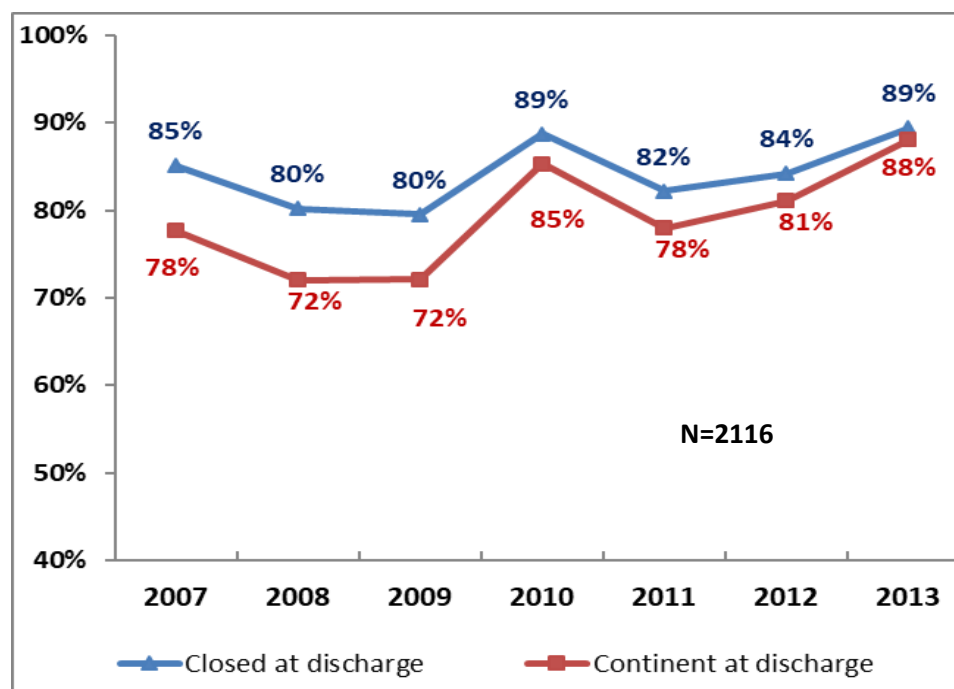


Figure 6. Annual trend in treatment outcomes at hospital discharge in women undergoing surgical repair for fistula in Guinea, 2007 to 2013.

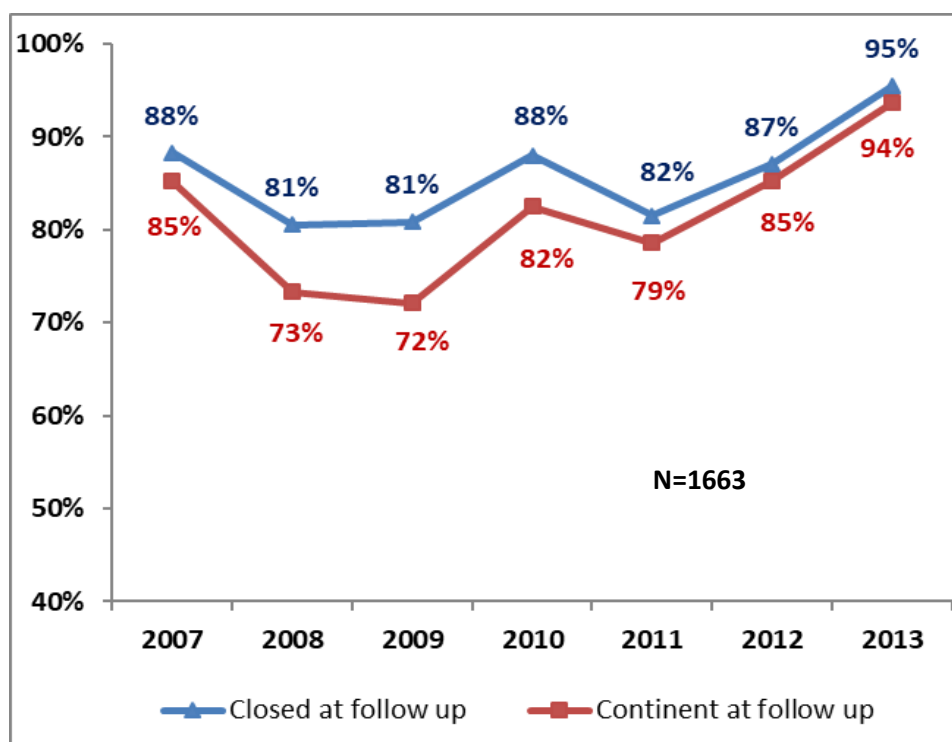


Figure 7. Annual trend in treatment outcomes at 3 months of follow up for women undergoing surgical repair for fistula in Guinea, 2007 to 2013.

At hospital discharge, all women with a recto-vaginal fistula (RVF) had a closed fistula and remained dry. Among those with vesico-vaginal fistula, 80% had a closed fistula and were dry while 5% had a closed fistula with residual incontinence. Among those with both a VVF and an RVF 56% were closed and dry and 2% were closed but had residual incontinence.

Closure and continence rates increased over time at hospital discharge (Figure 6) and at three-months post hospital discharge (Figure 7). In addition, better surgical outcomes were recorded in women with no history of previous repair attempts, those who had their fistula fewer than five years and women with recto-vaginal fistula as compared with women who had not these characteristics. It is to note that the proportion of women who were lost to follow-up increased over time (which represents a selection bias and may lead in this case to an overestimation of the closed or continent fistula status, as women who find themselves in a better status may be more likely to come back at three months).

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First repaired fistula represented 57% of the sample (Table 5). Of them, 87% achieved closure at the time of hospital discharge (85% for all fistula). Of the 1067 fistula that were closed at hospital discharge, 96% achieved continence.

Table 5. Fistula closure and continence status by type, number of previous repair attempts and duration of fistula for women undergoing surgical repair for obstetric fistula at hospital discharge in Guinea, 2007 to 2013.

Selected variables	Surgical outcome				P*
	Fistula closed			Fistula status unknown	
	Dry	Residual incontinence	Fistula not closed		
Type of fistula (n=2116)					
VVF	1630(79.7)	114(5.6)	297(14.5)	4(0.2)	< 0.001
RVF	23(100.0)	0(0.0)	0(0.0)	0(0.0)	
VVF & RVF	27(56.3)	1(2.0)	20(41.7)	0(0.0)	
Previous repair attempts (n=2076)					
No previous repair attempt	1019(83.6)	48(3.8)	153(12.5)	1(0.1)	0.001
≥1 previous repair attempt	634(74.0)	67(7.8)	153(17.9)	3(0.3)	
Duration of fistula (1870)					
≤ 1 year	350(86.4)	13 (3.2)	41 (10.1)	1 (0.2)	0.003
2 to 4 years	371(82.8)	23 (5.1)	54 (12.1)	0 (0.0)	
≥ 5 years	777(76.4)	72 (7.1)	167 (16.4)	1 (0.1)	

* Comparing proportions of closed fistula

5.2.2 Why women do not attend three months follow-up visits?

5.2.2.1 Loss to follow-up

Between 1 January 2007 and 30 September 2013, 448 women out of 2080 who got fistula surgery in EngenderHealth supported repair hospitals did not attend the three months follow-up visit despite been asked to do so. The proportion of loss to follow-up varied across repair hospitals and over time, i.e. lower in 2009 (2%) but higher in 2013 (52%), Figure 8.

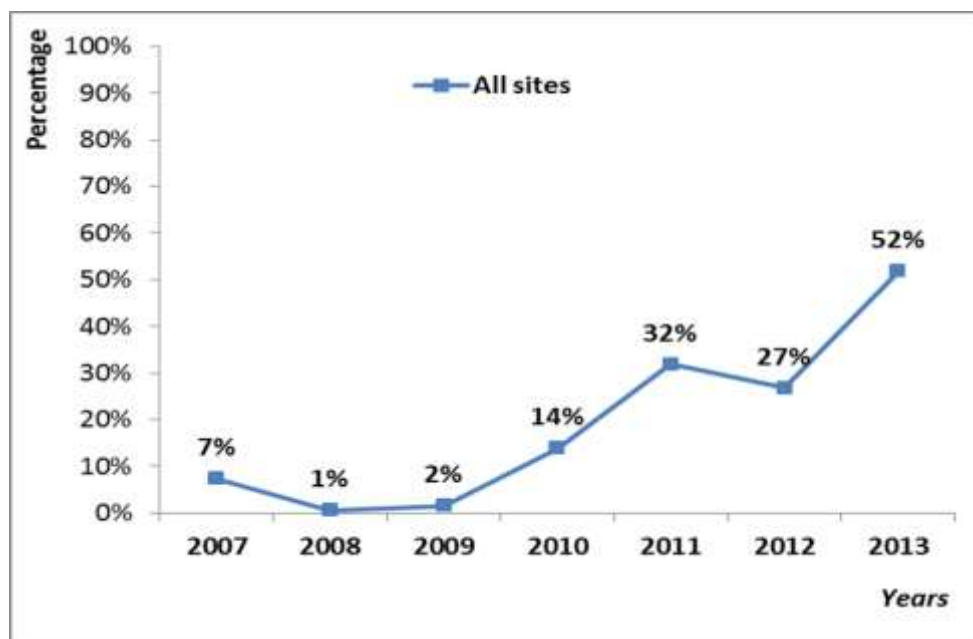


Figure 8. Annual trend in the proportions of loss to follow up among women undergoing surgical repair for obstetric fistula in three repair hospitals in Guinea, 2007 to 2013

Half of the repairs were done at Kissidougou hospital (52%). Included women (n=2080) had a mean age of 34 years, (Standard deviation of 12 years), were married or in union (n=1413, 69%), were illiterate (1865, 94%) presented with vesico-vaginal fistula (2011, 98%) and had experienced child loss (95% stillbirth).

5.2.2.2 Factors associated with loss to follow-up

After conducting multivariable analyses, the factors that remained statistically significantly associated with loss to follow-up at three months post-repair included the repair hospital, the continence status at discharge, the year of surgery and the distance between the repair hospital and a woman's current residence. Women who got surgery at Labé hospital and at Kissidougou hospital were respectively 51 times and 12 times as likely to be LTFU as women operated at Jean Paul II hospital. The odds of LTFU was three times as high among women having their fistula closed at hospital discharge than women with a fistula not closed. Women admitted in 2011 were three times as likely to be LTFU as women admitted in 2010. Similarly, those admitted 2012 and 2013 were respectively two times and five times as likely to be LTFU as women admitted in 2010. Finally, the more a woman's current residence was far from the repair hospital, the more likely she was LTFU.

5.2.3 What makes a fistula surgery unsuccessful in Guinea?

This study included the records of 754 women who underwent surgical repair for female genital fistula at the three EngenderHealth supported repair hospitals between 1 January 2012 and 31 October 2013. The three hospitals had similar pre- and post-repair procedures with high coverage of post-operative antibiotic treatment (from 96 to 100%). Jean Paul II Hospital in Conakry received more complicated cases as compared to other repair hospitals.

Included women had a mean age of 35.2 years (Standard deviation of 12.7 years). Most women were married (n=523, 69.4%) with no formal education (691, 91.6%) and lived in rural areas (677, 89.8%). Most of them delivered vaginally (n=489, 64.9%) had 91% stillbirths for the referent pregnancy.

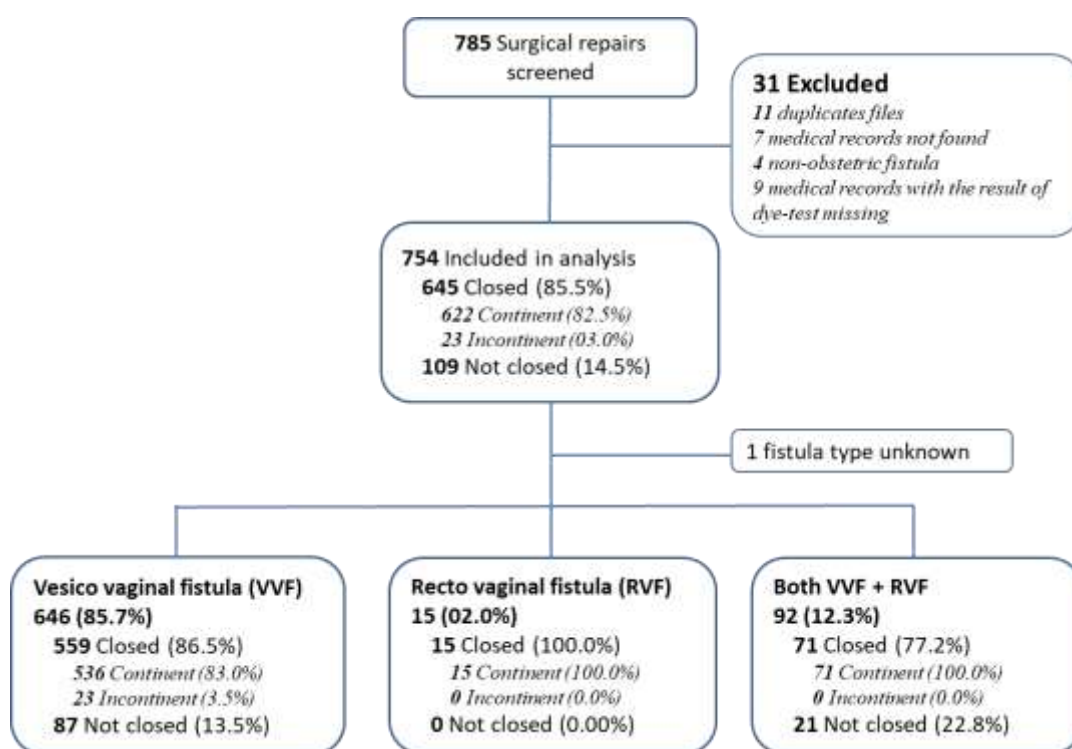


Figure 9. Patient flow and surgical repair outcomes by type of fistula at hospital discharge in three fistula repair hospitals in Guinea, 2012 to 2013

About 15% of the 754 included women had unsuccessful repairs at discharge and 3% residual incontinence despite a closure of their fistula (Figure 9). All women with rectovaginal fistula (RVF) had successful repairs and were continent of stools while

respectively 14% of women with vesico-vaginal fistula (VVF) and 23% of those with both VVF and RVF had unsuccessful repairs (Figure 9).

The mode of causative delivery, the status of the urethra and repair hospital were the factors independently associated with the failure of fistula closure. Women who delivered vaginally were two times as likely to continue leaking after surgery compared to women who delivered by C-section. Those with a partially damaged urethra or totally damaged urethra were respectively two times and six times as likely to continue leaking after surgery compared to women with a urethra not damaged. As for residual incontinence despite fistula closure, women who had a partially damaged urethra or a totally damaged urethra were respectively about three times and six times as likely to experience post-repair urinary incontinence compared to women who had their urethra not damaged.

5.3. Women's health after obstetric fistula repair in guinea

5.3.1 Evidence synthesis on pregnancy and childbirth post-repair

Of the 2746 studies identified through initial searches and other sources, 16 studies were found eligible and were included in the qualitative synthesis (Figure 10).

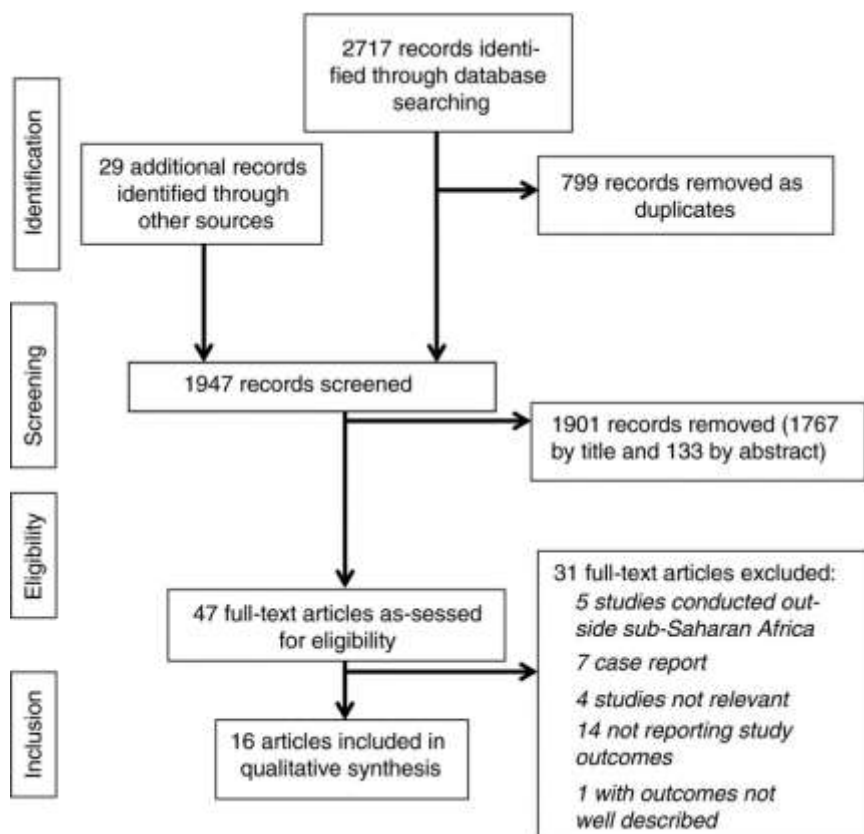


Figure 10. PRISMA flow chart of the studies selection process

Studies were conducted in only seven sub-Saharan African countries (Nigeria, Ethiopia Malawi, Niger, Mali, Sierra Leone and Eritrea), most were conducted at referral hospitals (10 out of 16) and used cohort design (12 out of 16). Included studies presented several variations in terms of sample size, length of follow-up and outcomes assessed. For instance, 12 over 16 studies reported on the mode of delivery and neonatal outcomes and nine over 16 documented maternal complications during pregnancy and at delivery.

The proportion of pregnancy post-repair was estimated in 11 studies at 17.4% (range 2.5–40%) and that of abortion was 5.4%. Overall, 465 term pregnancies resulted in 463

deliveries with two reported maternal deaths. 45% of delivery were by elective cesarean section, 39% by emergency cesarean section and the remaining 16% by vaginal delivery.

Recurrence of the fistula (23/463 deliveries; 5%), maternal death (1%) were the most common maternal complications noted across studies. Neonatal outcomes included stillbirth (8%) overall. However, there were significantly more stillbirths recorded in women who delivered vaginally (21%) as compared to women who delivered by emergency (7%) or elective (3%) cesarean section (CS).

Vaginal delivery and emergency CS were identified as factors increasing the risk of recurrence of a fistula post-repair. Only one study reported that early resumption of sexual activity (within 3 months post-repair) was associated with the recurrence of fistula.

Because of methodological limitations associated with most of the included studies, the evidence generated by this review could not provide a precise estimates of maternal and child outcomes thus confirming the need for more research.

5.3.2 Registering observational studies in public registries

Currently, most studies conducted in humans are observational rather than experimental (114). Observational studies are in nature prone to publication and reporting bias. According to the 2013 revision of the Declaration of Helsinki, any type of research study involving humans requires registration, especially for studies assessing long-term outcomes (114). However, registration of observational studies remains low (115).

To ensured transparency in my research, mitigate publication bias and avoid duplication, I registered the protocol of my longitudinal study on a public registry (ClinicalTrials.gov Identifier: NCT02686957) and published it in a peer-reviewed journal.

5.3.3 Recurrence of fistula, pregnancy and childbirth post-repair

Overall 682 women were eligible for inclusion in the study. However, although women had their fistula repaired in three repair hospitals, they were scattered throughout the country (Figure 11).



Figure 11. Distribution across the country of eligible women (n=682), 2012 to 2016, Guinea.

481 out of the 682 eligible women (70%) could be located and consented to inclusion in the analysis for the primary outcome (fistula recurrence).

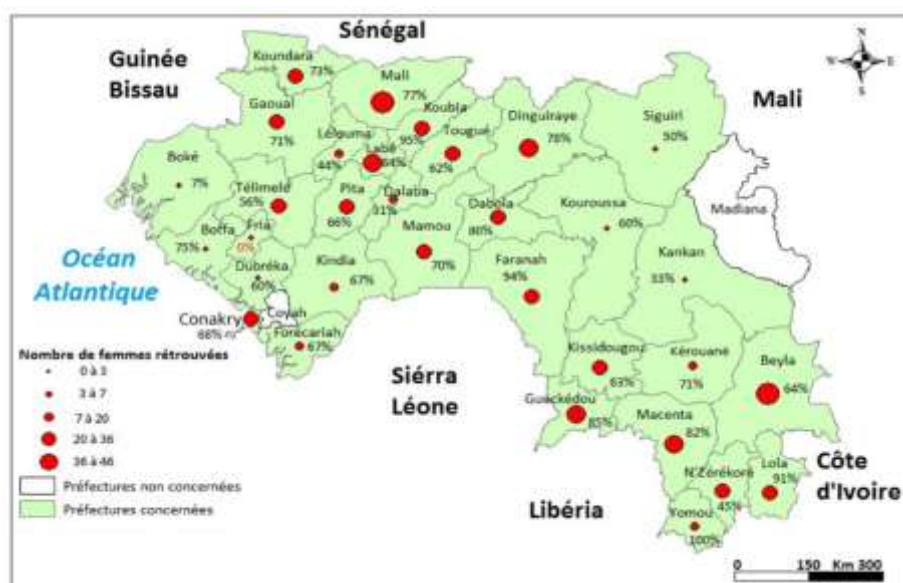


Figure 12. Distribution across the country women included in the study (n=481), 2012 to 2016, Guinea.

Of these women, 305 (75%) of reproductive age reported being sexually active after surgery and were considered in the pregnancy-related analyses. As for eligible women, those women included originated from across the country (Figure 12). While other characteristics were similar between eligible study participants who participated in the study and those who did not participate, those women who participated in the study had experienced more stillbirths during the delivery leading to the fistula than had eligible women not participating in the study.

Some sociodemographic characteristics of women included in the study had changed at the time of follow-up as compared to the time of surgery. For instance, the proportion of women reporting urban residence had doubled and that of women reporting an occupation other than housewife had increased (Table 6)

Table 6. Comparison between selected demographic characteristics of study participants at surgery and at follow-up, 2012 to 2016 in Guinea (n=481).

Variables	At hospital at surgery Number (%)	At follow-up visit Number (%)	P-value ^c
Number	481	481	
Residence			<0.001
Rural	449 (93.4)	419 (87.1)	
Urban	30 (6.2)	62 (12.9)	
Unknown	2 (0.4)	0	
Marital status			0.370
Married/Union	339 (70.5)	360 (74.8)	
Other ^a	133 (27.6)	121 (25.2)	
Unknown	9 (1.9)	0	
Occupation			<0.001
Housewife	445 (92.5)	311 (64.7)	
Other occupation ^b	29 (6.0)	170 (35.3)	
Unknown	7 (1.5)	0	

^aSingle, widow or divorced/separated. ^bOffice worker, farming, market vendor or student. ^cP-value was derived after excluding "Unknown" values.

After a median follow-up of 28.0 months (Interquartile range 14.6–36.6), we recorded 73 recurrent fistulas among 481 women, corresponding to 18.4% (95% Confidence intervals: 14.8–22.8). In 447 women who were continent at hospital discharge, we recorded 24 cases of post-repair residual urinary incontinence, corresponding to 10.3% (95% CI 5.2–19.6).

In 305 women at risk of pregnancy, we recorded 67

first pregnancies, corresponding to 28.4% (22.8–35.0) of these women. Of 50 women who had delivered by the time of follow-up, 82% did not deliver by elective caesarean section resulting in 12 stillbirths (24%), seven delivery-related fistula recurrences (14%), and one maternal death (Figure 13). Among nine women who delivered by elective C-section, no maternal and neonatal adverse outcome was recorded.

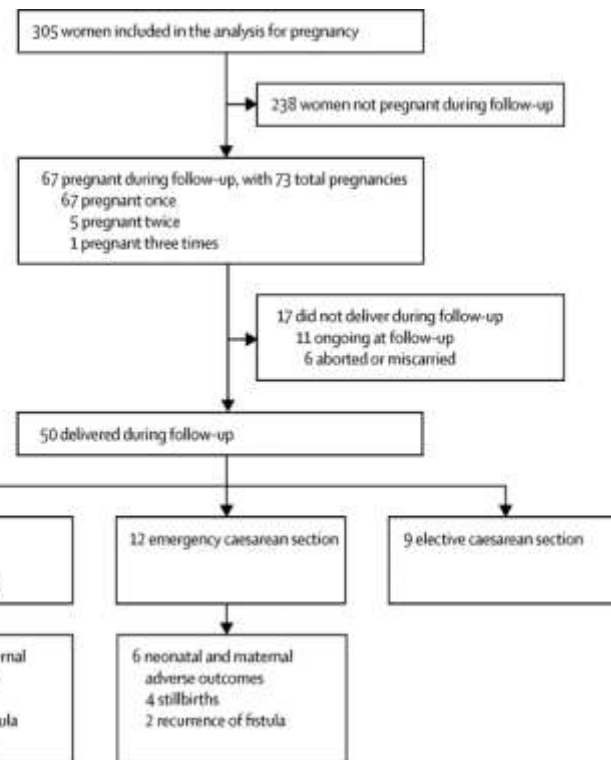


Figure 14. Post-repair pregnancy and delivery outcomes among sexually active study participants of reproductive age

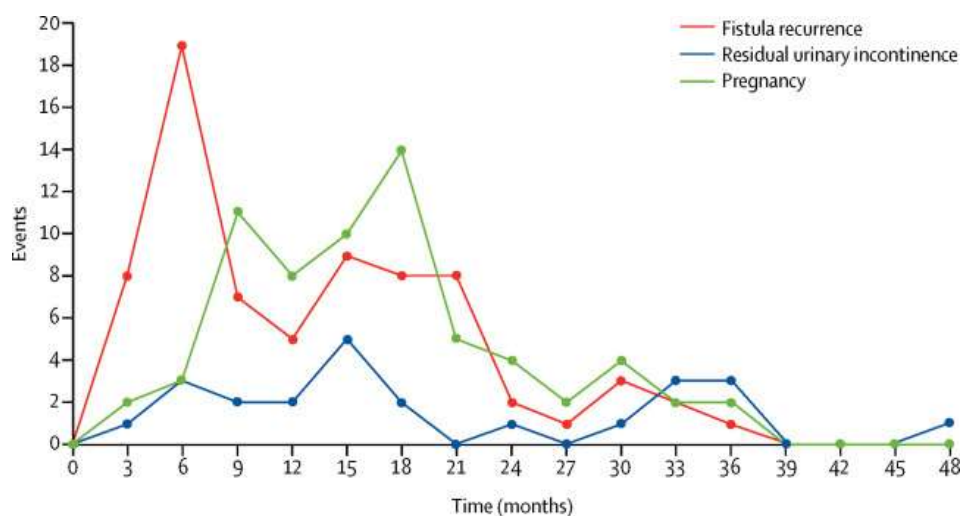


Figure 13. Incidence of fistula recurrence (n=73), first post-repair pregnancy (n=67), and residual urinary incontinence (n=24) over time in study participants

More than half of the fistula recurrences occurred during the first 12 months after discharge and 37% were during the first 6 months. For first post-repair pregnancies, 48 out of 67 (72%) occurred within the first 18 months, and 57 (85%) within the first 24 months following hospital discharge. As for residual urinary incontinence, eight (33%) occurred during the first 12 months after discharge.

The study found that fistula recurrence was associated with sexual activity, status of the urethra, bladder neck at fistula surgery and vaginal scarring. Women who were not sexually active were three times as likely to resume leaking after surgery compared to women who were sexually active. Women with urethral involvement in the fistula at the time of surgery were about three times as likely to resume leaking after surgery compared to women who had no urethral involvement. Those women who had a damaged bladder neck or vaginal scarring were about two times as likely to resume leaking after surgery compared to women who had a normal bladder neck or had no vaginal scarring.

Among the 50 women who delivered their first pregnancy post repair, 76% achieved the first antenatal visit but less than half (46%) completed three or more antenatal care visits as recommended in Guinea. In addition, women who became pregnant within the first six months post discharge were more likely to experience stillbirth at delivery compared to women who became pregnant at least six months after their fistula repair ($p=0.0470$). Furthermore, all women with incontinence at follow-up were continent at hospital discharge (100%), reporting the incontinence to have occurred mainly after the vaginal delivery (5 women; 50%) or emergency C-section (2 women; 20%) of their first post-repair pregnancy or from an unknown origin (30%) (Unpublished data).

5.4. Dissemination of research findings in Guinea

Researchers are more and more encouraged to disseminate their research findings to enhance the uptake of knowledge gained into routine practice and/or policy (116).

The findings of this thesis were disseminated with OF key stakeholders in Guinea through a series of three interactive one-day dissemination workshops conducted in Conakry (21 December 2017), Labé (27 December 2017) and Kissidougou (30 December 2017). Each dissemination workshop gathered stakeholders from the locality. Overall, 106 participants attended the three dissemination workshops including 28 in Conakry, 45 in Labé and 33 in Kissidougou. Participants were policy makers (05), health services managers (03), representatives of NGOs and funding bodies (09), health care workers at health post, health center and hospital levels (47), women treated for fistula (06), community leaders (20), media representatives (03) and schools' managers (03).

Each interactive dissemination workshop consisted of a presentation of the main research findings followed by questions (2 hours), testimonies by women who participated in the longitudinal study (1 hours), group work (followed by a plenary) on the key results and how to use the results to improve practice and inform policy making (2 hours). In addition, a poster session displaying all the six studies was organized during breaks and 200 copies of a leaflet summarizing studies in accessible language was printed and distributed during the workshops or sent to additional stakeholders. Furthermore, two radio programs were recorded and broadcast in local languages in Labé and Kissidougou to ensure key messages are spread within the community.

These workshops provided venue for enriching and refining the thesis main conclusions and recommendations.

5.5. Challenges encountered during the conduct of the thesis

In its nature, a sandwich PhD is challenging as it requires from the student to travel between place and manage a changing agenda of thesis supervisors. The conduct of this thesis work faced several challenges that required patience, flexibility, commitment and sense or organization to achieve the project within the planned timeframe.

5.5.1 Conducting research at the time of Ebola

As already mentioned, the thesis was conducted entirely in the context of the context of the 2014/2016 Ebola virus disease outbreak in Guinea and West Africa (86). This required us to implement a follow-up at community level instead of a hospital-based follow-up to deal with the EVD related mistrust and reluctance towards health care workers and health structures (70;117-119). Flexibility in the field research agenda and adaptability to a changing security context were key to the success of data collection.

5.5.2 Conducting multiple studies as part of the thesis

As part of this thesis, we conducted five studies that required the development of separate protocols from study I to Study V. Four out of the five protocols developed required ethical approvals. Because this was a sandwich PhD Program, we had to seek ethics approval from three institutions including two in Belgium (ITM IRB and the Ethics Committee of the University of Antwerp) and one in Guinea (the Guinean National Ethics Committee for Health Research). This implied a cumbersome and stressful paperwork before securing an approval in a timely manner to start data collection for each of the studies. For each study, we had to plan and conduct/supervise data collection, identify and train additional data collectors, deal with administrative issues (information of research sites, obtaining of travel authorizations, logistics, etc.) and data management issues (quality control and queries generation and resolving, data transfer, data analysis and archiving, etc). Moreover, all this work was conducted in the context of the EVD outbreak and with limited funding.

5.5.3 Implementing a follow up at community level

Implementing a follow-up of study participants at community level follow-up in an insecure Ebola-related context was challenging for the whole research team. The longitudinal study was conducted with women treated in three fistula repair hospital but who originated from the whole country (Figure 11 and 12). We had to locate them and seek informed consent at home and then plan additional home visits as part of their follow-up. This was challenging as Guinea has two mountainous natural regions (Forest and Middle Guinea) that have hard to reach areas, especially during the rainy season. About 60% of USAID funded fistula repairs in Guinea from the three research hospitals between 2012 and 2015 originated from health districts located in these two natural regions

(120). Tracing women from these two regions increased our research costs and put our field staff at risk. In 2015, one of our data collectors in Mamou health district had a car accident that resulted in a double fracture of the tibia and required surgery and a nine months convalescence period.

Other times, women mentioned the name of their village, but we found later that there were two or three villages with the same name in the same health district, making the search more complex than initially expected.

5.5.4 Data quality

In addition to all the limitations and risks of bias reported in this thesis, we faced additional challenges related to the quality of research data. This had to do with data quality for our retrospective cohorts. For instance, the quality of medical records kept at repair hospitals was and the completeness of information to identify and trace eligible women. For instance, despite investment from EngenderHealth to ensure good record keeping in repair hospitals, the quality of the data was not necessarily guaranteed. Some medical records were missing, or some data were missing in medical records. In addition, there were many duplicate medical records when we triangulated information from the three repair hospitals, i.e. two or three medical records located at different hospitals but belonging to the same woman. Sometimes, women had voluntarily changed their given names (or shortened them or used their nick names) making it difficult to trace them in the community.

CHAPTER 6. DISCUSSION

This thesis has investigated the surgical management of obstetric fistula and the long-term health outcomes of women after OF surgery in Guinea. Our discussion is built around several topics from primary prevention of Obstetric to provision of medical care and support for women's social and economic reintegration.

6.1 Are existing obstetric fistula repair programs really achieving good clinical outcomes?

The findings of our thesis raise the question of whether performance of current female genital fistula management programs should be assessed using short term versus long term indicators. The World Health Organization expects fistula repair hospitals to achieve a successful fistula closure rate of 85% for first repair, with continence achievement at 90% among the closed cases (1). In Study I, almost 85% of all repaired fistulas were closed at hospital discharge including 87% of first repaired fistulas which is in line with WHO expectations and quite satisfactory (121). However, Study V revealed alarming proportions of fistula recurrence (18%) and residual urinary incontinence (10%) in two years following repair (120). Therefore, one could fairly estimate the overall failure of closure rate at 33% over two years (15% at hospital discharge + 18% at two years post hospital discharge) and the proportion with residual incontinence at 15% (5% at hospital discharge + 10% at two years post hospital discharge). Using these estimates, the performance of current fistula repair programs at two years post repair in Guinea would roughly be estimated at 62% closed and continent, 15% closed with residual incontinence, and 33% not closed. Taking the long-term perspective, it is clear that the outcomes achieved after by surgery could not be maintained over time. Study I also showed that the loss to follow-up at three months increased over time which questions the actual fistula status results at three months. Study II showed that the loss to follow-up at three months increased over time which questions the actual fistula status results at three months.

Unfortunately, adopting a broader perspective on outcomes of fistula repair is challenged by a lack of attention to women's quality of life and health conditions after repair, despite our findings emphasizing the importance of care provision for women beyond surgery (61;122-124). Most services currently offered are facility-based, limited in time, and not sustained once the woman leaves the repair hospital. These services include sexual and

reproductive health counselling at discharge, psychological counselling, skill empowerment, literacy classes or support groups (57;58;60;125). For instance, in Uganda (126) an ongoing intervention includes health education, physical rehabilitation to strengthen pelvic floor musculature, psychological therapy to address depression, anxiety and traumatic stress and economic empowerment by linking women with existing programs. However, in Uganda, almost all the intervention activities are delivered at the fistula care site where women stay for at least 14 days post-surgery and progress is evaluated at 3-months post fistula repair.

In Guinea, physical therapy is part of the routine care provided to women in repair hospitals. However, providing these services after hospital discharge is challenging. This suggests the need for an intervention that goes beyond repair and hospital stay to address challenges such as family and community perceptions or behaviors, geographical barriers, transportation costs, and addresses the absence of supportive priorities or resources in many fistula programs (28;127-129).

6.2 Specialized versus decentralized care for obstetric fistula

In the current strategic plan for the prevention and management of obstetric fistula (2016-2020), the Ministry of Health (MoH) of Guinea has envisioned the integration of fistula management units into all eight regional hospitals across the country to reduce geographical barriers to access care for women suffering from fistula, including reduction of the existing backlog of cases (66). The decision to decentralize fistula care in Guinea was probably inspired by similar experiences from fistula programs in other countries and HIV programs in Africa that recorded increased antiretroviral treatment enrollment, decreased travel distance, and increased retention in care after decentralization (130).

Given the current funding mechanisms for these services whereby the country mainly relies on external funding to provide fistula care, this raises the question whether a decentralized approach (versus specialized care) is relevant and adequate in the current Guinean context. Decentralization of fistula care began in 2018 with two fistula units opened within the maternity units of the regional hospitals of Boke and Nzerekore. To maintain quality of care and program performance, there is a need to invest in the continued training of staff at the new fistula repair units (surgeons, nurses, anesthetists, counsellors) while ensuring that the existing repair hospitals maintain and improve their standards. Close monitoring and evaluation of these two decentralized sites is needed to

decide the best way forward. At present there is no available evidence regarding the respective merits of special OF clinics versus decentralized care. This organizational issue could presumably be best addressed by a cluster randomized trial.

6.3 The role of clinical predictors in the occurrence of fistula repair outcomes and post-repair adverse events

The rates of fistula closure and continence usually depend on several factors that include the severity of the fistula, the repair surgeon's skills and the quality of pre, intra and post-surgery care (46-51). In Guinea, EngenderHealth provided continuous training to fistula surgeons to increase their skills and expertise while building the capacities of nurses, midwives and anesthetists in the provision of quality fistula care from women's arrival for fistula related care to their surgical discharge (63). In addition, the EngenderHealth supported hospitals followed the same clinical procedures for the management of obstetric fistula including infection prevention and control. Furthermore, quarterly supervision of providers by project's technical advisors offered a venue to discuss challenges, provide support and improve quality.

6.3.1 Clinical characteristics of the fistula

Our work has identified certain clinical characteristics which played a crucial role in the occurrence of our outcomes of interest. Study III showed that women with a partially or totally damaged urethra were more likely to experience surgical repair failure compared to women whose urethra was not damaged. This is consistent with prior studies which have identified urethral involvement as an indicator of fistula severity and repair complexity because it affects sphincter mechanisms functionality and bladder size, making the repair of the fistula difficult and increasing risk of repair failure (50;74;131;132). This implies that women who present with a damaged urethra at fistula repair hospitals need careful attention and require a highly skilled surgeon because they are more difficult to treat than others. Also, when fistula surgery is unsuccessful, any subsequent surgery is more likely to fail. Therefore, this attention should extend beyond surgery to ensure that women are not exposed to conditions that could lead to a repair breakdown in the post-repair period. In fact, Study V revealed that recurrence was significantly higher in women who had a damaged urethra or bladder neck, and who presented vaginal scarring at time of fistula surgery. As previously mentioned, studies conducted in the African context have implicated vaginal scarring and status of bladder

neck in the occurrence of repair breakdown and emphasized the fact that peri-urethral fistulas are more delicate to repair and more likely to break down than are higher fistulas (50;133). Therefore, it is possible that differences observed in other African contexts could be related to over representation of women with 'higher-risky' fistula characteristics than those in our sample. For instance, in Study V, four out of 10 women had a damaged urethra or damage bladder neck at the time of fistula surgery and six out of 10 women had vaginal scarring. In addition, some characteristics such as vaginal scarring might encumber sexual intercourse after fistula repair, thereby limiting women's fertility post-repair (31).

6.3.2 The association between repair hospitals, skills of the fistula surgeon and fistula repair outcomes

Because the three study repair hospitals were part of the same project, with the same short trainings, clinical procedures, equipment and surgical trainers, the differences in surgical outcomes observed across hospitals in Guinea might relate to differing skill levels among surgeons or to the level of complexity of the repaired fistula. For instance, more 'complex' fistulas (e.g., with vaginal scarring, partially or totally damaged bladder neck and urethra) were repaired in Jean Paul II hospital in Conakry as compared to the two other hospitals because this hospital was considered a referral hospital due to its proximity to surgical fistula trainers. We also observed in this research that the UNFPA supported Kankan regional hospital had a lower proportion of surgical failure at hospital discharge as compared to repair hospitals supported by EngenderHealth (Unpublished data). The reason was that more simple cases of fistula were repaired in UNFPA Kankan hospital in comparison to EngenderHealth supported ones, suggesting the differential selection of women due to the level of expertise of fistula surgeons.

6.3.3 The quality of the care provided to women

We also found that the occurrence of postoperative complications was significantly higher in the UNFPA supported Kankan hospital compared to EngenderHealth supported hospitals (Unpublished data). These results point out differences in the two fistula management approaches (UNFPA versus EngenderHealth). While EngenderHealth had staff dedicated to its programs with regular onsite trainings and monitoring visits, including on infection prevention measures, the UNFPA approach consisted of subcontracting with repair hospitals without direct involvement in the provision of care. This suggests that the quality of surgery, the skills and training of nursing staff along with

the level of implementation of infection prevention and control measures and pre/post-operative protocols might have been different between the two types of repair hospitals.

6.3.4 The need for a “level of care” approach in fistula surgery

Our findings have important implications for current and future fistula management programs. In fact, up to now, when facing a case, fistula surgeons have mainly relied on their own assessment of their skills and their consciousness to decide whether they will attempt to perform surgery or refer to another surgeon. It is common to hear surgeons using the expression ‘let’s give it a try’. However, because living with fistula is typically the most dramatic experience in a woman’s life (134) combined with reduced likelihood of successful closure with subsequent repair attempts (54;55) and the cost of fistula repair (76;135), it is crucial to ensure the woman has the best chance of success with the first repair at the initial surgery.

6.4 The effects of the Ebola Virus Disease outbreak on fistula management and programming in Guinea

Most studies related to this thesis were conducted during the West African 2014/2016 Ebola virus disease (EVD) outbreak. The outbreak started in Guinea in March 2014, almost at the same time as this thesis (86). When the disease rapidly spread to Sierra Leone and Liberia, becoming a global public health emergency, most ongoing health programs, including fistula management programs were suspended for health security purposes (93). As of 14 February 2016, a total of 3,804 EVD cases from 26 of 34 country-wide health districts were reported in Guinea including 211 cases among healthcare workers (HCW). The case-fatality rates were 67% in HCWs and 55% in the general population. Given the high burden of disease in HCWs (94) and the need to conduct clinical research to test available therapeutic drugs against Ebola, I suspended my PhD for six months and returned to Guinea to coordinate an ITM-led clinical trial on convalescent plasma to treat EVD (1 January to 30 June 2015) (136). While in the field, I rapidly engaged in the debate on the effects of the EVD outbreak on reproductive health (118) and health workforce (86).

HCWs were at higher risk of contracting Ebola than the general population because of their direct involvement in case management (117;137), particularly those providing obstetric care, resulting in HCWs desertion of facilities (118). Because of HCW desertion and fear of transmission in health facilities, miscommunication from authorities and

existing mistrust between communities and the health system, the EVD led to significant reductions in population use of health care services (70;119;138). In this context, women seeking surgery for obstetric fistula had to stay for 21 days before they could undergo surgery to confirm absence of EVD, prolonging the hospital stay for women and their relatives and increasing the costs of fistula repair. To assess the effect of the EVD outbreak on maternal and child health services in Guinea, we conducted operational research across the country. The findings of our study were published in the Lancet Global Health journal (70). In this study, we observed a strong negative trend in access to maternal and child care during the EVD outbreak, characterized by a reversal in the increasing trend of institutional deliveries and antenatal care visits, for example before the outbreak compared to during the outbreak, with the use of maternal and child health services not completely re-established in the months following the end of the outbreak in 2016. The same trend was observed for most under-five vaccinations (70).

In west Africa in general, maternal and child health services were particularly affected by the epidemic (70;139-142). In the context of community reluctance to engage in any health-related activity, conducting our field research was difficult and sometimes risky. Women who needed health care, i.e., those becoming pregnant after fistula repair, might have simply decided to deliver at home in fear of contracting Ebola at health facilities. This might have led to more home deliveries in our longitudinal cohort, which might have exposed study participants to greater risk of adverse reproductive health outcomes than post-repair pregnancies during a different time period.

6.5 Are women more at risk of adverse reproductive health outcomes after fistula surgery in Guinea than elsewhere in Africa?

First, it should be stated that according to studies that have estimated the prevalence of OF symptoms in women of reproductive age, Guinea has a prevalence twice that of sub-Saharan Africa overall (18;19). Regarding adverse reproductive health outcomes after fistula repair, fistula recurrence and maternal and neonatal complications during post-repair pregnancy and delivery were more frequent among women who underwent fistula repair in Guinea than what has been reported from other settings in Africa, such as in Malawi and Ethiopia (as presented in Studies IV and V) (31;32;35).

In Study V, about one fifth of women had fistula recurrence and one in ten had residual urinary incontinence during the 28 months median study follow-up time. Even though three-quarters of pregnant women achieved at least one antenatal care visit for the first post-repair pregnancy, four-fifths delivered vaginally or by emergency C-section, despite the recommendation that women have future deliveries by elective C-section (1). In Study IV, a synthesis of 16 studies published on pregnancy and childbirth after obstetric fistula repair in sub-Saharan Africa revealed an overall proportion of pregnancy during study follow-up that was low while maternal and neonatal complications post-repair were high (143).

The findings of studies IV and V indicate that Guinean women who have undergone repair for fistula are at high risk of experiencing fistula recurrence and maternal and neonatal complications post-repair than women in other African countries. However, such interpretation should be nuanced as most previous studies were qualitative (not providing the estimates of study outcomes) or if quantitative, carried heterogeneity of recruitment strategies and follow-up of women (143).

A recent study by Kopp et al. (144) in Malawi reported that of 148 women who had reproductive potential, 30 women (21%) became pregnant following their fistula repair and 22 women delivered during study follow-up. The authors found that all deliveries occurred in a health facility compared to 62% in our study. In addition, two-thirds (68.2%) of the women from their sample delivered by C-section compared to 42.0% in our study (144). Moreover, 21 out of the 22 deliveries they recorded (95.4%) ended in livebirth compared to 76.0% in our study ($p=0.054$) (144). There were, however, some methodological differences between this study and ours.

First, the study by Kopp et al (145) was conducted in Lilongwe, Malawi, with women presenting to one fistula management center (the Freedom from Fistula Foundation Fistula Care Centre at Bwaila Hospital) where a clinical database was in place. This database systematically captured demographic data, physical exam findings, surgical procedures, post-operative findings and information from three follow-up visits (at months 1, 3, and 12) in the first year after repair. In Guinea repair hospitals, we abstracted these characteristics from medical records and as found in Study II, 27% and 52% respectively were already lost to follow-up at month three post-repair in 2012 and 2013.

Second, while we included women residing in Guinea with no geographical restriction, in Malawi, eligibility criteria included language restrictions and residence in a district that was no more than 4 hours' driving distance from the repair center.

Third, access and use of health facilities including emergency obstetric and neonatal care might have been better in Malawi than in Guinea. In the study in Malawi, the perinatal mortality rate ([stillbirths and early neonatal deaths]/deliveries) was only 9.1% compared to 24% in our study. Furthermore, 73.3% in the Malawian sample had a stillbirth at the delivery that resulted in their OF compared to 93% in our sample, suggesting that even in the absence of fistula, the quality of EmONC in Malawi was more effective than in Guinea. It is, however, important to consider the EVD outbreak context which, as mentioned before, might have discouraged women from using health facilities (70). In Guinea, there was a lower elective C-section rate than in Malawi. Reasons for low caesarean deliveries might include the Ebola crisis (as mentioned above) but also the fact that many women from our sample lived far from a referral hospital. This was contrary to the participants in the study by Kopp et al (144) where women residing in the furthest health districts were excluded, limiting generalizability of the study findings. Despite the existing free obstetric care policy in Guinea, women living far from a referral hospital (where C-section is available) might not be able to afford the transportation, accommodation and extra payment cost related to obtaining C-section in such a facility. As mentioned previously, reimbursement of transport and residence closer to the referral hospital were the main factors associated with reducing loss to follow-up in women undergoing obstetric fistula repair in Guinea (127).

Fourth, it has been reported that women who benefit from a strong social support network after repair (57;58) and have easy access to and use of health services (145) might be more protected against adverse health outcomes than those who do not. In our study, fistula recurrence largely occurred in women who engaged in heavy physical activities such as farming, confirming what has previously been reported (35-37). In addition, although patients are often encouraged to return for a follow-up visit and to deliver by elective C-section in a health facility, this advice is not followed by women from our study for reasons that include health systems factors, poverty or refusal due to cultural reasons or husband or family opposition (28;32;37;56). We found that stillbirth

and fistula recurrence were more likely to occur with vaginal delivery and emergency C-section than with an elective C-section (28;32;32;36;37;56;56;147).

6.6 The necessary role of obstetric fistula primary prevention, including gender inequalities

The primary prevention of fistula occurrence remains the most relevant and powerful answer towards a fistula free generation. From our perspective it is imperative that primary prevention efforts include attention to both clinical and socio-cultural components.

The clinical component encompasses adolescent and maternal nutrition, responsible parenthood, birth preparedness (148), skilled attendance at every birth, provision of quality emergency obstetric and neonatal care and monitoring of every labor with the partograph for early recognition of obstructed labor and referral. In fact, Guinea has a maternal mortality ratio estimated at 679 (95% CI: 504 – 927) per 100,000 live births (91) which is one of the highest maternal mortality ratio in Africa. This maternal mortality level suggests a lack of access to quality emergency obstetric care. Fewer than half of women (45%) delivered with skilled birth attendants between 2007 and 2012. This varied significantly by socio-economic status and residence at 19% among women belonging to the poorest quintile and 32% among women living in rural areas (19). A national needs assessment conducted in 2012 showed low availability of emergency obstetric and neonatal care (EmONC) services and underutilization of available services (149). This nationally representative study found that only 15 referral hospitals (facilities with surgical capacity including C-section) out of the 502 health facilities visited (3%) were fully functioning EmONC facilities. The met need for EmONC was 12.2% and the availability of fully functioning EmONC was one EmONC facility per 745,415 inhabitants (149). The situation is exacerbated due to the negative effects of the EVD outbreak that disrupted an already fragile and poor health system, compromising reproductive health care management of pregnancy, childbirth and post-partum related complications, including hemorrhage, eclampsia, obstructed labor and abortion (70;117). However, women's health goes beyond providing quality health services. Women's status, gender equality and equity are crucial in reproductive health outcomes. More than 9 out of 10 women aged 15 to 49 years have experienced female genital cutting (97%) and 6% of

girls under the age of 15 who were excised had the vagina closed and sewn (19). There is no evidence that this rate is decreasing over time.

The sociocultural component the primary prevention should include activities that reduce gender inequalities and empower women and communities to access and use of health services. Health education and promotion activities that involve men will increase community awareness of causes and prevention measures and contribute to delaying marriage and early child bearing, In Guinea, 21% get married by the age of 15 years and 52% by the age of 18 years (150). From our data, we noted that among the 2116 women included in Study I, 1212 (57%) were married before the age of 17 years (121).

6.7 The untold story of non-fistula incontinence in women

While this thesis focused on female genital fistula related incontinence, it is important to recall that women in Guinea and worldwide also suffer non-fistula related incontinence. This kind of incontinence includes stress or urge incontinence or the combination of both types. Most available data are related to the epidemiology of incontinence in the county of Nord-Trøndelag study (EPINCONT), a sub study of the Norwegian Nord-Trøndelag health survey 2 (HUNT 2) conducted between 1995 and 1997. A three years' community-based epidemiological survey with 27,936 Norwegian women aged 20 years or more recorded 25% urinary leakage in participating women including 7% with moderate or severe incontinence (151). The study (151) found that the prevalence of incontinence increased with increasing age and that half of the incontinence was of stress type, 11% of urge and 36% of mixed incontinence. Incontinence has been shown to have weak statistically significant association with birth weight 4000 g or greater (odds ratio [OR] 1.1, 95% CI 1.0-1.2) (152). In addition, incontinence is found to be associated with parity with the first delivery being the most significant, i.e a strongest association in the age group 20-34 years among primiparous women (Risk Ratio (RR) 2.2; 95% confidence interval [CI] 1.8, 2.6) and grand multiparous women (RR 3.3; 95% CI 2.4, 4.4) (153). Other studies found that 1) the prevalence of urinary incontinence increases substantially during pregnancy (154); 2) the risk of urinary incontinence is higher among women who have had cesarean sections than among nulliparous women (155); and 3) women are more likely to develop urinary incontinence if their mother or older sisters are incontinent (156).

6.8 Strengths and weaknesses of the study designs

In the sub-section “4.7 Methodological considerations”, we have already mentioned some limitations inherent to the study designs used in this thesis, including retrospective cohorts and longitudinal study designs. We have also discussed the lack of qualitative data that could have been used to explain or contextualize some of our findings.

6.8.1 Strengths of study designs used

In this thesis, we took advantage of a large sample size to create a dataset that captured information on many exposure variables and outcomes. The design accommodated the use of medical records from patients already repaired. Because fistula repair is very costly, taking advantage of existing routine program data to generate some evidence about the management of the condition was cost-effective. Our longitudinal design (Study V) allowed a follow-up of women who underwent surgery at three different study sites to record the occurrence of study outcomes (recurrence of fistula, pregnancy and childbirth, and perinatal outcome) over time. Our results contributed to the generation of evidence from previous studies examining these outcomes, by assessing a wide variety of variables, and by adjusting for potential confounding factors such as case mix and skill set.

At a personal level, the designs used in this thesis allowed me to expand my skills in statistical analysis and interpretation. For instance, I became familiar with descriptive and statistical inference, including logistic regression and survival analysis. I also increased my knowledge and practice of literature synthesis through our scoping review.

6.8.2 Weaknesses of the study designs

Our work has some limitations related to the statistical analyses performed and the bias inherent to the nature of the epidemiological studies conducted as part of this thesis, particularly selection and information bias that might have affected the interpretation of our results.

6.8.2.1 Statistical analysis related weaknesses

We acknowledge “a posteriori” that the choice of some continuous exposure variables was not ideal. For example, in papers related to Studies II and III the number of previous repairs and distance to health facilities were reported as means (SD), and analyzed as

continuous variables. It is possible that these variables were not normally distributed and therefore, should have been analyzed as dichotomous or categorical variables. In addition, we used logistic regression in most of our multivariable analyses because the outcomes of interest were dichotomous variables. Because logistic regression provides adjusted odds ratios (aOR) for each predictor, it is important to mention that the odds ratios differ from the risk ratios. In fact, the estimate of the association is usually overestimated by the odds ratio as compared to the risk ratio (157). Finally, because data on each participant were mainly recorded only once, our ability to establish temporal association between an exposure and an outcome was challenged.

6.8.2.2 Interpretation related weaknesses

Selection bias

One limitation to our design is selection bias. Selection bias occurs when the study population does not represent the target population (158;159). In Study I and II, women returning for a follow-up visit are expected to be different from those women who were lost-to-follow-up. For instance, women who experience a recurrence of fistula or who still carry a residual incontinence might be overrepresented among those returning for a follow-up visit. This would exaggerate the strength of association between various exposure variables and the outcomes of interest. This may be the reason for our findings in Study I (121) where we noted an increasing trend in the proportion of women remaining continent over time which might have been influenced by the effect of (an increased) loss-to-follow-up over time, but then in the other direction. In that case, continent women might attend follow-up care to receive confirmation of their healing while incontinent women feel exhausted by an unfruitful surgical experience and just stay home. Another example is the varying trend of loss to follow-up recorded in Study II (127). Furthermore, lost-to-follow-up varied across fistula repair hospitals. This might have either over or underestimated the strength of association between the study outcomes and various exposures. In Study IV, selection bias might have occurred when full text of the included articles was not able to be found for some of the selected studies included in the review (143). As for Study V, there was differential selection of women who were closed and continent at hospital discharge compared to those who experienced stillbirth during the pregnancy leading to the fistula (120). In both cases, it is possible that the outcomes recorded were overestimated because women with a closed and

continent fistula at hospital discharge are more likely to resume a normal social and sexual life and those who experienced stillbirth are eager to compensate the loss of a child if they still have the potential for child bearing.

Information bias

Another limitation of our work is information bias which is the result of misclassification of study participants with respect to the outcome of interest or exposure status (160;161). The misclassification might be non-differential if it is equal between subjects that have or do not have the health outcome or between exposed and unexposed subjects. It might be differential when the probability of misclassification of exposure is different in diseased versus non-disease individuals, or the probability of misclassification of disease is different in exposed versus non-exposed people (161). In all studies, misclassification of exposure might have occurred when discrepancies were noted about the closure or continence status of a fistula at hospital discharge or at follow-up. In Studies II and III (121;127), non-differential misclassification of exposure could have occurred when we analyzed some variable such as number of previous repairs and distance to repair hospital as continuous variables (161). In study V, differential exposure misclassification was possible as women who had a closed and continent fistula may have been more likely to report having resumed sexual activity or be in a marital relationship than those women who were not continent (120). In these cases, our analyses attenuated the association in a way that the effect estimate would have been underestimated (biased towards the null value of Odds Ratio = 1).

Misclassification of outcome might have occurred in Study V where we found that the odds of recurrence of fistula was higher in women who were not sexually active compared to women who reported being sexually active (120). In this case, the directionality of the association was not established because both exposure and outcome information were collected only at the time of follow-up. Also, a divorce or abandonment might have led to socioeconomic precariousness that resulted in greater risk for recurrence.

CHAPTER 7. CONCLUSIONS

The findings of this thesis have shown that a huge effort is required in Guinea to achieve a fistula free generation. In addition to strengthening efforts for primary prevention of obstetric fistula through women's empowerment, male involvement and provision of quality reproductive health services, there is need for a paradigm shift within current fistula management programs:

1. The use of short term clinical outcomes such as closure and continence after surgery or at hospital discharge to assess programs performance is misleading and should be replaced by long-term outcomes that include fistula closure and continence and livebirth at 24 months (or at least 12 months) post hospital discharge;
2. Reimbursement of transport and the reduction of geographical barriers to care for women with OF are key to sustaining fistula care positive outcomes.
3. Fistula-related clinical characteristics such as involvement of the urethra or the bladder neck in the fistula, vaginal delivery during the pregnancy leading to the fistula and vaginal scarring were associated with surgical failure or recurrence of the fistula in the post-repair period.
4. The proportion of women becoming pregnant after OF repair was low and for women becoming pregnant, maternal complications such as recurrence of the fistula and abortion, and adverse neonatal outcomes such as stillbirth were common after OF repair in Guinea and sub-Saharan Africa. Free access to relevant care and transportation including caesarean before labor and consequently dating ultrasound scan are mandatory in this context. Cost benefit assessment may be useful.

CHAPTER 8. RECOMMENDATIONS

The findings of this doctoral research have important implications for current and future fistula management programs. They provide relevant knowledge and guidance to fistula care program developers, implementers and managers along with policy makers and researchers at local, national and global levels.

8.1 Improving the prevention of obstetric fistula formation and re-formation

- ✓ Address the root causes of obstetric fistula that in our context relate to gender inequalities (for instance in health related decision making) and poor access and use of maternal and reproductive health, especially emergency obstetric and neonatal care.
- ✓ Target men as partner in the community awareness-raising efforts through information, education and communication to inform and educate on the root causes of fistula, clinical signs, availability of fistula services for surgery and reintegration after surgery.
- ✓ Deliver health education and promotion activities to all women undergoing fistula surgery and their relatives. These activities are needed to improve their understanding of OF and health risks after repair and discuss the reintegration process, nutrition and reproductive health intentions (family planning, sexuality, pregnancy, ANC and birth preparedness in case of pregnancy).
- ✓ Reduce geographical and financial barriers to access and use of health facilities with operative capacity for women becoming pregnant with and without a history of fistula living in hard to reach areas. This can be achieved through a strengthened referral system or innovative funding mechanisms that provide transportation costs using for example mobile money, vouchers or local community insurance schemes.

8.2 Rethinking the performance of fistula management programs in Guinea and beyond

- ✓ Revise the way the performance of current obstetric fistula management programs is assessed.
Up to now, most fistula care programs are assessed on the number of fistula repairs performed and the outcomes after surgery and at hospital discharge in terms of the proportion of fistula closure and fistula continence. Our findings show that there is a need to go beyond repair to assess the actual performance of fistula management programs and weight the cost-effectiveness of current strategies.
- ✓ Integrate post-repair follow-up into fistula management programs (67) that uses and strengthen the capacities of the local health system for a duration of 24 months post hospital discharge (or at least 12 months). Strategies to achieve this would include the use of mobile phones for follow up (162) and community-based follow (32). If needed, community health workers could conduct outreach for follow-up for women who do not have cell phones. This is of importance as many women are repaired far from their residence or sent from one repair hospital to another, depending on the availability of the surgeon.
- ✓ Evaluate long-term follow-up not only in terms of fistula repair and reproductive health outcomes, but also in term of quality of life including mental health.

8.3 Improving the quality of fistula management programs in the context of decentralization of fistula care in Guinea

- ✓ As the Government of Guinea has started to decentralize fistula care into the regional hospitals, there is a need to establish a “level of care” approach into fistula surgery to guide cases screening at community level and inform surgical decision making. The principle is to tailor fistula surgery to the level of the surgeon’s skills. EngenderHealth has implemented the same level of care approach while integrating fistula management activities in the Guinean health system by using three levels of health system strengthening for obstetric fistula services integration (67). Level one included fistula prevention services only while level two encompassed level one activities and simple fistula repair, post-operative care and referral of complex fistula. Finally, level three included activities of levels one and two in addition to the repair of complex cases, training and coaching (67). To this end, a harmonized checklist that matches the level of the fistula surgeon to the level of complexity of the fistula could be developed using the International Federation of Gynecology and Obstetrics (FIGO) and partners’ Global Competency-Based Fistula Surgery Training Manual (163). Furthermore, the “level of care” in fistula surgery would also increase surgeons’ accountability.
- ✓ Implement a regular training program for providers (surgeons, nurses and anesthetists) with adequate follow-up supervision for service delivery improvement. This is particularly important to maintain the repair outcomes achieved after surgery.
- ✓ Collect data, monitor and evaluate the decentralized fistula repair hospitals to inform decision making.
- ✓ Include nutritional supplementation component into fistula care programs to improve women’s general health status.

8.4 Implementing interventions to improve reproductive health of women after fistula repair

Achieving a fistula free generation includes interventions to maintain the health of women discharged from fistula repair hospital with a successfully closed fistula. This is of importance during the first 24 months post-repair, a period during which most of the recurrences and first deliveries have been recorded in our study. In addition to the medical follow-up mentioned previously, the following recommendations are made:

- ✓ Provide social support to women post-repair: social immersion program.
Social support could build on previous counseling and psychological support initiatives for women repaired from OF (62;125;164), successful experiences of social immersion program after repair (165) and community involvement in maternal and child health (166;167).
 - Social immersion program is an activity that assigns the repaired woman for three weeks to a trained volunteer host family to help the woman gradually resume social roles before her return home (165). The aim is to help the woman regain self-confidence and self-esteem. For women who still bear reproductive potential, having the host family in the city where the nearest referral hospital from woman's place of residence is located could allow them to be hosted again for elective C-section, should they become pregnant after repair.

- ✓ Implement economic empowerment activities to support women successfully repaired through income generating activities. This would improve women's contribution to health care decision making, increase their income and value in the home and address any medical or other social needs. Improving the economic condition of women after repair is critical for both optimizing their reintegration and improving their contribution to health care decision making.

9. REFERENCES

- (1) de Bernis L. Obstetric fistula: guiding principles for clinical management and programme development, a new WHO guideline. *Int J Gynaecol Obstet* 2007 Nov;99 Suppl 1:S117-S121.
- (2) Capes T, Ascher-Walsh C, Abdoulaye I, Brodman M. Obstetric fistula in low and middle income countries. *Mt Sinai J Med* 2011 May;78(3):352-61.
- (3) Raassen T, Ngongo C, Mahendeka M. Iatrogenic genitourinary fistula: an 18-year retrospective review of 805 injuries. *Int Urogynecol J* 2014;25(12):1699-706.
- (4) Wall LL. A framework for analyzing the determinants of obstetric fistula formation. *Stud Fam Plann* 2012 Dec;43(4):255-72.
- (5) Miller S, Lester F, Webster M, Cowan B. Obstetric fistula: a preventable tragedy. *J Midwifery Womens Health* 2005 Jul;50(4):286-94.
- (6) Osotimehin B. Obstetric fistula: ending the health and human rights tragedy. *Lancet* 2013 May 18;381(9879):1702-3.
- (7) Polan ML, Sleemi A, Bedane MM, Lozo S, Morgan MA. Obstetric Fistula. 2015 Apr 2.
- (8) Wall LL. Obstetric vesicovaginal fistula as an international public-health problem. *Lancet* 2006 Sep 30;368(9542):1201-9.
- (9) UNITED NATIONS. United Nations General Assembly. Sixty-second session. Agenda item 66 (a): Resolution 62/138. Supporting efforts to end obstetric fistula. New York: United Nations General Assembly; 2007.
- (10) UNITED NATIONS. United Nations General Assembly. Sixty-seventh session. Agenda item 28 (a): Resolution 67/147. Supporting efforts to end obstetric fistula. New York: United Nations General Assembly; 2012.
- (11) Wall LL. Obstetric fistula is a "neglected tropical disease". *PLoS Negl Trop Dis* 2012;6(8):e1769.
- (12) Arrowsmith S, Hamlin EC, Wall LL. Obstructed labor injury complex: obstetric fistula formation and the multifaceted morbidity of maternal birth trauma in the developing world. *Obstet Gynecol Surv* 1996 Sep;51(9):568-74.
- (13) Ahmed S, Anastasi E, Laski L. Double burden of tragedy: stillbirth and obstetric fistula. *Lancet Glob Health* 2016 Feb;4(2):e80-e82.
- (14) Vangeenderhuysen C, Prual A, Ould el JD. Obstetric fistulae: incidence estimates for sub-Saharan Africa. *Int J Gynaecol Obstet* 2001 Apr;73(1):65-6.
- (15) Kelly J. Outreach programmes for obstetric fistulae. *J Obstet Gynaecol* 2004 Feb;24(2):117-8.
- (16) Stanton C, Holtz SA, Ahmed S. Challenges in measuring obstetric fistula. *Int J Gynaecol Obstet* 2007 Nov;99 Suppl 1:S4-S9.
- (17) Adler AJ, Ronsmans C, Calvert C, Filippi V. Estimating the prevalence of obstetric fistula: a systematic review and meta-analysis. *BMC Pregnancy Childbirth* 2013 Dec 30;13:246.

- (18) Maheu-Giroux M, Filippi V, Samadoulougou S, Castro MC, Maulet N, Meda N, et al. Prevalence of symptoms of vaginal fistula in 19 sub-Saharan Africa countries: a meta-analysis of national household survey data. *Lancet Glob Health* 2015 May;3(5):e271-e278.
- (19) Institut National des Statistiques G. Enquete Demographique et de sante - Etude a indicateurs multiples (EDS-MICS), Guinee 2012. Conakry: INS; Macro Int; 2014.
- (20) Muleta M, Hamlin EC, Fantahun M, Kennedy RC, Tafesse B. Health and social problems encountered by treated and untreated obstetric fistula patients in rural Ethiopia. *J Obstet Gynaecol Can* 2008 Jan;30(1):44-50.
- (21) Tennfjord MK, Muleta M, Kiserud T. Musculoskeletal sequelae in patients with obstetric fistula - a case-control study. *BMC Womens Health* 2014 Nov 8;14:136.
- (22) Siddle K, Mwambingu S, Malinga T, Fiander A. Psychosocial impact of obstetric fistula in women presenting for surgical care in Tanzania. *Int Urogynecol J* 2013 Jul;24(7):1215-20.
- (23) Gutman RE, Dodson JL, Mostwin JL. Complications of treatment of obstetric fistula in the developing world: gynaesthesia, urinary incontinence, and urinary diversion. *Int J Gynaecol Obstet* 2007 Nov;99 Suppl 1:S57-S64.
- (24) Ahmed S, Holtz SA. Social and economic consequences of obstetric fistula: life changed forever? *Int J Gynaecol Obstet* 2007 Nov;99 Suppl 1:S10-S15.
- (25) Weston K, Mutiso S, Mwangi JW, Qureshi Z, Beard J, Venkat P. Depression among women with obstetric fistula in Kenya. *Int J Gynaecol Obstet* 2011 Oct;115(1):31-3.
- (26) Wilson SM, Sikkema KJ, Watt MH, Masenga GG. Psychological Symptoms Among Obstetric Fistula Patients Compared to Gynecology Outpatients in Tanzania. *Int J Behav Med* 2015 Oct;22(5):605-13.
- (27) Pope R, Bangser M, Requejo JH. Restoring dignity: social reintegration after obstetric fistula repair in Ukerewe, Tanzania. *Glob Public Health* 2011;6(8):859-73.
- (28) Donnelly K, Oliveras E, Tilahun Y, Belachew M, Asnake M. Quality of life of Ethiopian women after fistula repair: implications on rehabilitation and social reintegration policy and programming. *Cult Health Sex* 2015;17(2):150-64.
- (29) Bukabau B. Impact de la fistule sur la vie sexuelle des femmes a l'Hopital Saint Joseph de Kinshasa, Republique Democratique du Congo. International Society of Obstetric Fistula Surgeons (ISOFS); 6th Bienal Scietific Congress, Restoring the past and securing the future for obstetric fistula patients; 26 to 28 October, Abuja, Nigeria 2016.
- (30) Anzaku SA, Lengmang SJ, Mikah S, Shephard SN, Edem BE. Sexual activity among Nigerian women following successful obstetric fistula repair. *Int J Gynaecol Obstet* 2017 Apr 20;137(1):67-71.
- (31) Wilson AL, Chipeta E, Kalilani-Phiri L, Taulo F, Tsui AO. Fertility and pregnancy outcomes among women with obstetric fistula in rural Malawi. *Int J Gynaecol Obstet* 2011 Jun;113(3):196-8.

- (32) Nielsen HS, Lindberg L, Nygaard U, Aytenu H, Johnston OL, Sorensen B, et al. A community-based long-term follow up of women undergoing obstetric fistula repair in rural Ethiopia. *BJOG* 2009 Aug;116(9):1258-64.
- (33) Tang JH, Steiner A, Bengtson A, Moyo M, Mwale M, Makanani B, et al. Cross-sectional study of the ultrasonographic and hormonal characteristics of obstetric fistula patients with and without secondary amenorrhea. *Int J Gynaecol Obstet* 2017;136(2):238-40.
- (34) Browning A. Pregnancy following obstetric fistula repair, the management of delivery. *BJOG* 2009 Aug;116(9):1265-7.
- (35) Browning A, Menber B. Women with obstetric fistula in Ethiopia: a 6-month follow up after surgical treatment. *BJOG* 2008 Nov;115(12):1564-9.
- (36) Aimakhu VE. Reproductive functions after the repair of obstetric vesicovaginal fistulae. *Fertil Steril* 1974 Jul;25(7):586-91.
- (37) Emembolu J. The obstetric fistula: factors associated with improved pregnancy outcome after a successful repair. *Int J Gynaecol Obstet* 1992 Nov;39(3):205-12.
- (38) Harrison KA. Obstetric fistula: one social calamity too many. *Br J Obstet Gynaecol* 1983 May;90(5):385-6.
- (39) Wright J, Ayenachew F, Ballard KD. The changing face of obstetric fistula surgery in Ethiopia. *Int J Womens Health* 2016;8:243-8.
- (40) McCarthy J, Maine D. A framework for analyzing the determinants of maternal mortality. *Stud Fam Plann* 1992;23(1):23-33.
- (41) UNFPA. Campaign to End Fistula 10th Anniversary. Tracking progress in the Campaign to End Fistula. New York; 2013.
- (42) Tebeu PM. Soins peri operatoires des fistules obstetricales et non obstetricales. Paris; 2016.
- (43) Lozano R, Wang H, Foreman K, Rajaratnam J, Naghavi M, Marcus J, et al. Progress towards Millennium Development Goals 4 and 5 on maternal and child mortality: an updated systematic analysis. *Lancet* 2011 Sep 24;378(9797):1139-65.
- (44) WHO. 10 facts on obstetric fistula. WHO, editor. http://www.who.int/features/factfiles/obstetric_fistula/en/. 2014. Geneva, WHO.
- (45) Mohr S, Brandner S, Mueller MD, Dreher EF, Kuhn A. Sexual function after vaginal and abdominal fistula repair. *Am J Obstet Gynecol* 2014 Jul;211(1):74-6.
- (46) Ruminjo JK, Frajzyngier V, Bashir AM, Asiimwe F, Barry TH, Bello A, et al. Clinical procedures and practices used in the perioperative treatment of female genital fistula during a prospective cohort study. *BMC Pregnancy Childbirth* 2014;14:220.
- (47) Tayler-Smith K, Zachariah R, Manzi M, van den Boogaard W, Vandeborne A, Bishinga A, et al. Obstetric fistula in Burundi: a comprehensive approach to managing women with this neglected disease. *BMC Pregnancy Childbirth* 2013 Aug 21;13:164.

- (48) Wall LL, Karshima JA, Kirschner C, Arrowsmith SD. The obstetric vesicovaginal fistula: characteristics of 899 patients from Jos, Nigeria. *Am J Obstet Gynecol* 2004 Apr;190(4):1011-9.
- (49) Arrowsmith SD, Barone MA, Ruminjo J. Outcomes in obstetric fistula care: a literature review. *Curr Opin Obstet Gynecol* 2013 Oct;25(5):399-403.
- (50) Barone MA, Frajzyngier V, Ruminjo J, Asimwe F, Barry TH, Bello A, et al. Determinants of postoperative outcomes of female genital fistula repair surgery. *Obstet Gynecol* 2012 Sep;120(3):524-31.
- (51) Frajzyngier V, Ruminjo J, Barone MA. Factors influencing urinary fistula repair outcomes in developing countries: a systematic review. *Am J Obstet Gynecol* 2012 Oct;207(4):248-58.
- (52) Waaldijk K. The immediate management of fresh obstetric fistulas. *Am J Obstet Gynecol* 2004 Sep;191(3):795-9.
- (53) Waaldijk K. The immediate surgical management of fresh obstetric fistulas with catheter and/or early closure. *Int J Gynaecol Obstet* 1994 Apr;45(1):11-6.
- (54) Gupta NP, Mishra S, Mishra A, Seth A, Anand A. Outcome of repeat supratrigonal obstetric vesicovaginal fistula repair after previous failed repair. *Urol Int* 2012;88(3):259-62.
- (55) Maulet N, Keita M, Macq J. Medico-social pathways of obstetric fistula patients in Mali and Niger: an 18-month cohort follow-up. *Trop Med Int Health* 2013 May;18(5):524-33.
- (56) Otubu JA, Kumi GO, Ezem BU. Pregnancy and delivery after successful repair of vesicovaginal fistula. *Int J Gynaecol Obstet* 1982 Apr;20(2):163-6.
- (57) Lombard L, de St JJ, Geddes R, El Ayadi AM, Grant L. Rehabilitation experiences after obstetric fistula repair: systematic review of qualitative studies. *Trop Med Int Health* 2015 May;20(5):554-68.
- (58) Degge HM, Hayter M, Laurenson M. An integrative review on women living with obstetric fistula and after treatment experiences. *J Clin Nurs* 2017 Jun 29;26(11-12):1445-57.
- (59) Drew LB, Wilkinson JP, Nundwe W, Moyo M, Mataya R, Mwale M, et al. Long-term outcomes for women after obstetric fistula repair in Lilongwe, Malawi: a qualitative study. *BMC Pregnancy Childbirth* 2016 Jan 5;16:2.
- (60) Landry E, Frajzyngier V, Ruminjo J, Asimwe F, Barry TH, Bello A, et al. Profiles and experiences of women undergoing genital fistula repair: findings from five countries. *Glob Public Health* 2013;8(8):926-42.
- (61) Alio AP, Merrell L, Roxburgh K, Clayton HB, Marty PJ, Bomboka L, et al. The psychosocial impact of vesico-vaginal fistula in Niger. *Arch Gynecol Obstet* 2011 Aug;284(2):371-8.
- (62) *Fistula Care. Counseling the obstetric fistula client: A training curriculum, 2012.* New York: Fistula Care/EngenderHealth; 2012.
- (63) *Fistula Care. Project Report: October 2007 to December 2013, Part 1I: Country Accomplishments.* New York: Fistula Care/EngenderHealth; 2013.

- (64) Institut National des Statistiques Guinée. Pauvreté et inégalités en Guinée de 1994 à 2012: analyse à partir d'enquêtes auprès des ménages. Conakry: INS; PAM; BM; BAD; PNUD; EU; 2013.
- (65) Ministère de la santé de Guinée. Stratégie nationale de prévention et de prise en charge des fistules obstétricales en Guinée. Conakry: Ministère de la santé de Guinée.; 2012.
- (66) Ministère de la santé de Guinée. Stratégie nationale de prévention et de prise en charge des fistules obstétricales en Guinée, 2016-2020. Conakry: Ministère de la santé de Guinée; 2016.
- (67) Mattison C, Fiorentino R. Strengthening Health Systems Through the Levels of Fistula Care Framework - A Literature Review . New York; 2011.
- (68) UNFPA. Evaluation finale du 6ème programme de Coopération Guinée – UNFPA 2007-2011. New York: UNFPA; 2012.
- (69) UNFPA. Plan d'action du programme pays 2013-2017 entre le Gouvernement de la République de Guinée et le Fonds des Nations Unies pour la Population (UNFPA). Conakry: UNFPA; 2012.
- (70) Delamou A, El Ayadi AM, Sidibe S, Delvaux T, Camara BS, Sandouno SD, et al. Effect of Ebola virus disease on maternal and child health services in Guinea: a retrospective observational cohort study. *Lancet Glob Health* 2017 Apr;5(4):e448-e457.
- (71) Osotimehin B. Seizing the moment to end obstetric fistula. *Lancet Glob Health* 2014 Jul;2(7):e381-e382.
- (72) Osotimehin B. Statement on the 2015 International Day to End Obstetric Fistula .<http://www.unfpa.org/press/statement-international-day-end-obstetric-fistula-dr-babatunde-osotimehin-united-nations-under> . 10-11-2016.
- (73) Barone MA, Widmer M, Arrowsmith S, Ruminjo J, Seuc A, Landry E, et al. Breakdown of simple female genital fistula repair after 7 day versus 14 day postoperative bladder catheterisation: a randomised, controlled, open-label, non-inferiority trial. *Lancet* 2015 Jul 4;386(9988):56-62.
- (74) Hawkins L, Spitzer RF, Christoffersen-Deb A, Leah J, Mabeya H. Characteristics and surgical success of patients presenting for repair of obstetric fistula in western Kenya. *Int J Gynaecol Obstet* 2013 Feb;120(2):178-82.
- (75) De Ridder D, Abubacar K, Raassen T, Waaldijk K, Stanford E. Surgical treatment of obstetric fistula. In: Abraham P, De Ridder D, Devries C, Elneil S, Esegbona G, Mourad S, et al., editors. *Obstetric fistula in the developing world*. Montreal (QB): Societe Internationale d'Urologie (SIU); 2012. p. 87-122.
- (76) Fistula Care. Estimating Costs to Provide Fistula Services in Nigeria and Ethiopia: Key Findings. New York: Engenderhealth; 2012.
- (77) Lopoosso MN, Ndundu J, De WG, Ost D, Punga AM, De RD. Obstetric fistula in a district hospital in DR Congo: Fistula still occur despite access to caesarean section. *Neurourol Urodyn* 2015 Jun;34(5):434-7.
- (78) Ahmed S, Tuncalp O. Burden of obstetric fistula: from measurement to action. *Lancet Glob Health* 2015 May;3(5):e243-e244.

- (79) Ahmed S, Genadry R, Stanton C, Lalonde AB. Dead women walking: neglected millions with obstetric fistula. *Int J Gynaecol Obstet* 2007 Nov;99 Suppl 1:S1-S3.
- (80) Pathfinder International. Strengthening the continuum of care for fistula prevention and repair in Ethiopia. Pathfinder International, editor. 2014. Watertown, MA, Pathfinder International. 13-10-2017.
- (81) Kerber KJ, de Graft-Johnson JE, Bhutta ZA, Okong P, Starrs A, Lawn JE. Continuum of care for maternal, newborn, and child health: from slogan to service delivery. *Lancet* 2007 Oct 13;370(9595):1358-69.
- (82) Lopoosso M, Hakim L, Ndundu J, Lufuma S, Punga A, De RD. Predictors of Recurrence and Successful Treatment Following Obstetric Fistula Surgery. *Urology* 2016 Aug 2;97:80-5.
- (83) Arrowsmith SD, Ruminjo J, Landry EG. Current practices in treatment of female genital fistula: a cross sectional study. *BMC Pregnancy Childbirth* 2010 Nov 10;10:73.
- (84) Benfield N, Kinsindja R, Kimona C, Masoda M, Ndume J, Steinauer J. Fertility desires and the feasibility of contraception counseling among genital fistula patients in eastern Democratic Republic of the Congo. *Int J Gynaecol Obstet* 2011;114:265-7.
- (85) Wegner MN, Ruminjo J, Sinclair E, Pessa L, Mehta M. Improving community knowledge of obstetric fistula prevention and treatment. *Int J Gynaecol Obstet* 2007 Nov;99 Suppl 1:S108-S111.
- (86) Baize S, Pannetier D, Oestereich L, Rieger T, Koivogui L, Magassouba N, et al. Emergence of Zaire Ebola virus disease in Guinea. *N Engl J Med* 2014 Oct 9;371(15):1418-25.
- (87) Presidence de la Republique G. Troisieme recensement general de la population et de l'habitat 2014. Decret D/2015/229/PRG/SSG. Conakry: Secretariat General du Gouvernement.; 2015.
- (88) Ministere du Plan de Guinée. Document de stratégie de réduction de la pauvreté en Guinée (DSRP-III, 2013-2015). Conakry: Ministere du Plan; 2013.
- (89) WHO. Comptes Nationaux de Santé: Guinée. Geneva; 2017.
- (90) Ministere de la santé de Guinée. Plan national de developement sanitaire, PNDS (2015-.2024). Conakry: Ministère de la santé de Guinée.; 2015.
- (91) WHO, UNICEF, UNFPA, THE WORLD BANK, UNITED NATIONS. Trends in maternal mortality: 1990 to 2015. Estimates by WHO, UNICEF, UNFPA, The World Bank and the United Nations Population Division. Geneva; 2015.
- (92) Delamou A, Dubourg D, Beavogui AH, Delvaux T, Kolie JS, Barry TH, et al. How Has the Free Obstetric Care Policy Impacted Unmet Obstetric Need in a Rural Health District in Guinea? *PLoS One* 2015;10(6):e0129162.
- (93) WHO. Ebola response roadmap situation report 29 October 2014. http://apps.who.int/iris/bitstream/10665/137091/1/roadmapsitre22Oct2014_eng.pdf?ua=1 . 2014.

- (94) Coordination Nationale Ebola Guinée. Rapport de la Situation Epidémiologique, Maladie à Virus Ebola en Guinée du 14 Février 2016. Sit_Rep_no 670. <http://guinea-ebov.github.io/> . 14-2-2016. Conakry, Coordination Ebola Guinee & OMS. 20-5-2017.
- (95) Delamou A, Delvaux T, El Ayadi AM, Beavogui AH, Okumura J, Van DW, et al. Public health impact of the 2014-2015 Ebola outbreak in West Africa: seizing opportunities for the future. *BMJ Glob Health* 2017;2(2):e000202.
- (96) Ministère de la sante G. Plan national de relance du système de santé (2015-2017). Conakry: Ministère de la santé de Guinée; 2015.
- (97) Fistula Care. Project Report: October 2007 to December 2013, Part 1I: Country Accomplishments. New York: Fistula Care/EngenderHealth; 2013.
- (98) Song JW, Chung KC. Observational studies: cohort and case-control studies. *Plast Reconstr Surg* 2010 Dec;126(6):2234-42.
- (99) Mann CJ. Observational research methods. Research design II: cohort, cross sectional, and case-control studies. *Emerg Med J* 2003 Jan;20(1):54-60.
- (100) Bishinga A, Zachariah R, Hinderaker S, Tayler-Smith K, Khogali M, van GJ, et al. High loss to follow-up following obstetric fistula repair surgery in rural Burundi: is there a way forward? *Public Health Action* 2013 Jun 21;3(2):113-7.
- (101) Peters MD, Godfrey CM, Khalil H, McInerney P, Parker D, Soares CB. Guidance for conducting systematic scoping reviews. *Int J Evid Based Healthc* 2015 Sep;13(3):141-6.
- (102) University of Toronto. Systematic & Scoping Reviews : Methodology Behind the Search Strategies. 2017. 13-10-2017.
- (103) The Joanna Briggs Institute. Joanna Briggs Institute Reviewers' Manual: Methodology for JBI Scoping Reviews. Adelaide; 2015.
- (104) Caruana EJ, Roman M, Hernandez-Sanchez J, Solli P. Longitudinal studies. *J Thorac Dis* 2015 Nov;7(11):E537-E540.
- (105) Barone M, Frajzyngier V, Arrowsmith SD, Ruminjo J, Seuc A, Landry E, et al. Non-inferiority of short-term urethral catheterization following fistula repair surgery: study protocol for a randomized controlled trial. *BMC Pregnancy Childbirth* 2012;12(5):doi: 10.1186/1472-6874-12-5.
- (106) Andersen P, Geskus R, de Witte T, Putter H. Competing risks in epidemiology: possibilities and pitfalls. *Int J Epidemiol* 2012;41:861-70.
- (107) Wall LL. A bill of rights for patients with obstetric fistula. *Int J Gynaecol Obstet* 2014 Dec;127(3):301-4.
- (108) Wall LL. Ethical issues in vesico-vaginal fistula care and research. *Int J Gynaecol Obstet* 2007 Nov;99 Suppl 1:S32-S39.
- (109) Shivayogi P. Vulnerable population and methods for their safeguard. *Perspect Clin Res* 2013;4(1):53-7.

- (110) von Elm E, Altman D, Egger M, Gøtzsche P, Vandenbroucke J. STROBE Initiative: The strengthening the reporting of observational studies in epidemiology (STROBE) statement: guidelines for reporting observational studies. *J Clin Epidemiol* 2008;61(344):349.
- (111) Flick U. *An introduction to qualitative research*. Fifth edition ed. Sage Publications Ltd; 2009.
- (112) Dahlgren L, Emmelin M, Winkvist A. *Qualitative methodology for international public health*. Umea University: Epidemiology and Public Health Sciences; 2007.
- (113) Carr L. The strengths and weaknesses of quantitative and qualitative research: what method for nursing? *J Adv Nurs* 1994;20(4):716-21.
- (114) Dal-Re R, Delgado M, Bolumar F. [Registration of observational studies: it is time to comply with the Declaration of Helsinki requirement]. *Gac Sanit* 2015 May;29(3):228-31.
- (115) Boccia S, Rothman KJ, Panic N, Flacco ME, Rosso A, Pastorino R, et al. Registration practices for observational studies on ClinicalTrials.gov indicated low adherence. *J Clin Epidemiol* 2016 Feb;70:176-82.
- (116) Holmes B, Scarrow G, Schellenberg M. Translating evidence into practice: the role of health research funders. *Implement Sci* 2012 Apr 24;7:39.
- (117) Delamou A, Beavogui AH, Konde MK, van GJ, De B, V. Ebola: better protection needed for Guinean health-care workers. *Lancet* 2015 Feb 7;385(9967):503-4.
- (118) Delamou A, Hammonds RM, Caluwaerts S, Utz B, Delvaux T. Ebola in Africa: beyond epidemics, reproductive health in crisis. *Lancet* 2014 Dec 13;384(9960):2105.
- (119) Thiam S, Delamou A, Camara S, Carter J, Lama EK, Ndiaye B, et al. Challenges in controlling the Ebola outbreak in two prefectures in Guinea: why did communities continue to resist? *Pan Afr Med J* 2015;22 Suppl 1:22.
- (120) Delamou A, Delvaux T, El Ayadi AM, Tripathi V, Camara BS, Beavogui AH, et al. Fistula recurrence, pregnancy, and childbirth following successful closure of female genital fistula in Guinea: a longitudinal study. *Lancet Glob Health* 2017 Sep 20;5(11):e1152-e1160.
- (121) Delamou A, Diallo M, Beavogui AH, Delvaux T, Millimono S, Kourouma M, et al. Good clinical outcomes from a 7-year holistic programme of fistula repair in Guinea. *Trop Med Int Health* 2015 Jun;20(6):813-9.
- (122) Murphy M. Social consequences of vesico-vaginal fistula in northern Nigeria. *J Biosoc Sci* 1981 Apr;13(2):139-50.
- (123) Wilson SM, Sikkema KJ, Watt MH, Masenga GG, Mosha MV. Psychological Symptoms and Social Functioning Following Repair of Obstetric Fistula in a Low-Income Setting. *Matern Child Health J* 2016 May;20(5):941-5.
- (124) Imoto A, Matsuyama A, Ambauen-Berger B, Honda S. Health-related quality of life among women in rural Bangladesh after surgical repair of obstetric fistula. *Int J Gynaecol Obstet* 2015 Jul;130(1):79-83.

- (125) Watt MH, Wilson SM, Sikkema KJ, Velloza J, Mosha MV, Masenga GG, et al. Development of an intervention to improve mental health for obstetric fistula patients in Tanzania. *Eval Program Plann* 2015 Jun;50:1-9.
- (126) El Ayadi A, Nalubwama H, Barageine J, Neilands TB, Obore S, Byamugisha J, et al. Development and preliminary validation of a post-fistula repair reintegration instrument among Ugandan women. *Reprod Health* 2017 Sep 2;14(1):109.
- (127) Delamou A, Delvaux T, Utz B, Camara BS, Beavogui AH, Cole B, et al. Factors associated with loss to follow-up in women undergoing repair for obstetric fistula in Guinea. *Trop Med Int Health* 2015 Nov;20(11):1454-61.
- (128) Murray C, Goh JT, Fynes M, Carey MP. Urinary and faecal incontinence following delayed primary repair of obstetric genital fistula. *BJOG* 2002 Jul;109(7):828-32.
- (129) Wright JT. Prevention and management of obstetric fistulae requires both a long-term strategy and long-term care. *Lancet Glob Health* 2017 Sep 20;5(11):e1062-e1063.
- (130) Bilinski A, Birru E, Peckarsky M, Herce M, Kalanga N, Neumann C, et al. Distance to care, enrollment and loss to follow-up of HIV patients during decentralization of antiretroviral therapy in Neno District, Malawi: A retrospective cohort study. *PLoS One* 2017;12(10):e0185699.
- (131) Nardos R, Browning A, Chen CC. Risk factors that predict failure after vaginal repair of obstetric vesicovaginal fistulae. *Am J Obstet Gynecol* 2009 May;200(5):578-4.
- (132) Kayondo M, Wasswa S, Kabakyenga J, Mukibi N, Senkungu J, Stenson A, et al. Predictors and outcome of surgical repair of obstetric fistula at a regional referral hospital, Mbarara, western Uganda. *BMC Urol* 2011 Dec 7;11:23.
- (133) Delamou A, Delvaux T, Beavogui AH, Toure A, Kolie D, Sidibe S, et al. Factors associated with the failure of obstetric fistula repair in Guinea: implications for practice. *Reprod Health* 2016;13(1):135.
- (134) Mselle LT, Moland KM, Evjen-Olsen B, Mvungi A, Kohi TW. "I am nothing": experiences of loss among women suffering from severe birth injuries in Tanzania. *BMC Womens Health* 2011 Nov 15;11:49.
- (135) Ndiaye P, Amoul KG, Adama F, Idrissa A, Tal-Dia A. [Obstetric urogenital fistula (OUGF): cost analysis at the Niamey National Hospital (Niger)]. *Rev Epidemiol Sante Publique* 2009 Oct;57(5):374-9.
- (136) van Griensven J, Edwards T, de L, X, Semple MG, Gallian P, Baize S, et al. Evaluation of Convalescent Plasma for Ebola Virus Disease in Guinea. *N Engl J Med* 2016 Jan 7;374(1):33-42.
- (137) Toure A, Traore F, Sako F, Delamou A, Tonguino F, Sylla D, et al. Knowledge, attitudes, and practices of health care workers on Ebola virus disease in Conakry, Guinea: A cross-sectional study. *J Public Health Epidemiol* 2016;8(2):12-6.
- (138) Plucinski MM, Guilavogui T, Sidikiba S, Diakite N, Diakite S, Dioubate M, et al. Effect of the Ebola-virus-disease epidemic on malaria case management in Guinea, 2014: a cross-sectional survey of health facilities. *Lancet Infect Dis* 2015 Sep;15(9):1017-23.

- (139) Barden-O'Fallon J, Barry MA, Brodish P, Hazerjian J. Rapid Assessment of Ebola-Related Implications for Reproductive, Maternal, Newborn and Child Health Service Delivery and Utilization in Guinea. *PLoS Curr* 2015 Aug 4;7.
- (140) Brolin Ribacke KJ, van Duinen AJ, Nordenstedt H, Hoijer J, Molnes R, Froseth TW, et al. The Impact of the West Africa Ebola Outbreak on Obstetric Health Care in Sierra Leone. *PLoS One* 2016;11(2):e0150080.
- (141) Camara BS, Delamou A, Diro E, El AA, Beavogui AH, Sidibe S, et al. Influence of the 2014-2015 Ebola outbreak on the vaccination of children in a rural district of Guinea. *Public Health Action* 2017 Jun 21;7(2):161-7.
- (142) Camara BS, Delamou A, Diro E, Beavogui AH, El Ayadi AM, Sidibe S, et al. Effect of the 2014/2015 Ebola outbreak on reproductive health services in a rural district of Guinea: an ecological study. *Trans R Soc Trop Med Hyg* 2017 Jan 1;111(1):22-9.
- (143) Delamou A, Utz B, Delvaux T, Beavogui AH, Shahabuddin A, Koivogui A, et al. Pregnancy and childbirth after repair of obstetric fistula in sub-Saharan Africa: Scoping Review. *Trop Med Int Health* 2016 Sep 6;21(11):1348-65.
- (144) Kopp DM, Wilkinson J, Bengtson A, Chipungu E, Pope RJ, Moyo M, et al. Fertility outcomes following obstetric fistula repair: a prospective cohort study. *Reprod Health* 2017 Nov 28;14(1):159.
- (145) Khisa W, Wakasiaka S, McGowan L, Campbell M, Lavender T. Understanding the lived experience of women before and after fistula repair: a qualitative study in Kenya. *BJOG* 2016 Feb 19.
- (146) Pope R, Moyo M, Wilkinson J. She did the right thing: the high price of poor access to obstetric care. *BJOG* 2015 Jan;122(2):182.
- (147) Maulet N, Macq J. Obstetric fistula patients' reproductive health paths and perspectives. *Int J Gynaecol Obstet* 2012;119(S2):S841.
- (148) Chukwuma A, Wosu AC, Mbachu C, Weze K. Quality of antenatal care predicts retention in skilled birth attendance: a multilevel analysis of 28 African countries. *BMC Pregnancy Childbirth* 2017 May 25;17(1):152.
- (149) Baguiya A, Meda IB, Millogo T, Kourouma M, Mouniri H, Kouanda S. Availability and utilization of obstetric and newborn care in Guinea: A national needs assessment. *Int J Gynaecol Obstet* 2016 Nov;135 Suppl 1:S2-S6.
- (150) Girls Not Brides. Child marriage around the world: Guinea. <https://www.girlsnotbrides.org/child-marriage/guinea/> . 2016. 2018.
- (151) Hannestad YS, Rortveit G, Sandvik H, Hunskaar S. A community-based epidemiological survey of female urinary incontinence: the Norwegian EPINCONT study. *Epidemiology of Incontinence in the County of Nord-Trøndelag. J Clin Epidemiol* 2000 Nov;53(11):1150-7.
- (152) Rortveit G, Daltveit AK, Hannestad YS, Hunskaar S. Vaginal delivery parameters and urinary incontinence: the Norwegian EPINCONT study. *Am J Obstet Gynecol* 2003 Nov;189(5):1268-74.

- (153) Rortveit G, Hannestad YS, Daltveit AK, Hunnskaar S. Age- and type-dependent effects of parity on urinary incontinence: the Norwegian EPINCONT study. *Obstet Gynecol* 2001 Dec;98(6):1004-10.
- (154) Wesnes SL, Rortveit G, Bo K, Hunnskaar S. Urinary incontinence during pregnancy. *Obstet Gynecol* 2007 Apr;109(4):922-8.
- (155) Rortveit G, Daltveit AK, Hannestad YS, Hunnskaar S. Urinary incontinence after vaginal delivery or cesarean section. *N Engl J Med* 2003 Mar 6;348(10):900-7.
- (156) Hannestad YS, Lie RT, Rortveit G, Hunnskaar S. Familial risk of urinary incontinence in women: population based cross sectional study. *BMJ* 2004 Oct 16;329(7471):889-91.
- (157) Ranganathan P, Aggarwal R, Pramesh CS. Common pitfalls in statistical analysis: Odds versus risk. *Perspect Clin Res* 2015 Oct;6(4):222-4.
- (158) Kleinbaum DG, Morgenstern H, Kupper LL. Selection bias in epidemiologic studies. *Am J Epidemiol* 1981 Apr;113(4):452-63.
- (159) Nohr EA, Liew Z. How to investigate and adjust for selection bias in cohort studies. *Acta Obstet Gynecol Scand* 2018 Feb 7.
- (160) Blair A, Stewart P, Lubin JH, Forastiere F. Methodological issues regarding confounding and exposure misclassification in epidemiological studies of occupational exposures. *Am J Ind Med* 2007 Mar;50(3):199-207.
- (161) Pearce N, Checkoway H, Kriebel D. Bias in occupational epidemiology studies. *Occup Environ Med* 2007;64:562-8.
- (162) Fiander A, Ndahani C, Mmuya K, Vanneste T. Results from 2011 for the transportMYpatient program for overcoming transport costs among women seeking treatment for obstetric fistula in Tanzania. *Int J Gynaecol Obstet* 2013 Mar;120(3):292-5.
- (163) FIGO, ISOFs, UNFPA, RCOG. Global competency-based fistula surgery training manual. London; 2011.
- (164) Johnson KA, Turan JM, Hailemariam L, Mengsteab E, Jena D, Polan ML. The role of counseling for obstetric fistula patients: lessons learned from Eritrea. *Patient Educ Couns* 2010 Aug;80(2):262-5.
- (165) Diallo M. Social immersion strategy for reintegration and empowerment of obstetric fistula survivors. *International Journal of Gynaecology and Obstetrics* 107[Supl. 2], S156-S157. 2009.
- (166) August F, Pembe AB, Mpembeni R, Axemo P, Darj E. Community health workers can improve male involvement in maternal health: evidence from rural Tanzania. *Glob Health Action* 2016;9:30064.
- (167) Turinawe EB, Rwemisisi JT, Musinguzi LK, de GM, Muhangi D, de Vries DH, et al. Traditional birth attendants (TBAs) as potential agents in promoting male involvement in maternity preparedness: insights from a rural community in Uganda. *Reprod Health* 2016 Mar 12;13:24.

10. THESIS PAPERS

Good clinical outcomes from a 7-year holistic programme of fistula repair in Guinea

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Abstract

OBJECTIVES Female genital fistula remains a public health concern in developing countries. From January 2007 to September 2013, the Fistula Care project, managed by EngenderHealth in partnership with the Ministry of Health and supported by USAID, integrated fistula repair services in the maternity wards of general hospitals in Guinea. The objective of this article was to present and discuss the clinical outcomes of 7 years of work involving 2116 women repaired in three hospitals across the country.

METHODS This was a retrospective cohort study using data abstracted from medical records for fistula repairs conducted from 2007 to 2013. The study data were reviewed during the period April to August 2014.

RESULTS The majority of the 2116 women who underwent surgical repair had vesicovaginal fistula ($n = 2045$, 97%) and 3% had rectovaginal fistula or a combination of both. Overall 1748 (83%) had a closed fistula and were continent of urine immediately after surgery. At discharge, 1795 women (85%) had a closed fistula and 1680 (79%) were dry, meaning they no longer leaked urine and/or faeces. One hundred and fifteen (5%) remained with residual incontinence despite fistula closure. Follow-up at 3 months was completed by 1663 (79%) women of whom 1405 (84.5%) had their fistula closed and 80% were continent. Twenty-one per cent were lost to follow-up.

CONCLUSION Routine programmatic repair for obstetric fistula in low resources settings can yield good outcomes. However, more efforts are needed to address loss to follow-up, sustain the results and prevent the occurrence and/or recurrence of fistula.

keywords obstetric fistula, Guinea, fistula care, operational research, SORT-IT

Introduction

Female genital fistula is a serious medical condition in which a perforation develops either between most commonly bladder and vagina [vesicovaginal fistula (VVF)], between rectum and vagina [rectovaginal fistula (RVF)] or a combination of both. It occurs most commonly after prolonged labour when the head of the unborn child compresses the birth canal and leads to tissue necrosis [1, 2]. More rarely, fistula may be caused by genital cutting such as *yankan gishiri*, sexual violence, iatrogenic reasons (from

c-section, hysterectomy or poorly performed abortions), pelvic fractures, and malignancy or radiation [3–5].

Female genital fistula is no longer prevalent in the developed world, but remains a common public health concern in developing countries [6, 7]. There are no good estimates of the burden of fistula, but the most recent estimates of its prevalence range from one to two million worldwide, based on reviews by Stanton *et al.* and Adler *et al.* [8, 9].

In Guinea, 0.6% of women experienced obstetric fistula in their lifetime [10]. As in many other resource-limited settings, the local capacity to diagnose and to

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perform surgical repair is very limited. Up to 2006, only the Department of Urology of the Ignace Deen Hospital was recognised and was performing quality surgical repair for female genital fistula in Guinea. In 2007, EngenderHealth (an international reproductive health non-governmental organisation) helped to establish and strengthen three additional centres for fistula management in Guinea, of which three continued to perform surgical repair up to the end of this project in 2013.

While immediate post-operative closure rates for obstetric fistula can be as high as 90% [11, 12], this rate varies by repair centre and other factors such as the size of fistula, surgeon's experience, pre-operative bladder size, degree of vaginal scarring, degree of urethral involvement and number of previous repairs [13, 14]. Although urinary continence is not always achieved immediately after surgical repair even with closure of the fistula, residual incontinence can improve or be resolved with time [15]. Repair breakdown can happen as a consequence of inadequate post-operative care or poor catheter management and has been reported following hospital discharge, for reasons including heavy work, sexual intercourse, wound infections and at the subsequent pregnancy in case of prolonged labour or poor management of vaginal delivery [16].

Many published studies have reported on fistula characteristics, risk factors and outcomes of repair from different settings [11, 12, 17–20]. However, all previous studies in West Africa either focused on outcomes at discharge or most used a relatively small sample size from one repair centre [21, 22]. This study assesses the characteristics of more than 2000 women and their clinical outcomes after fistula repair from three local repair hospitals across Guinea. Routine programme data could yield useful and reliable information to guide future fistula programmes in Guinea.

Using data on women who underwent surgical repair of female genital fistula at three hospitals in Guinea with repair services supported by Fistula Care, we report on (i) the demographic and clinical characteristics of patients; (ii) the number and proportion of fistula types; and (iii) the outcomes of the treatment up to 3-month follow-up (fistula closed and dry, fistula closed with residual incontinence and fistula not closed) stratified by fistula type, number of previous repairs, duration of fistula and year of repair at the time of hospital discharge.

Methods

Study design

This was a retrospective cohort study using data abstracted from medical records for fistula repairs conducted from 2007 to 2013.

Setting

Guinea is a West African country with a population of about 12 million [6]. It is among the poorest countries in the world with the majority (65%) of the population living in rural areas. Health indicators are poor including a maternal mortality ratio of 724 per 100 000 live births [10].

Fistula Care supported both prevention and treatment, with a focus on treatment at three geographically dispersed centres, as well as reintegration of fistula patients into the community. The three centres that continued with repairs during the Fistula Care project are integrated within the maternity unit of hospitals in geographically dispersed regions of Guinea (Jean Paul II Hospital in Conakry, the Regional Hospital of Labé and the Prefectoral Hospital of Kissidougou).

Building capacity included ongoing training of surgeons, training of nursing staff, counselling training, quality improvement, medical monitoring, equipment provision and mentorship for continuous skills building [23]. Surgeons from the Geneva Foundation for Medical Education and Research (GFMER) travelled to Guinea on a quarterly basis to lead training sessions and monitor progress of trainees. Sixteen Guinean local surgeons received training with support from Fistula Care. They attended an average of 22 training sessions, with 12 continuing to provide surgery after the Fistula Care ended. Each centre was staffed by two or three surgeons, an anaesthetist, a counsellor and two to four nurses all trained in fistula prevention and management. Community awareness campaigns on fistula and the availability of fistula management services were conducted regularly through collaboration with rural radio, community leaders and community volunteers (village safe motherhood committees).

The three centres collectively performed on average 300–400 surgical repair operations per year. Treatment in the centres was free and included assessment and surgical repair by a surgeon, and counselling about exercises, family planning methods and restrictions on sexual intercourse and heavy labour during the healing period.

For each woman, surgical outcomes (fistula closed and dry, fistula closed with residual incontinence and fistula not closed) were assessed immediately after surgery, at hospital discharge and 3 months later. Women with a fistula that was not closed at the time of the follow-up visit were usually scheduled for another repair surgery. Patients were considered lost to follow-up if they failed to attend the follow-up appointment within 6 months of their discharge for reasons that could include residence out of the country, death and farming.

The fistula was considered not closed (immediately after surgery or in the case of initial closure breakdown within 3 months of surgery) if the woman reported an uncontrolled and continuous leakage of urine. Residual incontinence, some incontinence remaining despite fistula closure, could be urge, stress or overflow incontinence. The woman was considered dry if the fistula was closed and there was no leakage of urine or faeces.

Study population and participants

We included all women who underwent fistula repair surgery in each of the three sites between 1 January 2007 and 30 September 2013.

Data variables, source of data and data collection

The sociodemographic and clinical characteristics of fistula patients were extracted from patient files and included age at admission in the repair site, marital status, age at marriage, occupation, level of education, residence (rural/urban), parity, number of previous repairs, duration of fistula, mode of delivery causing fistula, neonatal outcome at causal delivery and type of fistula (VVF, RVF or both). Treatment outcomes (fistula closed and dry, fistula closed with residual incontinence and fistula not closed) were assessed by a dye test immediately after surgery, at the time of hospital discharge and at 3-month follow-up visit in most, but not all cases. Data were sourced from patients' files, kept at each fistula care repair hospital, using structured forms. Patient files were reviewed between April and August 2014.

Data analysis

Collected data were double-entered by two independent encoders into EpiData Entry software (version 3.1; EpiData Association, Odense, Denmark). The two data files were compared and discordances resolved by cross-checking with the data collection forms. Data were analysed using STATA 13 software (STATA Corporation, College Station, TX, USA). Frequencies (%) were calculated to describe patients' characteristics and treatment outcomes. Pearson's chi-square (χ^2) was used to compare proportions of treatment outcomes for selected variables with a level of significance set at $P = 0.05$ and a 95% confidence intervals.

Ethics

Ethics approval was obtained from the Guinean National Ethics Committee for Health Research, the MSF Ethics Review Board (Geneva, Switzerland) and the Ethics

Advisory Group of the International Union Against Tuberculosis and Lung Disease, Paris, France.

Results

Sociodemographic and clinical characteristics

Overall 2116 women underwent surgical repair for female genital fistula at the three repair hospitals. The demographic and clinical characteristics of these women are presented in Table 1. The median age at presentation was 32 years (interquartile range (IQR) 25–40). The majority of women ($n = 2045$, 97%) had vesicovaginal fistula and 3% had rectovaginal fistula or a combination of both. Half of the women were married before the age of 17 years and 29% developed the fistula at their first pregnancy and 1978 women (93%) had stillbirths for the referent pregnancy. Almost one of five women had the fistula for 5 years or more at the time they came to the hospital for repair.

Treatment outcomes

Figure 1 shows patient flow and treatment outcomes after surgery, at discharge and 3 months after follow-up. Of the 2116 women who underwent surgical repair, 1748 (83%) had a closed fistula and were dry immediately after surgery. At discharge, 1795 (85%) of all the repaired women had a closed fistula. A total of 1680 of these (79%) were closed and dry of urine and/or faeces, while 115 (5%) had residual incontinence despite fistula closure. Of the 1663 (79%) who completed 3 months of follow-up, 1405 (84.5%) had a closed fistula and 80% were continent (dry). Overall 453 women (21%) were lost to follow-up.

Over the 7-year duration of the project, fistula closure rate at discharge increased from 85% in 2007 to 89% in 2013, and the continence rate rose from 78% in 2007 to 88% in 2013 (Figure 2). At 3 months of follow-up, fistula closure rate increased from 88% in 2007 to 95% in 2013, and the continence rate from 85% in 2007 to 94% in 2013 (Figure 2).

At hospital discharge, all women with a rectovaginal fistula (RVF) had a closed fistula and remained dry (Table 2). Of those with vesicovaginal fistula, 80% had a closed fistula and were dry, while 5% had a closed fistula with residual incontinence. Of those with both a VVF and an RVF, 56% were closed and dry and 2% were closed but had residual incontinence. Compared to women with a previous history of repair attempts, women with no previous history of repair attempts had statistically significantly better surgical outcomes ($P = 0.001$). Women who

A. Delamou *et al.* **Outcomes of fistula repair in Guinea****Table 1** Demographic and clinical characteristics of women who underwent fistula repair in hospitals supported by Fistula Care in Guinea, 2007 to 2013

Variables	Number (%)
Total	2116
Age at presentation to repair centre (in years)	
<17	63 (3.0)
17–24	402 (19.0)
25–49	1293 (61.1)
≥50	326 (15.4)
Unknown	32 (1.5)
Marital status	
Single	82 (3.9)
Married/Union	1442 (68.1)
Separated	378 (17.9)
Widow	189 (8.9)
Unknown	25 (1.2)
Age at marriage (in years)	
<17 [†]	1212 (57.3)
≥17	279 (13.2)
Unknown	625 (29.5)
Occupation	
Housewife	2026 (95.7)
Worker	65 (3.1)
Unknown	25 (1.2)
Education	
None	1896 (89.6)
Primary	99 (4.7)
Secondary and higher	22 (1.0)
Unknown	99 (4.7)
Residence	
Rural	1912 (90.4)
Urban	195 (9.2)
Unknown	9 (0.4)
Parity	
1 birth	625 (29.5)
2–5 births	950 (44.9)
≥6 birth	510 (24.1)
Unknown	31 (1.5)
Previous repairs attempts	
0	1219 (57.6)
1	514 (24.3)
2	236 (11.1)
≥3	107 (5.1)
Unknown	40 (1.9)
Duration of fistula (in years)	
≤1	405 (19.1)
2 to 4	448 (21.2)
≥5	1017 (48.1)
Unknown	246 (11.6)
Mode of causal delivery	
Vaginal	1377 (65.1)
Caesarean section	698 (33.0)
Unknown	41 (1.9)
Neonatal outcome	
Alive	102 (4.8)

Table 1 (Continued)

Variables	Number (%)
Stillborn	1978 (93.5)
Unknown	36 (1.7)
Type of fistula	
Vesicovaginal fistula (VVF)	2045 (96.6)
Rectovaginal fistula (RVF)	23 (1.1)
VVF + RVF	48 (2.3)

[†]In Guinea, the legal age of marriage for women is 17 years.

had their fistula fewer than 5 years had a better outcome than women with 5 years or more duration ($P = 0.003$). Also surgical outcomes were better in women with rectovaginal fistula than those with vesicovaginal fistula or both types ($P < 0.001$).

Discussion

This is the first retrospective study of data from Guinea reporting on cumulative outcomes at 3-month follow-up among women who underwent surgical repair for female genital fistula over a period of 7 years. Overall, the study showed high rates of fistula closure and continence at discharge and at 3-month follow-up. The rate of loss to follow-up at 3 months in this setting is low compared to 40% reported by Bishinga *et al.* [15] from Burundi.

We observed a high closure rate at discharge (85%) and at 3 months of follow-up (84.5%), similar to what was reported in other studies in African settings [11, 24–27]. The continence rate was 79% at discharge and 80% at 3 months of follow-up, which falls within the range reported by Arrowsmith *et al.* [13] and higher than what was reported by Bishinga *et al.* (67%) [15] in Burundi. Even though rates of closure and continence depend on the severity of the fistula, making comparison of different settings difficult, one explanation could be the fact that our programme built on experience in surgical repair of fistula over time, with closure and continence rates increasing over time, while the one in Burundi was in its first year of implementation. In addition, fistula management requires specialised training for not only surgeons but also medical staff involved in the hospital management of patients to ensure good and sustainable results. Our results showed an improvement in the continence rate over time suggesting an improvement in the quality of care due to continuous training and supervision throughout the project life cycle. It has been reported that fistula that is repaired sooner after occurrence, as well as simple fistula provides better results [12, 20], and our results could suggest the unusual situa-

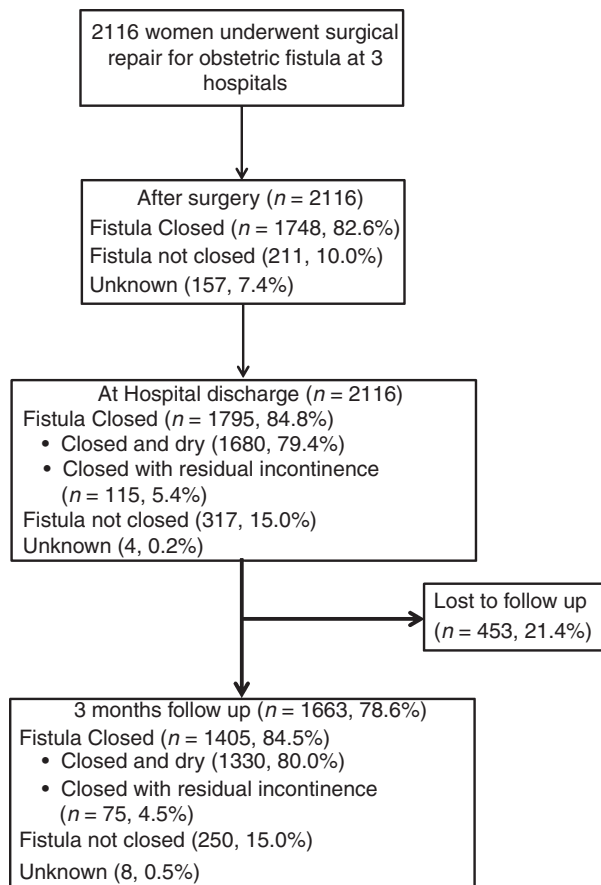


Figure 1 Patient flow and follow-up at three fistula repair hospitals supported by the Fistula Care Project in Guinea, 2007 to 2013.

tion of an established programme seeing progressively ‘earlier’ and ‘simpler’ cases. Introducing physiotherapy in the package of fistula care at the repair hospitals could also contribute in improving outcomes and reducing residual incontinence [28].

Our loss to follow-up rate at 3 months (21%) was lower than that reported from a routine programme setting (41%) in Burundi by Bishinga *et al.* [15] and by Browning *et al.* [16] at 6 months (39.5%). However, some of the women in our study (17%) were part of either a prospective cohort study or a randomised controlled trial conducted at one of the sites, which used specific proactive strategies to reduce loss to follow-up [14, 24], thus potentially causing an artificial inflation of our follow-up rate.

Our loss to follow-up rate was, however, higher than the 8% reported by Maulet *et al.* [25] from a 18-month prospective follow-up of a 120 fistula patients’ cohort conducted in Mali and Niger, and the 14% reported by Nielsen *et al.* [26] in Western Ethiopia after a 14-

28-month community-based follow-up. In both studies, active search of women was conducted and could explain the low rate of loss to follow-up observed.

We observed a high rate of stillbirths with the referent delivery, better repair outcomes in women with no history of previous repair attempt, women with shorter duration of fistula and women having rectovaginal fistula, consistent with the findings reported by other studies from Africa [12, 20].

Finally, prevention of fistula occurrence is the definite answer towards a fistula-free generation. This must include education about community awareness to reduce sociocultural factors that increase risk of obstetric fistula, promotion of deliveries in health facilities, improvement of contraceptive methods use [27] and advocacy for compliance with country laws aimed to reduce pregnancies in teenagers.

As the government in Guinea is planning to launch a new fistula project, we concur with Bishinga *et al.* [15] that fistula programmes might benefit from a model of cohort monitoring such as that used routinely with chronic diseases such as tuberculosis, where patients are closely followed up for longer periods with various strategies (phones, home visits, community health workers, etc.) to evaluate programmes success.

For instance, a study in Ethiopia [16] reported 22 women who came back leaking at 6 months of follow-up among 141 women initially cured at discharge. This confirms the risk of late breakdown after successful repair and warrants more research into the causes and associations of late fistula.

The main limitation of this study was that the reasons for loss to follow-up could not be determined, as patients lost to follow-up were not routinely followed up using home visits or phone calls. A strength of our study is the large number of patients with different types of fistula, making this the largest reported national cohort of fistula patients. Because some data were routinely collected during the course of the Fistula Care project at the three repair hospitals, capacity building in the area of data recording and review, with regular monitoring and supervision, was routinely carried out; thus, the data are likely to be accurate and representative of what was actually going on at the sites. Finally, we report our results using the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines [29].

Conclusion

In conclusion, routine repair services for female genital fistula in low resources settings are feasible and can yield good outcomes. However, for clinical services to be successful, they must be couched in a ‘holistic pro-

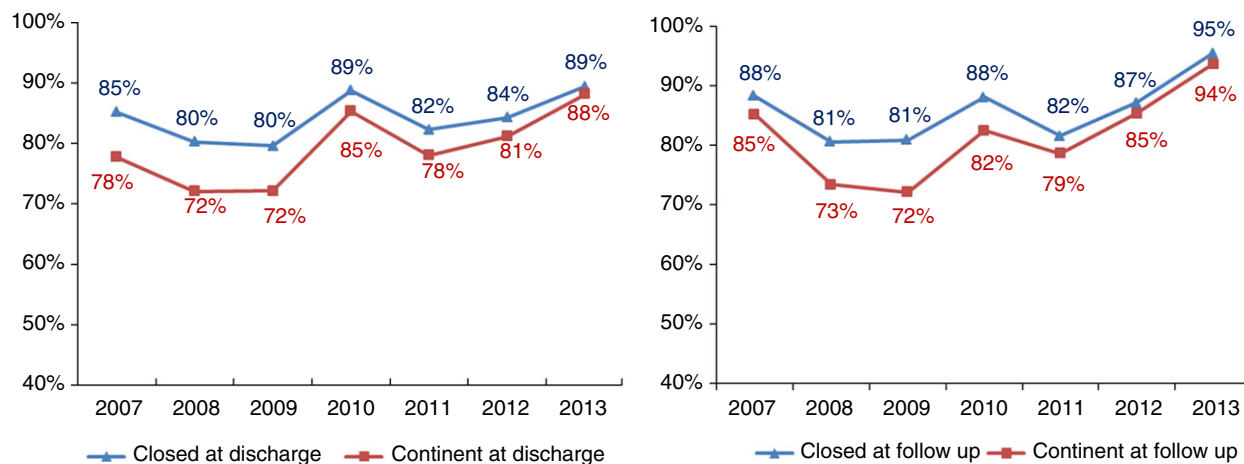
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Figure 2 Annual trend in treatment outcomes at hospital discharge and at 3 months of follow-up for women undergoing surgical repair for fistula in Guinea, 2007 to 2013.

Table 2 Fistula closure and continence status by type, number of previous repair attempts and duration of fistula for women undergoing surgical repair for obstetric fistula at hospital discharge in Guinea, 2007 to 2013

Selected variables	Surgical outcome				P*
	Fistula closed				
	Dry	Residual incontinence	Fistula not closed	Fistula status unknown	
Type of fistula (<i>n</i> = 2116)					
VVF	1630 (79.7)	114 (5.6)	297 (14.5)	4 (0.2)	<0.001
RVF	23 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	
VVF and RVF	27 (56.3)	1 (2.0)	20 (41.7)	0 (0.0)	
Previous repair attempts (<i>n</i> = 2076)					
No previous repair attempt	1019 (83.6)	48 (3.8)	153 (12.5)	1 (0.1)	0.001
≥1 previous repair attempt	634 (74.0)	67 (7.8)	153 (17.9)	3 (0.3)	
Duration of fistula (1870)					
≤1 year	350 (86.4)	13 (3.2)	41 (10.1)	1 (0.2)	0.003
2 to 4 years	371 (82.8)	23 (5.1)	54 (12.1)	0 (0.0)	
≥5 years	777 (76.4)	72 (7.1)	167 (16.4)	1 (0.1)	

*Comparing proportions of closed fistula.

gramme' that encompasses supportive policies, active community engagement and partnership, and psychosocial support in addition to an effective and functioning supply of services. Further work is needed to trace women who are lost to follow-up and to maintain excellent repair services throughout Guinea and other countries where obstetric fistulas are common.

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References

1. Wall LL. A framework for analyzing the determinants of obstetric fistula formation. *Stud Fam Plann* 2012; **43**: 255–272.
2. Zheng AX, Anderson FW. Obstetric fistula in low-income countries. *Int J Gynaecol Obstet* 2009; **104**: 85–89.
3. Capes T, Ascher-Walsh C, Abdoulaye I, Brodman M. Obstetric fistula in low and middle income countries. *Mt Sinai J Med* 2011; **78**: 352–361.
4. Longombe A, Claude K, Ruminjo J. Fistula and traumatic genital injury from sexual violence in a conflict setting in Eastern Congo: case studies. *Reprod Health Matters* 2008; **16**: 132–141.
5. Raassen T, Ngongo C, Mahendeka M. Iatrogenic genitourinary fistula: an 18-year retrospective review of 805 injuries. *Int Urogynecol J* 2014; **25**: 1699–1706.
6. Wall LL. Obstetric fistula is a “neglected tropical disease”. *PLoS Negl Trop Dis* 2012; **6**: e1769.
7. Osotimehin B. Obstetric fistula: ending the health and human rights tragedy. *Lancet* 2013; **381**: 1702–1703.
8. Stanton C, Holtz SA, Ahmed S. Challenges in measuring obstetric fistula. *Int J Gynaecol Obstet* 2007; **99**(Suppl 1): S4–S9.
9. Adler AJ, Ronsmans C, Calvert C, Filippi V. Estimating the prevalence of obstetric fistula: a systematic review and meta-analysis. *BMC Pregnancy Childbirth* 2013; **13**: 246.
10. Institut National des Statistiques G. *Enquête Démographique et de Santé et a Indicateurs Multiples, Guinée* 2012. INS & Macro: Claverton, MD, USA, 2014.
11. Tayler-Smith K, Zachariah R, Manzi M *et al.* Obstetric Fistula in Burundi: a comprehensive approach to managing women with this neglected disease. *BMC Pregnancy Childbirth* 2013; **14**: 164.
12. Hawkins L, Spitzer RF, Christoffersen-Deb A, Leah J, Mabeya H. Characteristics and surgical success of patients presenting for repair of obstetric fistula in western Kenya. *Int J Gynaecol Obstet* 2013; **120**: 178–182.
13. Arrowsmith SD, Barone MA, Ruminjo J. Outcomes in obstetric fistula care: a literature review. *Curr Opin Obstet Gynecol* 2013; **25**: 399–403.
14. Barone MA, Frajzyngier V, Ruminjo J *et al.* Determinants of postoperative outcomes of female genital fistula repair surgery. *Obstet Gynecol* 2012; **120**: 524–531.
15. Bishinga A, Zachariah R, Hinderaker S, Tayler-Smith K, van den Boogaard W, Taryor R. High loss to follow-up following obstetric fistula repair surgery in rural Burundi: is there a way forward? *Public Health Action* 2013; **3**: 113–117.
16. Browning A, Menber B. Women with obstetric fistula in Ethiopia: a 6-month follow-up after surgical treatment. *BJOG* 2008; **115**: 1564–1569.
17. Frajzyngier V, Ruminjo J, Barone MA. Factors influencing urinary fistula repair outcomes in developing countries: a systematic review. *Am J Obstet Gynecol* 2012; **207**: 248–258.
18. Landry E, Frajzyngier V, Ruminjo J *et al.* Profiles and experiences of women undergoing genital fistula repair: Findings from five countries. *Glob Public Health* 2013; **8**: 926–942.
19. Muleta M, Rasmussen S, Kiserud T. Obstetric fistula in 14,928 Ethiopian women. *Acta Obstet Gynecol Scand* 2010; **89**: 945–951.
20. Kayondo M, Wasswa S, Kabakyenga J *et al.* Predictors and outcome of surgical repair of obstetric fistula at a regional referral hospital, Mbarara, western Uganda. *BMC Urol* 2011; **11**: 23.
21. Umoiyoho AJ, Inyang-Etoh EC, Etukumana EA. Obstetric fistula repair: experience with hospital-based outreach approach in Nigeria. *Glob J Health Sci* 2012; **4**: 40–45.
22. Leye MM, Ndiaye P, Diongue M *et al.* [Socio-demographic factors and the treatment of obstetric fistula in southeastern Senegal]. *Sante Publique* 2012; **24**: 47–54.
23. Fistula C. *Project Report: October 2007 to December 2013, Part 1I: Country Accomplishments*. Fistula Care/EngenderHealth: New York, 2013.
24. Barone M, Frajzyngier V, Arrowsmith SD *et al.* Non-inferiority of short-term urethral catheterization following fistula repair surgery: study protocol for a randomized controlled trial. *BMC Pregnancy Childbirth* 2012; **12**: 5. doi: 10.1186/1472-6874-12-5.
25. Maulet N, Keita M, Macq J. Medico-social pathways of obstetric fistula patients in Mali and Niger: an 18-month cohort follow-up. *Trop Med Int Health* 2013; **18**: 524–533.
26. Nielsen HS, Lindberg L, Nygaard U *et al.* A community-based long-term follow-up of women undergoing obstetric fistula repair in rural Ethiopia. *BJOG* 2009; **116**: 1258–1264.
27. Delamou A, Koivogui A, Dubourg D, Delvaux T. Family planning in Guinea: a need for better public commitment. *Trop Med Int Health* 2014; **19**: 65–73.
28. Castille YJ, Avocetien C, Zaongo D, Colas JM, Peabody JO, Chatat CH. Impact of a program of physiotherapy and health education on the outcome of obstetric fistula surgery. *Int J Gynaecol Obstet* 2014; **124**: 77–80.
29. von Elm E, Altman D, Egger M, Gøtzsche P, Vandenbroucke J. STROBE Initiative: The strengthening the reporting of observational studies in epidemiology (STROBE) statement: guidelines for reporting observational studies. *J Clin Epidemiol* 2008; **61**: 349.

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Factors associated with loss to follow-up in women undergoing repair for obstetric fistula in Guinea

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Abstract

OBJECTIVES To analyse the trend of loss to follow-up over time and identify factors associated with women being lost to follow-up after discharge in three fistula repair hospitals in Guinea.

METHODS This retrospective cohort study used data extracted from medical records of fistula repairs conducted from 1 January 2007 to 30 September 2013. A woman was considered lost to follow-up if she did not return within 4 months post-discharge. Factors associated with loss to follow-up were identified using a subsample of the data covering the period 2010–2013.

RESULTS Over the study period, the proportion of loss to follow-up was 21.5% (448/2080) and varied across repair hospitals and over time with an increase from 2% in 2009 to 52% in 2013. After adjusting for other variables in a multivariate logistic regression model, women who underwent surgery at Labe hospital and at Kissidougou hospital were more likely to be lost to follow-up than women operated at Jean Paul II hospital (OR: 50.6; 95% CI: 24.9–102.8) and (OR: 11.5; 95% CI: 6.1–22.0), respectively. Women with their fistula closed at hospital discharge (OR: 3.2; 95% CI: 2.1–4.8) and women admitted for repair in years 2011–2013 showed higher loss to follow-up as compared to 2010. Finally, loss to follow-up increased by 2% for each additional kilometre of distance a client lived from the repair hospital (OR: 1.002; 95% CI: 1.001–1.003).

CONCLUSION Reimbursement of transport was the likely reason for change over time of LTFU. Reducing geographical barriers to care for women with fistula could sustain fistula care positive outcomes.

keywords Obstetric fistula, loss to follow-up, Guinea, Conakry, Fistula care

Introduction

According to the recent estimates, the lifetime prevalence of obstetric fistula in women aged 15–49 years is 1.57 per 1000 in sub-Saharan Africa [1, 2]. In Guinea, 6 per 1000 of women of reproductive age carry the lifetime risk of experiencing obstetric fistula [3]. Although significant progress has been made in more than 50 countries in the prevention and management of obstetric fistula, significant gaps remain [4]. First, access to emergency obstetric care including skilled birth attendance in many countries in sub-Saharan Africa is still low [5]. Second, despite high fistula closure rates (80–90%) observed after surgery [6, 7], studies in sub-Saharan Africa have

reported late repair breakdown ranging from 2.6% to 4.3% between 6 and 24 months after discharge from hospital [8–10]. Third, the loss to follow-up rates for women discharged after repair can be high [8, 11].

Data on the post-repair period in fistula programmes are scarce, but in the literature, the young maternal age, low maternal level of education, housewife/unemployed mothers, transportation costs related to long distances to the hospital and inadequate counselling at facilities are often reported to be associated with LTFU in maternal health programmes in developing countries [12, 13].

There is no standard prescribed time period for follow-up after fistula repair. However, a routine post-operative visit at 3–6 months is usually reported [8, 11, 14, 15].

Bishinga *et al.* reported 40% and 80% loss to follow-up at 3 and 6 months, respectively, among 479 women repaired for fistula at the Medecins Sans Frontieres (MSF) supported Gitega Fistula Centre in Burundi, and Browning *et al.* reported 40% loss to follow-up among 390 women at 6 months post-repair at the Bahir Dar Hamlin Fistula Centre in Ethiopia [8, 11]. In Burundi, the authors could not examine all the factors associated with loss to follow-up because of limited available information. In Ethiopia, the authors underlined the importance of monitoring late breakdown and emphasised the need for reinforcing follow-up after repair to sustain long-term outcomes for programmes [8, 16].

Previous reports show that repair breakdown can occur after discharge [9, 10] or, conversely, that incontinence may either improve or resolve after discharge [8]. Therefore, from a programme perspective, the 3 months follow-up visit provides useful information about the dynamic of repair outcomes over time [11], while from the woman's perspective, it is an opportunity for the doctor to confirm the closure/continence status and release her to resume daily activities including sexual relations, as it is routine practice in many fistula repair programmes to advise women not to perform heavy work or resume sexual relations for 3 months post-op [15]. Furthermore, if the repair has broken down, the visit is an opportunity to provide continued care to the woman and can identify her current needs. Following up women after repair is essential to better understand their reintegration process, their health status including any persistent urinary symptoms and their quality of life in the post-repair period [9, 17]. Therefore, understanding the predictors of loss to follow-up is important for optimising care.

In 2007, EngenderHealth (an international reproductive health non-governmental organisation) helped to establish and strengthen fistula management services at three hospitals in Guinea through the Fistula Care project [18]. An evaluation of the repair outcomes from these facilities was published in a previous paper [19]. In this study, our objective was to analyse the trend of loss to follow-up over time and identify factors associated with women being lost to follow-up after discharge in three fistula repair hospitals in Guinea.

Methods

Study design

This was a retrospective cohort study using data extracted from medical records of all fistula repairs conducted from 1 January 2007 to 30 September 2013 at three hospitals in Guinea.

Setting

Guinea is among the poorest countries in the world with the majority (65%) of its 12 million inhabitants living in rural areas and a maternal mortality ratio of 724 per 100 000 live births [3]. The maternity units of three urban hospitals in three regions of Guinea (Jean Paul II Hospital in Conakry, the Regional Hospital of Labé and the Prefectural Hospital of Kissidougou) where obstetric fistula repair was supported by the Fistula Care Project. Each three hospitals were staffed by two or three surgeons, an anaesthetist, a counsellor and two to four nurses all trained in fistula prevention and management. They collectively performed on average 300–400 fistula surgical repair per year. Treatment in these hospitals was free and included assessment and surgical repair by a surgeon, and counselling about exercises, family planning methods, and restrictions on sexual intercourse and heavy labour up to 3 months post-repair [19].

Study population and participants

We included all women originating from Guinea ($N = 2080$) who underwent fistula repair in each of the three hospitals between 1 January 2007 and 30 September 2013. Women coming from outside Guinea (36 women, 1.7% of the total sample) were excluded from this study because they were originally given financial support for residence in nearby facility-sponsored social houses and could therefore bias the results.

Data and key indicators

The socio-demographic and clinical characteristics of fistula patients available from patient records included the following: age at admission at hospital (in years), marital status (single, married, divorced or widow), residence (rural or urban), woman's occupation (housewife or worker – defined as working for pay), level of education (none versus primary or higher), duration of fistula (in years), place of delivery (home, home with traditional birth attendant and health structure), neonatal outcome (alive and stillborn), mode of delivery (vaginal and Caesarean section), type of obstetric fistula (vesicovaginal fistula – VVF, rectovaginal fistula – RVF, and both – VVF + RVF), previous repairs, residential distance from the repair centre and year of surgery (2007 to 2013).

Treatment outcomes were fistula closure (Yes or No) continence status after surgery at hospital discharge (Yes or No), assessed by a dye test prior to hospital discharge. Loss to follow-up (LTFU), defined as the woman failing to return for a follow-up visit within 4 months after

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being discharged, was recorded as a dichotomous variable (Yes or No). Study data were abstracted from patients' files kept at each fistula care repair hospital by two members of the study team, using structured forms. Data were extracted from medical records between 1 April and 31 August 2014 and covered 69 months, from 1 January 2007 to 30 September 2013.

Data analysis

Data collected from patients' files were double-entered by two independent encoders into EpiData software (EpiData Association, Odense, Denmark). The two data files were compared and discordances resolved by cross-checking with the paper registers. Data were analysed using STATA 13 software (STATA Corporation, College Station, TX, USA). We used the whole sample ($N = 2080$) to summarise demographic and clinical characteristics, treatment outcomes and LTFU using frequencies (%) and means (with standard deviation). Because essentially in the early years, there was no variation of LTFU to examine, we considered the subsample of women operated from 2010 to 2013 at the three repair hospitals for the bivariate and multivariate analyses. Pearson's chi-square test (χ^2) or Student's *t*-test were used, respectively, to compare proportions or means of variables between women lost to follow-up and those not lost to follow-up with a level of significance set at $P = 0.05$ and a 95% confidence interval. A logistic regression model was used to derive the unadjusted and adjusted odds ratios. The significance level was set at 5% with a 95% confidence interval. All study variables were considered *a priori* for inclusion in the logistic regression model looking at factors associated with LTFU. The adequacy of the final model was tested by the Hosmer and Lemeshow test for goodness of fit.

Ethics approvals

Ethics approval was obtained from the Guinean National Ethics Committee for Health Research and the Scientific Committee of the Department of Public Health of the Faculty of Medicine of the University of Conakry.

Results**Sociodemographic and clinical characteristics**

Overall, 2080 women originating from Guinea underwent surgical repair for female genital fistula at the three repair hospitals. Table 1 shows the demographic and clinical characteristics of these women. More than

half of the repairs (1083, 52%) were done at Kissidougou hospital. The mean age at presentation was 34 ± 12 years. The majority of women ($n = 1413$, 69%) were married or in union, had no level of education (1865, 94%) and had vesicovaginal fistula (2011, 98%). Only 5% (101 women) had a livebirth for the referent pregnancy.

Loss to follow-up

Of the 2080 women repaired between 2007 and 2013, 448 women were reported LTFU (21.5%, 95% CI, 19.8–23.3). There was little variation in the overall proportion of LTFU in the early years of the Fistula Care Project (2007–2009), while this proportion varied drastically between repair hospitals and over time, increasing from 2% in 2009 to 52% in 2013 (Figure 1).

Bivariate analyses

In bivariate analyses, the demographic and clinical characteristics of women LTFU were similar to those were not LTFU (1632 women) at presentation. LTFU was significantly associated with repair hospital, age of the woman at admission, duration of fistula, level of education, place of delivery, continence status at discharge and year of surgery (Table 2).

Women operated at Labe hospital (odds ratio (OR): 13.2; 95% confidence interval (95% CI): 8.8–19.7) and Kissidougou hospital (OR: 4.9; 95% CI: 3.3–7.3) were more likely to be lost to follow-up than women operated at Jean Paul II hospital. The odds of LTFU increased by 1% for each additional year of age at presentation (OR: 1.01; 95% CI: 1.00–1.01) and 2% for each additional year of duration of fistula (OR: 1.02; 95% CI: 1.00–1.03). The odds of LTFU were higher among women with no education (OR: 2.4; 95% CI: 1.3–4.4), and those giving birth at home (OR: 1.7; 95% CI: 1.1–2.6). Women not continent at discharge (OR: 1.8; 95% CI: 1.4–2.4) and those admitted for surgery from 2011 to 2013 (OR: 2.8; 95% CI: 2.0–3.9), (OR: 2.2; 95% CI: 1.5–3.1) and (OR: 6.4; 95% CI: 4.4–9.4), respectively, were more likely to be lost to follow-up than those in 2010.

Multivariable analysis

After adjusting for possible confounding factors (Table 2), LTFU status remained significantly associated with repair hospital, continence status at discharge and year of surgery. Distance between the repair hospital and a woman's residence became significant after adjusting for other variables.

A. Delamou *et al.* **Fistula: loss to follow-up in Guinea****Table 1** Demographic and clinical characteristics of Guinean women undergoing repair for obstetric fistula in three hospitals from 2007 to 2013 in Guinea (*N* = 2080)

Variables	Mean (SD) or Median (IQR)	Number (%)
Total		2080
Repair hospital		
Jean Paul II hospital		549 (26.4)
Labé hospital		448 (21.5)
Kissidougou hospital		1083 (52.1)
Mean age at reception (SD), years	34.2 (12.3)	
Residence		
Rural		1890 (91.2)
Urban		182 (8.8)
Mean number of previous repairs (SD)	0.63 (0.88)	
Mean duration of fistula (SD), years	9.9 (9.0)	
Marital status		
Single		79 (3.8)
Married/Union		1413 (68.7)
Divorced/Separated		375 (18.2)
Widow		189 (9.2)
Occupation		
Housewife		1991 (96.9)
Worker		64 (3.1)
Level of education		
None		1865 (94.1)
Primary & higher		118 (5.9)
Mean parity (SD)	3.5 (2.5)	
Place of delivery		
Home		463 (22.8)
Home with traditional birth attendants (TBA)		217 (10.7)
Health structure		1354 (66.5)
Neonatal outcome		
Alive		101 (4.9)
Stillborn		1944 (95.1)
Mode of causal delivery		
Vaginal		1353 (66.3)
Caesarean section		687 (33.7)
Type of obstetric fistula		
Vesicovaginal fistula (VVF)		2011 (96.7)
Rectovaginal fistula (RVF)		23 (1.1)
VVF + RVF		46 (2.2)
Fistula status after surgery		
Closed		1726 (89.5)
Not closed		203 (10.5)
Continence status at discharge		
Continent		1653 (79.6)
Not continent		423 (20.4)
Year of surgery		
2007		178 (8.6)
2008		181 (8.7)
2009		246 (11.9)

Table 1 (Continued)

Variables	Mean (SD) or Median (IQR)	Number (%)
2010		381 (18.4)
2011		493 (23.8)
2012		369 (17.8)
2013		227 (10.9)
Mean distance from repair hospital (SD), km	260.7 (180.5)	

SD, Standard deviation.

Women who underwent surgery at Labe hospital and at Kissidougou hospital were more likely to be LTFU than women operated on at Jean Paul II hospital (OR: 50.6; 95% CI: 24.9–102.8) and (OR: 11.5; 95% CI: 6.1–22.0), respectively.

The odds of LTFU was higher among women with their fistula closed at hospital discharge (OR: 3.2; 95% CI: 2.1–4.8) and women admitted in 2011 (OR: 3.2; 95% CI: 2.0–4.9), in 2012 (OR: 1.9; 95% CI: 1.2–3.1) and 2013 (OR: 5.3; 95% CI: 3.2–8.5). Finally, the odds of LTFU increased by 2% for each additional km of distance a woman lived from the repair hospital (OR: 1.002; 95% CI: 1.001–1.003).

Discussion

This study provides an overview of the factors associated with loss to follow-up after discharge of women undergoing obstetric fistula repair in Guinea. About 22% of women who underwent repair for obstetric fistula between 2007 and 2013 were LTFU.

We found that LTFU significantly varied between repair hospitals and over time from 2010. In addition, year of surgery was associated with being LTFU in both bivariate and multivariate analyses. The main reason for this might be the reimbursement in cash of transportation costs to women during the early years of the Fistula Care Project (2007–2009). In 2010, this policy was changed and women were just counselled and encouraged to return at their own expense. However, Kissidougou Hospital was involved in a cohort study from September 2007 to September 2010 [14] and in a clinical trial in 2012 [20, 21]. In 2012, the hospital continued to provide transportation as well as gifts for women enrolled in the trial and returning for their follow-up visit, leading to a decrease in LTFU from 62% in 2011 to 11% in 2012 (Figure 1). Direct provision of resources such as cash reimbursement of transportation costs might improve the

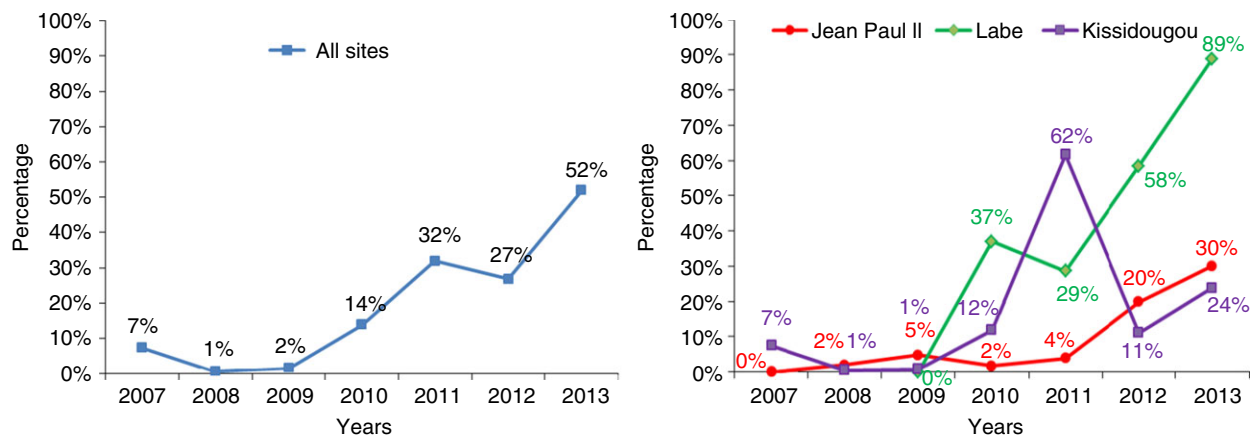
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Figure 1 Annual trend in the proportions of loss to follow-up among women undergoing surgical repair for obstetric fistula in three repair hospitals in Guinea, 2007 to 2013.

outcomes of fistula programmes, particularly those including social reintegration and long-term follow-up after repair.

We found that women who underwent surgery at Labe hospital and at Kissidougou hospital were more likely to be lost to follow-up than women operated at Jean Paul II hospital. One reason for this might be the geographical distribution of clients. Jean Paul II hospital is located in the capital city Conakry where transportation to and from surrounding localities is easy and cheap, allowing more women to come back for their follow-up visit. In contrast, Labe hospital (Middle Guinea) and Kissidougou hospital (Forest Guinea) are located in mountainous regions where the repair hospitals are far and not always easily accessible by women coming from remote areas. Another reason might be the way counselling sessions prior to discharge were conducted across repair hospitals might have differed (for instance the interaction between clients and providers). The odds of LTFU increased by 13% for each additional 50 km of distance a client lived from the repair hospital, suggesting that women living further away from repair hospitals were more likely to miss their follow-up visits. Distance to repair site has already been identified as a barrier to access to fistula care by Bishinga *et al.* [11] and Browning *et al.* [8] who reported high loss to follow-up at 3 and 6 months post-repair, respectively, in Burundi and Ethiopia, even in a context where transportation costs were reimbursed. As distance to facilities is an issue for access even in the presence of cost reimbursement [11], one possible solution would be to implement some type of post-discharge fistula care by providing decentralised follow-up through training and involvement of medical teams of district hos-

pitals and even health centres [22]. The use of mobile phones for follow-up could also yield good results, such as in Tanzania where the use of mobile phone technology to transfer funds to cover transport costs for fistula patients increased access to fistula care by 49% [23]. Community-based follow-up has also been suggested as a means to increase follow-up rates [9] and sustain good outcomes at discharge in many studies [6, 19, 24, 25].

In our context, there is a need to improve the coordination mechanism between repair hospitals to ensure every woman suffering from fistula is referred to the nearest repair hospital. The mean distance between a woman's residence and repair hospital observed in this study (261 ± 181 km) shows that many women were repaired far from their residence because repairs were planned in periodic repair sessions. Some women were sent from one repair hospital to another, depending on the availability of the surgery team.

Women who were successfully closed and dry at discharge (continent) were less likely to return for their 3 months follow-up visit. Previous studies have reported higher closure and continence rates in women with relatively simple and recently occurred fistula [24, 25]. This suggests that women with more complex fistula might give up their search for care and decide not to return for follow-up. These women are probably demoralised after years of living with their fistula and suffering of intractable social exclusion [26, 27]. However, Browning *et al.* [8] have reported from Ethiopia that 96.1% of those who returned for follow-up after 6 months were not completely healed at the time of discharge (including women with residual incontinence), while only 49.1% of those who were healed at discharge returned. Possible

A. Delamou *et al.* **Fistula: loss to follow-up in Guinea****Table 2** Logistic regression identifying factors associated with being lost to follow-up among women who have undergone fistula repair in three repair hospitals from 2010 to 2013 in Guinea (*N* = 1475)

Variables	Women LTFU N (%)	Bivariate analysis Unadjusted OR (95% CI)	Multivariate analysis Adjusted* OR (95% CI)
Total	1475	1475	1390
Repair hospital			
Jean Paul II hospital	33 (7.7)	1	1
Labé hospital	214 (52.2)	13.17 (8.79–19.73)	50.6 (24.86–102.98)
Kissidougou hospital	183 (28.9)	4.89 (3.30–7.26)	11.55 (6.07–22.00)
Age at reception, years	36.1 (12.4)	1.01 (1.00–1.02)	1.00 (0.98–1.01)
Residence			
Rural	398 (29.0)	1	1
Urban	32 (32.3)	1.17 (0.75–1.81)	1.02 (0.54–1.95)
Number of previous repairs	0.65 (0.9)	1.05 (0.93–1.20)	1.05 (0.88–1.25)
Duration of fistula, years	10.8 (8.9)	1.02 (1.00–1.03)	1.00 (0.97–1.02)
Marital status			
Single	11 (22.0)	1	1
Married/Union	292 (28.2)	1.39 (0.70–2.76)	0.75 (0.32–1.73)
Divorced/Separated	67 (29.8)	1.50 (0.73–3.11)	0.77 (0.32–1.87)
Widow	53 (35.8)	1.98 (0.94–4.18)	0.89 (0.34–2.34)
Occupation			
Housewife	415 (29.4)	1.82 (0.84–3.96)	0.62 (0.24–1.62)
Worker	8 (18.6)	1	1
Level of education			
None	400 (30.6)	2.41 (1.32–4.41)	0.64 (0.36–1.14)
Primary & higher	13 (15.5)	1	1
Parity	3.8 (2.5)	1.01 (0.97–1.06)	0.98 (0.95–1.02)
Place of delivery			
Home	117 (32.7)	1.68 (1.09–2.60)	1.36 (0.77–2.40)
Home with TBA	35 (22.4)	1	1
Health structure	268 (29.1)	1.42 (0.95–2.12)	1.16 (0.67–2.01)
Neonatal outcome			
Alive	30 (36.6)	1.44 (0.90–2.29)	1.30 (0.71–2.37)
Stillborn	390 (28.6)	1	1
Mode of causal delivery			
Vaginal	276 (28.8)	1	1
Caesarean section	143 (29.7)	1.05 (0.82–1.33)	1.06 (0.73–1.55)
Type of obstetric fistula			
Vesicovaginal fistula (VVF)	415 (29.2)	1.97 (0.55–6.74)	1.66 (0.40–6.82)
Rectovaginal fistula (RVF)	3 (17.7)	1	1
VVF + RVF	12 (31.6)	2.15 (0.52–8.93)	1.36 (0.26–7.07)
Continence status at discharge			
Continent	322 (26.7)	1	1
Not continent	106 (39.7)	1.81 (1.37–2.38)	3.20 (2.15–4.79)
Year of surgery			
2010	55 (14.4)	1	1
2011	158 (32.1)	2.80 (1.98–3.94)	3.17 (2.04–4.92)
2012	99 (26.8)	2.17 (1.51–3.14)	1.95 (1.23–3.11)
2013	118 (52.0)	6.42 (4.36–9.44)	5.26 (3.24–8.52)
Distance from repair hospital (km)	249.6 (178.6)	0.98 (0.942–1.010)	1.002 (1.001–1.003)

OR, Odds ratios; CI, Confidence interval; LTFU, Loss to follow-up.

Hosmer–Lemeshow test for goodness-of-fit: χ^2 (8 d.f.) = 9.80; *P* = 0.28.

*Multivariate analysis adjusting for possible confounding factors. Bold figures show significant confidence intervals.

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explanations they provided were that (i) women who were cured at discharge were more likely to reintegrate into a normal social life, resume sexual intercourse and become pregnant again in the short term; and/or (ii) they do not feel it is important to attend the follow-up because they consider themselves cured [8, 16].

The main limitation of this study was that it was based on data from medical records only, and no additional qualitative data were collected on why women did not return for follow-up. For women who did not return, we were unable to establish their closure and continence status at 3 months post-op nor were we able to evaluate their mental health status. Poorer mental health has been reported to be present in women with poorer acute outcomes [8]. Finally, we were unable to characterise the sample in relation to all women who have experienced fistula, or to the average woman in Guinea (for instance using Demographic and Health Survey data). However, this is one of the few studies to examine factors associated with loss to follow-up in women undergoing repair for obstetric fistula in low income countries using such a large dataset.

Conclusion

This study shows that repair hospital, fistula status at discharge, year of surgery and distance from repair hospital were the main factors associated with loss to follow-up status post-discharge in women repaired for obstetric fistula in Guinea. Providing resources to reduce geographical and financial barriers (in particular transportation costs) for women suffering from fistula, improving pre-discharge counselling and implementing active follow-up strategies could reduce LTFU and improve fistula programme performance. More mixed methods research, both qualitative and quantitative, is needed to trace women who are lost to follow-up to understand patients' reasons and motivations for not returning for follow-up visits and the cultural and family dynamics that influence these decisions.

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References

1. Adler AJ, Ronsmans C, Calvert C, Filippi V. Estimating the prevalence of obstetric fistula: a systematic review and meta-analysis. *BMC Pregnancy Childbirth* 2013; **13**: 246.
2. Osotimehin B. Obstetric fistula: ending the health and human rights tragedy. *Lancet* 2013; **381**: 1702–1703.
3. Institut National des Statistiques, Guinea. *Enquete Demographique et de sante - Etude a indicateurs multiples (EDS-MICS), Guinee 2012*. Macro Int.: Conakry: INS, 2014.
4. Peterman A, Johnson K. Facility-level services for obstetric fistula repair in Africa. *Int J Gynaecol Obstet* 2015; **128**: 77–79.
5. Lozano R, Wang H, Foreman K *et al.* Progress towards Millennium Development Goals 4 and 5 on maternal and child mortality: an updated systematic analysis. *Lancet* 2011; **378**: 1139–1165.
6. Tayler-Smith K, Zachariah R, Manzi M *et al.* Obstetric Fistula in Burundi: a comprehensive approach to managing women with this neglected disease. *BMC Pregnancy Childbirth* 2013; **13**: 164.
7. Hawkins L, Spitzer RF, Christoffersen-Deb A, Leah J, Mabeya H. Characteristics and surgical success of patients presenting for repair of obstetric fistula in western Kenya. *Int J Gynaecol Obstet* 2013; **120**: 178–182.
8. Browning A, Menber B. Women with obstetric fistula in Ethiopia: a 6-month follow up after surgical treatment. *BJOG* 2008; **115**: 1564–1569.
9. Nielsen HS, Lindberg L, Nygaard U *et al.* A community-based long-term follow up of women undergoing obstetric fistula repair in rural Ethiopia. *BJOG* 2009; **116**: 1258–1264.
10. Wilson AL, Chipeta E, Kalilani-Phiri L, Tauro F, Tsui AO. Fertility and pregnancy outcomes among women with obstetric fistula in rural Malawi. *Int J Gynaecol Obstet* 2011; **113**: 196–198.
11. Bishinga A, Zachariah R, Hinderaker S *et al.* High loss to follow-up following obstetric fistula repair surgery in rural Burundi: is there a way forward? *Public Health Action* 2013; **3**: 113–117.
12. Sidze LK, Faye A, Tetang SN *et al.* Different factors associated with loss to follow-up of infants born to HIV-infected or uninfected mothers: observations from the ANRS 12140-PEDIACAM study in Cameroon. *BMC Public Health* 2015; **15**: 228.
13. Lubega M, Musenze IA, Joshua G *et al.* Sex inequality, high transport costs, and exposed clinic location: reasons for loss to follow-up of clients under prevention of mother-to-child HIV transmission in eastern Uganda - a qualitative study. *Patient Prefer Adherence* 2013; **7**: 447–454.
14. Barone MA, Frajzyngier V, Ruminjo J *et al.* Determinants of postoperative outcomes of female genital fistula repair surgery. *Obstet Gynecol* 2012; **120**: 524–531.

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15. Arrowsmith SD, Ruminjo J, Landry EG. Current practices in treatment of female genital fistula: a cross sectional study. *BMC Pregnancy Childbirth* 2010; **10**: 73.
16. Maulet N, Keita M, Macq J. Medico-social pathways of obstetric fistula patients in Mali and Niger: an 18-month cohort follow-up. *Trop Med Int Health* 2013; **18**: 524–533.
17. De Ridder D, Abubacar K & Raassen T *et al.*, eds. *Obstetric Fistula in the Developing World*. Societe Internationale d'Urologie (SIU): Montreal (QB), 2012; 87–122.
18. Fistula Care. *Project Report: October 2007 to December 2013, Part 1: Country Accomplishments*. Fistula Care/EngenderHealth: New York, 2013.
19. Delamou A, Diallo M, Beavogui AH *et al.* Good clinical outcomes from a 7-year holistic programme of fistula repair in Guinea. *Trop Med Int Health*. 2015; **20**: 813–819.
20. Barone M, Frajzyngier V, Arrowsmith SD *et al.* Non-inferiority of short-term urethral catheterization following fistula repair surgery: study protocol for a randomized controlled trial. *BMC Pregnancy Childbirth* 2012;**12**:5. doi: 10.1186/1472-6874-12-5.
21. Barone MA, Widmer M, Arrowsmith S *et al.* Breakdown of simple female genital fistula repair after 7 day versus 14 day postoperative bladder catheterisation: a randomised, controlled, open-label, non-inferiority trial. *Lancet*. 2015. pii: S0140-6736(14)62337-0. doi: 10.1016/S0140-6736(14)62337-0
22. Mattison C, Fiorentino R. *Strengthening Health Systems through the Levels of Fistula Care Framework – A Literature Review*. Fistula Care/EngenderHealth: New York, 2011.
23. Fiander A, Ndahani C, Mmuya K, Vanneste T. Results from 2011 for the transportMYpatient program for overcoming transport costs among women seeking treatment for obstetric fistula in Tanzania. *Int J Gynaecol Obstet* 2013; **120**: 292–295.
24. Kayondo M, Wasswa S, Kabakyenga J *et al.* Predictors and outcome of surgical repair of obstetric fistula at a regional referral hospital, Mbarara, western Uganda. *BMC Urol* 2011; **11**: 23.
25. Hawkins L, Spitzer RF, Christoffersen-Deb A, Leah J, Mabeya H. Characteristics and surgical success of patients presenting for repair of obstetric fistula in western Kenya. *Int J Gynaecol Obstet* 2013; **120**: 178–182.
26. Yeakey MP, Chipeta E, Taulo F, Tsui AO. The lived experience of Malawian women with obstetric fistula. *Cult Health Sex* 2009; **11**: 499–513.
27. Mselle LT, Moland KM, Evjen-Olsen B, Mvungi A & Kohi TW. “I am nothing”: experiences of loss among women suffering from severe birth injuries in Tanzania. *BMC Womens Health* 2011;**11**:49. doi: 10.1186/1472-6874-11-49.


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RESEARCH

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Factors associated with the failure of obstetric fistula repair in Guinea: implications for practice

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Abstract

Background: The prevention and treatment of obstetric fistula still remains a concern and a challenge in low income countries.

The objective of this study was to estimate the overall proportions of failure of fistula closure and incontinence among women undergoing repair for obstetric fistula in Guinea and identify its associated factors.

Methods: This was a retrospective cohort study using data extracted from medical records of fistula repairs between 1 January 2012 and 30 September 2013. The outcome was the failure of fistula closure and incontinence at hospital discharge evaluated by a dye test. A sub-sample of women with vesicovaginal fistula was used to identify the factors associated with these outcomes.

Results: Overall, 109 women out of 754 (14.5 %; 95 % CI:11.9–17.0) unsuccessful repaired fistula at discharge and 132 (17.5 %; 95 % CI:14.8–20.2) were not continent.

Failure of fistula closure was associated with vaginal delivery (AOR: 1.9; 95 % CI: 1.0–3.6), partially (AOR: 2.0; 95 % CI: 1.1–5.6) or totally damaged urethra (AOR: 5.9; 95 % CI: 2.9–12.3) and surgical repair at Jean Paul II Hospital (AOR: 2.5; 95 % CI: 1.2–4.9).

Women who had a partially damaged urethra (AOR: 2.5; 95 % CI: 1.5–4.4) or a totally damaged urethra (AOR: 6.3; 95 % CI: 3.0–13.0) were more likely to experience post-repair urinary incontinence than women who had their urethra intact.

Conclusion: At programmatic level in Guinea, caution should be paid to the repair of women who present with a damaged urethra and those who delivered vaginally as they carry greater risks of experiencing a failure of fistula closure and incontinence.

Keywords: Obstetric fistula, Factors associated, Repair, Failure, Incontinence, Guinea

Plain English summary

Why was this study conducted?

This study was conducted to estimate the proportion of women who still leak urine after surgery for obstetric fistula and identify why the surgery was not successful in these women.

How was the study conducted?

We evaluated three hospitals in Guinea where surgery for OF is conducted. We collected data from the medical records of women who got surgery for obstetric fistula between 1 January 2012 and 30 September 2013. For each woman, we determined whether or not she was still leaking continuously (unsuccessful surgery) or had some residual leakage (the hole was closed but still some leakage remains) after surgery and at the time the woman left the hospital.

Only women who had vesicovaginal or both vesicovaginal and recto-vaginal fistulas were considered for the

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identification of factors that explain why a woman stop leaking or not after surgery.

What was found in this study?

The fistula was not closed in 109 women out of 754 (14.5 %) at the time they left the hospital. Overall 132 women (17.5 %) were still leaking urine either continuously or from time to time.

Women who delivered vaginally were two times as likely to continue leaking after surgery compared to women who delivered by C-section. Those with a partially damaged urethra or totally damaged urethra were respectively two times and six times as likely to continue leaking after surgery compared to women with a urethra not damaged.

What have we learned?

During routine hospital repair of obstetric fistula in Guinea, surgeons should pay more attention to women who present with a damaged urethra and those who report having delivered vaginally because these kind of women are more difficult to treat than others.

Background

Obstetric fistula is an abnormal opening between a woman's vagina and bladder (vesicovaginal fistula, VVF), vagina and rectum (rectovaginal fistula, RVF) or vagina and both bladder and rectum (VVF + RVF) [1]. It is a serious morbidity that primarily follows obstructed labour and results in continuous and uncontrolled leakage of urine [1].

Despite international and national efforts, the prevention and treatment of obstetric fistula (OF) still remains a concern and a challenge in low income countries where access to emergency obstetric care and skilled birth attendant are insufficient [2, 3].

In sub-Saharan Africa, the lifetime prevalence of OF was estimated to be 1.60 per 1000 women of reproductive age (95 % CI 1.16, 2.10) [4] to 3.0 cases per 1000 (95 % CI: 1.3–5.5) [5].

Because of the smell of urine that results, women suffering of fistula are often abandoned by their spouses and relatives, keeping victims in poverty, isolation and depression [6, 7]. These women are also frequently exposed to medical complications such as infection, pain, sexual dysfunction and secondary infertility [8, 9].

The diagnosis of OF is done clinically through a pelvic exam verified by a dye test or cystoscopy and the treatment is mainly surgical through transvaginal or transabdominal techniques [10]. Surgical closure rates are reported to be as high as 90 % but vary from one repair hospital to another [2, 11, 12]. Rates also vary according to different characteristics including the denominator used (first time repair versus all repairs), repair technique, expertise of the surgeon, fistula characteristics and

post-operative nursing care [13, 14]. In addition, authors might report the repair outcomes using different definitions [14, 15]. While some present the rates of fistula closure [16, 17], others clearly distinguish fistula closure and continence following repair surgery [2, 8]. As a result, comparisons of outcomes and performances from different contexts become difficult. To date there is no consensus on the classification of fistula and the definition of the outcomes of repair [13, 14].

Factors influencing the outcome of repair have been studied in different contexts. For instance, studies conducted by Barone et al. [17] with 1274 women in five countries in sub-Saharan Africa (including Guinea) and Asia, by Kayondo et al. [8] with 77 women at the referral regional hospital of Mbarara, Uganda, and by Nardos et al. [18] with 1045 fistula repairs conducted at the Addis Ababa Hamlin Fistula Hospital, showed that poor repair outcomes were significantly associated with complete urethral destruction, severe vaginal scarring, small bladders, and previous repairs.

While becoming continent after repair represents a rebirth for women suffering from fistula, failure of fistula closure can lead to further depression and isolation [19, 20]. In addition, repeat surgery for a fistula that has not been closed represents an additional social and economic burden for the woman and fistula care programmes as well as reduced likelihood of successful closure with subsequent repair attempts [21].

In Guinea, maternal health indicators are among the worst in Africa [22] and obstetric fistula is still prevalent [23]. From 2006 to 2013, more than 3000 repairs of female genital fistula (mostly OF) were supported by Engenderhealth in Guinea [24]. It is therefore important to document the country's past experience in the management of fistula, especially in the most recent years, by identifying the factors that lead to unsuccessful closure or incontinence following successful fistula closure. This could inform and improve the implementation and performance of fistula care programmes, and contribute to improving the quality of services at repair hospitals. Even though Barone et al. [17] used data from Guinea in their study, the sample was not sufficient to allow country specific analysis, calling for additional research to fill the existing knowledge gap.

Therefore, the objective of this study was to estimate the overall proportions of failures of fistula closure and incontinence (following successful closure) at hospital discharge, and analyse their predictors in women who underwent repair for obstetric fistula in 2012 and 2013 in Guinea.

Methods

Study setting

Guinea is a coastal West African country with an estimated population of 10.5 million people, most of whom

live in rural areas (65 %) and in poverty [25]. Guinea has an estimated lifetime prevalence of obstetric fistula of 0.6 % among women aged 15–49 with regional variations ranging from 0.2 to 1.2 %, although this figure is likely underestimated [23]. The country is characterised by a low national modern contraceptive prevalence (6 %), concurrent high fertility rate of 5.1 children per woman, and a high maternal mortality (724 deaths per 100,000 live births) [22, 26]. Over the period 2007–2012, the majority of births (54.7 %) were assisted by untrained individuals, and occurred at home (58.8 %) [23]. In 2013, Fistula repair services were available in five sites across the country, funded by international organizations such as UNFPA (Kankan Regional Hospital), WAHA International (Ignace Deen National Hospital) and EngenderHealth (Jean Paul II Hospital in Conakry, Labé Regional Hospital and Kissidougou Prefectural Hospital).

Management of fistula at the repair hospitals

At EngenderHealth supported repair hospitals, fistula surgery was free and included assessment and surgical repair by a surgeon, and counselling about physical rehabilitation, family planning methods, and restrictions on sexual intercourse and heavy labour during the healing period and up to three months post-repair. Clinical procedures before, during and after surgery were harmonized in the three repair hospitals and included a pre-operative medical check-up, systematic use of antibiotics before and during (overall five days), and catheterization immediately after surgery for up to 21 days. Repairs were performed by a national team (sometimes assisted with surgeons from the GFMER) and local surgeons who were being trained. HIV infection or nutritional status were assessed but not captured in the medical records. Transportation costs to and from repair hospital were reimbursed and women were provided accommodation during the hospital stay. For each woman, surgical outcomes included failure of fistula closure (yes/no) and fistula incontinence (yes/no) were assessed immediately after surgery and at hospital discharge for all women. Data on the management of fistula surgeries at the other repair hospitals were not collected as part of this study.

Study design

This was a retrospective cohort study examining the predictors of the failure of closure and urinary incontinence at discharge following the repair of obstetric fistula from 2012 to 2013 in three EngenderHealth supported repair hospitals in Guinea.

Study population

The study population initially included all women who underwent repair for female genital fistula in the three hospitals between January 1st, 2012 and October 31,

2013. Women with the result of the dye test at discharge missing in medical records, non-obstetric fistula and duplicates i.e. previous repairs at a different study hospital were excluded. Only women with a vesicovaginal fistula were considered in the analysis of the predictors of repair failure.

Data and key indicators

Study data were abstracted from patients' files kept at each fistula care repair hospital and covered 22 months. The socio-demographic characteristics of fistula patients included age at presentation (in years), residence (rural or urban), marital status (married/union or other -single, divorced or widow-), woman's occupation (housewife or worker) and level of education (none versus primary to higher). Gynecologic and clinical characteristics included parity, duration of labour (in days), mode of delivery (vaginal or caesarean section (CS)), neonatal outcome (alive or stillborn), and post-operative complications (fistula related or not). Fistula characteristics included type of fistula (vesicovaginal, rectovaginal, combined), vaginal scarring (yes or no), status of the urethra (intact, partially damaged or totally damaged), number of previous repairs and year of surgery. Treatment outcome was classified as follow: fistula closed (yes or no) and fistula continent (yes or no). Fistula was considered not closed when a woman had a positive dye test indicating continuous leakage of urine, as assessed by the surgeon, prior to hospital discharge. Women were considered to be incontinent at discharge when the result of the dye test was negative (fistula closed), but the woman reported a leakage of urine.

Data analysis

Patients' data were double entered by two independent data entry clerks into EpiData software (EpiData Association, Odense, Denmark), cleaned and exported for analysis in the STATA 13 software (STATA Corporation, College Station, TX, USA). We used the whole sample to summarise sociodemographic, clinical and fistula characteristics, and the outcome of repair with frequencies (%) and mean (with standard deviation). Pearson's Chi square test (χ^2) was used to compare study outcomes across categorical variables and the Student *t*-test to compare the means of study outcomes across age, parity, duration of labour and previous repair. We considered the subsample of women with vesicovaginal fistula in the bivariable and multivariate analyses. Logistic regression models derived the unadjusted and adjusted odds ratios considering both the failure of fistula closure and fistula incontinence. All study variables with a *p*-value < 0.20 in the bivariable analysis were considered for inclusion in the logistic regression model. The significance level for the logistic regression

model was set at 5 % with a 95 % confidence interval. The goodness of fit of the final model was tested by the Hosmer and Lemeshow test.

Results

Sociodemographic, clinical and fistula characteristics

Overall 785 medical records of women who underwent surgical repair for female genital fistula at the three repair hospitals were screened of which 754 records were included in the analyses (Fig. 1). The demographic, gynecologic and clinical characteristics of these women are presented in Table 1. The mean age at presentation was 35.2 ± 12.7 years. The majority of women were married (*n* = 523, 69.4 %) with no formal education (691, 91.6 %) and lived in rural areas (677, 89.8 %). Most women delivered vaginally (*n* = 489, 64.9 %) after a mean duration of labor of 3.2 (±1.6) days. A total of 687 women (91.1 %) had stillbirths for the referent pregnancy. In terms of fistula characteristics, 419 women (55.6 %) had no previous attempt of repair and 389 women (51.6 %) had intact urethra. Few women (26 women; 3.6 %) developed postoperative complications including fistula related complications (15 women; 2.1 %).

Study treatment outcomes

Figure 1 shows the study flow and repair outcomes at the time of hospital discharge by type of fistula. Overall, 109 women out of 754 (14.5 %; 95 % CI:11.9–17.0) had unsuccessful repairs at discharge and 23 additional women (3.0 %; 95 % CI:1.8–4.2) had successful repairs

but remained incontinent meaning that overall 132 (17.5 %; 95 % CI:14.8–20.2) were not continent. Of the 646 women who had VVF (86.5 % of the study sample), 87 (13.5 %; 95 % CI:10.9–16.1) had unsuccessful repairs and 23 (3.5 %; 95 % CI:2.1–4.9) remained incontinent. The 15 women who had an RVF (2.1 % of the sample) had successful repairs and were continent of stools. As for the 92 women who had both VVF and RVF (12.3 % of the sample), 21 (22.8 %; 95 % CI:14.2–31.4) had unsuccessful repairs.

Context of repair

The context of repair at the three hospitals where women were managed is presented in Table 2. Between 2012 and 2013, the three sites benefited from trainings in fistula repair and care, infection prevention and emergency obstetric care. The CS rate was significantly higher in Kissidougou hospital as compared to the other two hospitals. Overall, the systematic post-operative antibiotic treatment (up to 5 days) was high at the sites (from 96 to 100 %) with no statistically significant difference across repair hospitals. However, 51.1 % (45/88) of the women with totally damaged urethra and 79.4 % (73/92) of the combined (VVF + RVF) fistulas were repaired at the Conakry Jean Paul II Hospital (*p* < 0.001).

Factors associated with repair failure

Failure of fistula closure

In bivariable analysis, we found that mean age at presentation, mode of delivery, vaginal scarring, status of the

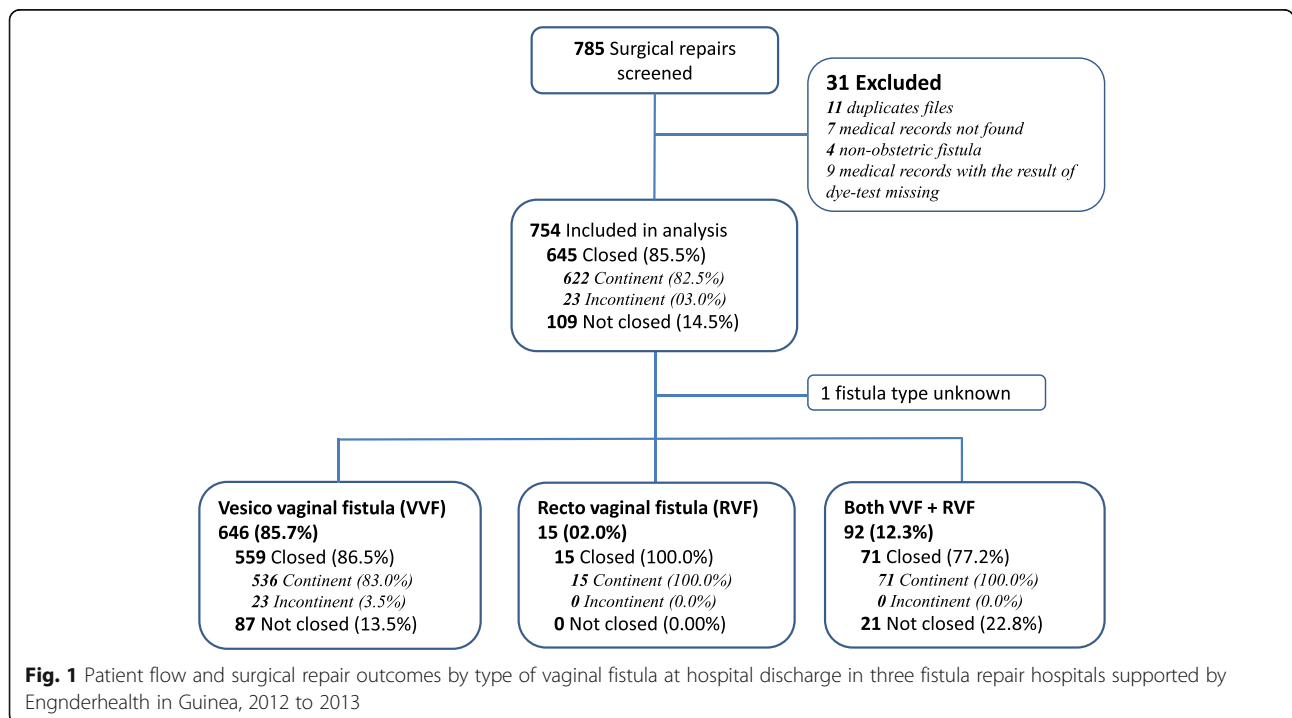


Fig. 1 Patient flow and surgical repair outcomes by type of vaginal fistula at hospital discharge in three fistula repair hospitals supported by Engenderhealth in Guinea, 2012 to 2013

Table 1 Demographic and clinical characteristics of women who underwent surgical repair of obstetric fistula in three Engenderhealth supported hospitals in Guinea, 2012 to 2013 (N = 754)

Variables	Number	Percentage
Total	754	100
Site		
Jean-Paul 2 Hospital	239	31.7
Labe regional Hospital	199	26.4
Kissidougou Distric Hospital	316	41.9
Mean age at presentation to repair centre (SD), years	35.2(12.7)	
Residence		
Rural	677	89.8
Urban	75	09.9
Unknown	2	00.3
Marital status		
Married/Union	523	69.4
Other (single, separated, widow)	208	27.6
Unknown	23	03.0
Occupation		
Housewife	711	94.3
Worker	25	03.3
Unknown	18	02.4
Education		
None	691	91.6
Primary and more	55	07.3
Unknown	8	01.1
Mean parity (SD), deliveries	3.6(2.6)	
Mean duration of labour (SD), days	3.2(1.6)	
Mode of delivery		
Vaginal	489	64.9
Caesarean section	237	31.4
Unknown	28	03.7
Neonatal outcome at delivery		
Alive	40	05.3
Stillborn	687	91.1
Unknown	27	03.6
Vaginal scarring		
Yes	373	49.2
No	371	49.5
Unknown	10	01.3
Status of the urethra		
Intact	389	51.6
Partially damaged	264	35.0
Totally damaged	88	11.7
Unknown	13	01.7

Table 1 Demographic and clinical characteristics of women who underwent surgical repair of obstetric fistula in three Engenderhealth supported hospitals in Guinea, 2012 to 2013 (N = 754) (Continued)

Variables	Number	Percentage
Previous surgical repair		
None	419	55.6
One	190	25.2
Two or more	137	18.2
Unknown	8	01.0
Route of repair		
Vaginal	732	97.1
Abdominal	14	01.8
Combined	6	00.8
Unknown	2	00.3
Year or repair		
2012	489	64.8
2013	265	35.2
Post-operative complications ^a		
None	728	96.5
Fistula related	15	02.0
Others	11	01.5

SD standard deviation, VVF vesicovaginal fistula, RVF rectovaginal fistula

^aFistula related complication: Haemorrhage (7), Wound infection (4), Urine retention (3), and Urethral narrowing (1). Other complications: Malaria (7), Hypertensive disorders (2), Diarrhoe (1), and Zona (1)

urethra and repair hospital were statistically significantly associated with the failure of fistula closure (Table 3). However, in multivariate analysis, only mode of delivery, status of the urethra and repair hospital were independently associated with the failure of fistula closure. The odds of experiencing failure of fistula closure were higher among women who delivered vaginally as compared to women who delivered by CS (AOR: 1.9; 95 % CI: 1.0–3.6). Women who had their urethra partially (AOR: 2.0; 95 % CI: 1.1–5.6) or totally damaged (AOR: 5.9; 95 % CI: 2.9–12.3) were more likely to have a fistula not closed as compared to women who had an intact urethra. Women who were repaired at Jean Paul II Hospital were more likely to have a fistula not closed at discharge than women repaired at Kissidougou hospital (AOR: 2.5; 95 % CI: 1.2–4.9).

Incontinence following successful closure

Bivariable analysis showed that age at presentation, mode of delivery, vaginal scarring, status of the urethra, previous surgical repair and repair hospital were statistically significantly associated with fistula incontinence. However, in multivariate analysis, only status of the urethra remained statistically significantly associated with fistula incontinence. Women who had a partially damaged urethra (AOR: 2.5; 95 % CI: 1.5–4.4) or a totally

Table 2 Selected characteristics of three Engenderhealth supported fistula repair hospitals in 2013 in Guinea

Variables	Hospitals		
	Jean-Paul II (Conakry)	Labe	Kissidougou
Total			
Fistula repair and care training			
Number of Fistula Surgeons	03	03	03
Number of Nurses and Midwives	12	13	07
Number of Anesthetists	02	03	03
Infection prevention training (number of attendees)	10	18	16
Obstetric care training (number of attendees)	20	17	17
Workload			
Annual number of deliveries	2024	2795	2426
Annual number of Caesarean sections (%)	342 (16.9 %)	762 (27.3 %)	791 (32.6 %)
Existence of fistula ward			
Yes	Yes	Yes	Yes
Number of beds dedicated to fistula	32	20	14
Infection prevention measures			
Sterilisation	Yes	Yes	Yes
Type of sterilisation	Autoclave	Autoclave	Autoclave
Post-operative antibiotic treatment			
Proportion of use ^a	95.7	100	98.7
Post-operative fistula related complications (number and %) ^a	7 (2.94 %)	3 (1.51 %)	5 (1.76 %)
Status of the urethra			
Intact	130 (56.5 %)	89 (44.7 %)	170 (54.5 %)
Partially damaged	55 (23.9 %)	81 (40.7 %)	128 (41.0 %)
Totally damaged	45 (19.6 %)	29 (14.6 %)	29 (4.5 %)
Type of fistula			
Vesicovaginal fistula (VVF)	159 (66.5 %)	182 (91.5 %)	305 (96.5 %)
Rectovaginal fistula (RVF)	6 (2.5 %)	5 (2.5 %)	4 (1.3 %)
Both VVF and RVF	73 (31.0 %)	12 (6.0 %)	7 (2.2 %)

^afrom the dataset

damaged urethra (AOR: 6.3; 95 % CI: 3.0–13.0) were more likely to experience post-repair urinary incontinence than women who had their urethra intact.

Discussion

This study provides an overview of the factors associated with the failure of obstetric fistula repair at hospital

discharge in Guinea, adding to the existing evidence on the subject.

The overall proportion of the failure of fistula closure observed in this study (14.5 %) is lower than what has been reported in different contexts in Africa [8, 17, 18]. These findings might be explained by differences in the level of complexity of fistula cases managed and/or characteristics of the repair hospitals (experience and skills of the staff, pre and post-surgical clinical procedures, infection prevention measures in place) [14, 15]. Barone et al. [17] who conducted their study in five countries including Guinea did not provide such information and did not stratify their results by country.

We found that failure of fistula closure varied significantly across repair hospitals. Because the three repair hospitals were part of the same project, with the same trainings, clinical procedures, equipment and trainer surgeons, the differences observed cannot be attributed to hospital characteristics unless the difference relates to differing skill levels among surgeons or to the characteristics of the fistulas repaired for which we could not adjust for in this analysis [14, 15]. It is also possible that differences in the uptake or implementation of trainings and interventions differed by repair hospital, which may have influenced the results. However, our data shows that Jean Paul II hospital in Conakry received more fistula with 'worse' characteristics than the two other hospitals, suggesting greater damage. The reasons might be because: 1) The hospital is situated in the Capital city where the national fistula trainers live, 2) It was the referral centre for fistula care during the Engenderhealth's Fistula Care Project.

After adjusting for confounding factors that were measured, we observed that failure of fistula closure was associated with mode of delivery, status of the urethra and repair hospital. However, fistula incontinence was only statistically significantly associated with the status of the urethra. Because the duration of labour was high for the women of this study (3 days or more), it is likely that the fistula already begins to develop before women are referred for a CS. Therefore, for women who benefit a CS, the extension of the fistula to involve the urethra is limited as compared to those who still deliver vaginally.

Previous studies have reported that urethral involvement might affect sphincter mechanisms and bladder size and therefore cannot be easily addressed surgically, leading to more repair failure [8, 17, 18, 27]. Vaginal scarring has been reported to be predictive of the failure of fistula closure [8, 17, 18]. However, the associations found in the bivariable analyses in our study were not sustained in multivariate analyses.

We found that fistula related postoperative complications were not associated with both failure of fistula closure and fistula incontinence in both bivariable and

Table 3 Logistic regression of the failure of fistula closure and incontinence among women with vesicovaginal fistula repaired in three Engenderhealth supported repair hospitals from 2012 to 2013 in Guinea ($N = 646$)

Variables	Failure of fistula closure (Yes)			Fistula incontinence (Yes)		
	N (%)	Unadjusted OR [95 % CI]	Adjusted ^{a,b} OR [95 % CI]	N (%)	Unadjusted OR [95 % CI]	Adjusted ^{a,c} OR [95 % CI]
Mean age at presentation (SD), years	38.9 (14.1)	1.02 (1.00–1.04)	1.02 (1.00–1.04)	38.2 (13.6)	1.02 (1.00–1.03)	1.01 (0.99–1.03)
Residence						
Rural	81 (13.4)	1	-	101 (16.7)	1	-
Urban	6 (14.0)	1.0 (0.4–2.5)		9 (20.9)	1.3 (0.6–2.8)	
Marital status						
Married/Union	55 (11.9)	1	1	70 (15.2)	1	1
Other (single, separated, widow)	29 (16.9)	1.5 (0.9–2.4)	1.1 (0.6–1.9)	36 (21.0)	1.5 (0.9–2.3)	1.2 (0.7–2.1)
Occupation						
Housewife	82 (13.4)	1	-	104 (17.0)	1	-
Worker	3 (15.8)	1.2 (0.3–4.2)		4 (21.0)	1.3 (0.4–4.0)	
Education						
None	79 (13.3)	1.0 (0.4–2.5)	-	102 (17.2)	1.4 (0.6–3.4)	-
Primary and more	6 (12.8)	1		6 (12.8)	1	
Mean parity (SD), deliveries	3.6 (2.8)	0.97 (0.89–1.06)	-	3.5 (2.8)	0.95 (0.87–1.03)	1.00 (0.90–1.11)
Mean duration of labor (SD), years	3.4 (1.6)	1.10 (0.95–1.28)	-	3.4 (1.5)	1.08 (0.95–1.24)	-
Mode of delivery						
Vaginal	65 (15.7)	2.3 (1.3–4.0)	1.9 (1.0–3.6)	80 (19.3)	1.9 (1.1–3.0)	1.5 (0.9–2.6)
Caesarean section	16 (7.6)	1	1	24 (11.4)	1	1
Neonatal outcome at delivery						
Alive	2 (6.9)	1	-	2 (6.9)	1	1
Stillborn	82 (13.6)	2.1 (0.5–9.1)		105 (17.5)	2.9 (0.7–12.2)	2.0 (0.4–9.1)
Vaginal scarring						
Yes	56 (16.8)	1.9 (1.1–2.9)	1.2 (0.7–2.0)	73 (21.9)	2.0 (1.3–3.1)	1.3 (0.7–2.1)
No	31 (10.1)	1	1	37 (12.1)	1	1
Status of the urethra						
Intact	26 (7.6)	1	1	32 (9.4)	1	1
Partially damaged	34 (14.5)	2.1 (1.2–3.5)	2.0 (1.1–5.6)	49 (20.9)	2.6 (1.6–4.1)	2.5 (1.5–4.4)
Totally damaged	27 (42.9)	9.1 (4.8–17.3)	5.9 (2.9–12.3)	29 (46.0)	8.3 (4.5–15.3)	6.3 (3.0–13.0)
Previous surgical repair	0.83 (0.99)	1.11 (0.90–1.38)	-	0.92 (1.13)	1.23 (1.02–1.48)	1.04 (0.83–1.31)
Year of repair						
2012	62 (15.2)	1.5 (0.9–2.5)	1.0 (0.6–1.8)	78 (19.1)	1.5 (1.0–2.4)	1.0 (0.6–1.6)
2013	25 (10.5)	1	1	32 (13.4)	1	1
Fistula related post-op complications						
No	84 (13.2)	1	1	107 (16.8)	1	-
Yes	3 (30.0)	2.8 (0.7–11.1)	2.9 (0.5–15.9)	3 (30.0)	2.8 (0.8–9.8)	
Repair site						
Jean-Paul 2 Hospital	33 (20.8)	2.7 (1.5–4.7)	2.5 (1.2–4.9)	36 (22.6)	1.6 (1.0–2.6)	1.6 (0.8–3.1)
Labe regional Hospital	27 (14.8)	1.8 (1.0–3.2)	1.6 (0.9–3.0)	27 (14.8)	1.0 (0.6–1.6)	0.8 (0.5–1.4)
Kissidougou District Hospital	27 (8.9)	1	1	47 (15.4)	1	1

SD standard deviation, OR odds ratios, CI confidence intervals, N number

^aMultivariate analysis adjusting for all confounding factors with p -value < 0.20 in bivariable analysis

^bHosmer-Lemeshow test for goodness-of-fit: χ^2 (8 d.f.) = 8.9; $p = 0.369$

^cHosmer-Lemeshow test for goodness-of-fit: χ^2 (8 d.f.) = 8.2; $p = 0.411$

multivariate analyses. Complications such as urine retention, wound infection and haemorrhage are likely to be linked to quality of services including quality of surgery, implementation of infection prevention measures or postoperative care and duration of catheterization [28]. Overall the occurrence of fistula related postoperative complications was low and the difference between repair hospitals was not statistically significant. This might be because antibiotics were systematically used before, during and after fistula surgery in Engenderhealth supported hospitals. Monitoring the quality of surgery and improving and sustaining quality postoperative care are needed to maintain surgeon's performance. Even though EngenderHealth had staff dedicated to its programmes with regular onsite trainings and monitoring visits, including on infection prevention measures, there might still be room for improvement.

In our study, most patient characteristics did not independently predict the failure of fistula closure nor fistula incontinence. This has previously been reported from different contexts in the literature [8, 11, 17, 18, 29]. Finally, we did not include fistula size as a variable because its assessment was unreliable in our dataset. However, in the existing literature, no relationship between fistula size and failure of fistula closure or incontinence is reported [15, 29–31].

Our study had some limitations: 1) as an observational study, it is possible that all confounding factors were not examined or controlled for; 2) because some variables such as demographic variables were self-reported, there was a possibility of inaccuracy and reporting bias; 3) there were some missing values for variables examined in the bivariable and multivariate analyses; 4) it was not clear how some fistula characteristics were recorded and there were no standard definition of complications; 5) the experience and skills of providers were not assessed and; 6) we could not account for the amount of time between surgery and discharge across repair hospitals.

However, this is one of the few studies to examine the predictors of fistula repair failure in Guinea and West Africa.

Conclusions

This study shows that in Guinea, status of the urethra was an independent predictor of failure of fistula closure and incontinence in women at discharge while mode of delivery was also a predictor of failure of fistula closure. Therefore, caution should be made when women present for repair with such characteristics. In addition, exploring others approaches such as the use of mixed methods in realist evaluation designs might provide additional insights on other factors/predictors not explored in our study [32].

Abbreviations

ANC: Antenatal care; CI: Confidence intervals; IRB: Institutional Review Board; ITM: Institute of Tropical Medicine; OF: Obstetric fistula; RVF: Rectovaginal fistula; UNFPA: United Nations Population Fund; USA: United States of America; USAID: United States Agency for International Development; WF: Vesicovaginal fistula

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Availability of data and materials

The datasets generated during and/or analysed during the current study are available from the authors upon reasonable request and with permission of the Guinean National Ethics Committee for Health Research.

Authors' contributions

AD, TD and VDB initiated the study and developed the study protocol. All authors approved the study protocol. AD, AHB, MC, KD, DK and THB collected the data. AD, SS and AT conducted the analysis and developed the draft manuscript with TD, WHZ and VDB. All authors commented on the draft manuscript and then read, and approved the final manuscript.

Competing interests

The authors declare that they have no competing interests.

Consent for publication

The protocol does not include any individual person's data; hence consent to publish is not applicable.

Ethical approval and consent to participate

This study protocol was approved by the Institutional Review Board of the Institute of Tropical Medicine of Antwerp, Belgium (IRB# 968/14), and the National Ethics Committee for Health Research of Guinea (Ref# 22/CNERS/14). Because this was a retrospective review of routine programmatic data, participants were not consented. However, the principle of confidentiality and anonymity were met.

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References

- WHO. Obstetric fistula. Guiding principles for clinical management and programme development. Geneva: Lewis G and de Bernis L; 2007. Assessed 28 Sept 2016. Available at: http://apps.who.int/iris/bitstream/10665/43343/1/9241593679_eng.pdf.
- Taylor-Smith K, Zachariah R, Manzi M, van den Boogaard W, Vandeborne A, Bishinga A, et al. Obstetric Fistula in Burundi: a

- comprehensive approach to managing women with this neglected disease. *BMC Pregnancy Childbirth*. 2014;14:164.
3. Osotimehin B. Obstetric fistula: ending the health and human rights tragedy. *Lancet*. 2013;381(9879):1702–3.
 4. Adler AJ, Ronsmans C, Calvert C, Filippi V. Estimating the prevalence of obstetric fistula: a systematic review and meta-analysis. *BMC Pregnancy Childbirth*. 2013;13:246.
 5. Maheu-Giroux M, Filippi V, Samadoulougou S, Castro MC, Maulet N, Meda N, Kirakoya-Samadoulougou F. Prevalence of symptoms of vaginal fistula in 19 sub-Saharan Africa countries: a meta-analysis of national household survey data. *Lancet Glob Health*. 2015;3(5):e271–8. doi:10.1016/S2214-109X(14)70348-1.
 6. Ahmed S, Holtz SA. Social and economic consequences of obstetric fistula: life changed forever? *Int J Gynaecol Obstet*. 2007;99 Suppl 1:S10–5.
 7. Wall LL. Obstetric vesicovaginal fistula as an international public-health problem. *Lancet*. 2006;368(9542):1201–9.
 8. Kayondo M, Wasswa S, Kabakyenga J, Mukiiibi N, Senkungu J, Stenson A, et al. Predictors and outcome of surgical repair of obstetric fistula at a regional referral hospital, Mbarara, western Uganda. *BMC Urol*. 2011;11:23.
 9. Gutman RE, Dodson JL, Mostwin JL. Complications of treatment of obstetric fistula in the developing world: gynatresia, urinary incontinence, and urinary diversion. *Int J Gynaecol Obstet*. 2007;99 Suppl 1:S57–64.
 10. Mohr S, Brandner S, Mueller MD, Dreher EF, Kuhn A. Sexual function after vaginal and abdominal fistula repair. *Am J Obstet Gynecol*. 2014;211(1):74–6.
 11. Wall LL, Karshima JA, Kirschner C, Arrowsmith SD. The obstetric vesicovaginal fistula: characteristics of 899 patients from Jos, Nigeria. *Am J Obstet Gynecol*. 2004;190(4):1011–9.
 12. Delamou A, Diallo M, Beavogui AH, Delvaux T, Millimono S, Kourouma M, Beattie K, Barone M, Barry TH, Khogali M, Edginton M, Hinderaker SG, Ruminjo J, Zhang WH, De Brouwere V. Good clinical outcomes from a 7-year holistic programme of fistula repair in Guinea. *Trop Med Int Health*. 2015;20(6):813–9. doi:10.1111/tmi.12489.
 13. Frajzyngier V, Ruminjo J, Barone MA. Factors influencing urinary fistula repair outcomes in developing countries: a systematic review. *Am J Obstet Gynecol*. 2012;207(4):248–58.
 14. Arrowsmith SD, Barone MA, Ruminjo J. Outcomes in obstetric fistula care: a literature review. *Curr Opin Obstet Gynecol*. 2013;25(5):399–403.
 15. Ruminjo JK, Frajzyngier V, Bashir AM, Asiiimwe F, Barry TH, Bello A, et al. Clinical procedures and practices used in the perioperative treatment of female genital fistula during a prospective cohort study. *BMC Pregnancy Childbirth*. 2014;14:220.
 16. Muleta M, Rasmussen S, Kiserud T. Obstetric fistula in 14,928 Ethiopian women. *Acta Obstet Gynecol Scand*. 2010;89(7):945–51.
 17. Barone MA, Frajzyngier V, Ruminjo J, Asiiimwe F, Barry TH, Bello A, et al. Determinants of postoperative outcomes of female genital fistula repair surgery. *Obstet Gynecol*. 2012;120(3):524–31.
 18. Nardos R, Browning A, Chen CC. Risk factors that predict failure after vaginal repair of obstetric vesicovaginal fistulae. *Am J Obstet Gynecol*. 2009;200(5):578.e1–4.
 19. Landry E, Frajzyngier V, Ruminjo J, Asiiimwe F, Barry T, Bello A, et al. Profiles and experiences of women undergoing genital fistula repair: Findings from five countries. *Glob Public Health*. 2013;8(8):926–42.
 20. Umoiyoho AJ, Inyang-Etoh EC, Abah GM, Abasiattai AM, Akaiso OE. Quality of life following successful repair of vesicovaginal fistula in Nigeria. *Rural Remote Health*. 2011;11(3):1734.
 21. Maulet N, Keita M, Macq J. Medico-social pathways of obstetric fistula patients in Mali and Niger: an 18-month cohort follow-up. *Trop Med Int Health*. 2013;18(5):524–33.
 22. WHO, UNICEF, UNFPA, World Bank Group and the United Nations Population Division. Trends in maternal mortality: 1990 to 2015: estimates by WHO, UNICEF, UNFPA, World Bank Group and the United Nations Population Division. Geneva: WHO, UNICEF, UNFPA, World Bank Group and the United Nations Population Division; 2015. Assessed 21 Mar 2016. Available at: <http://www.unfpa.org/publications/trends-maternal-mortality-1990-2015>.
 23. Institut National des Statistiques, Guinée. Enquete Demographique et de sante - Etude a indicateurs multiples (EDS-MICS), Guinée 2012. Conakry: INS; Macro Int; 2014.
 24. Fistula C. Project Report: October 2007 to December 2013, Part 11: Country Accomplishments. New York: *Fistula Care/EngenderHealth*; 2013.
 25. Institut National des Statistiques, Guinée. Pauvreté et inégalités en Guinée de 1994 à 2012: analyse à partir d'enquêtes auprès des ménages. Conakry: INS; PAM; BM; BAD; PNUD; EU; 2013.
 26. Delamou A, Koivogui A, Dubourg D, Delvaux T. Family planning in Guinea: a need for better public commitment. *Trop Med Int Health*. 2014;19(1):65–73.
 27. Hawkins L, Spitzer RF, Christoffersen-Deb A, Leah J, Mabeya H. Characteristics and surgical success of patients presenting for repair of obstetric fistula in western Kenya. *Int J Gynaecol Obstet*. 2013;120(2):178–82.
 28. Barone MA, Widmer M, Arrowsmith S, Ruminjo J, Seuc A, Landry E, Barry TH, Danladi D, Djangnikpo L, Gbawuru-Mansaray T, Harou I, Lewis A, Muleta M, Nembunzu D, Olupot R, Sunday-Adeoye I, Wakasiaka WK, Landoulsi S, Delamou A, Were L, Frajzyngier V, Beattie K, Gülmezoglu AM. Breakdown of simple female genital fistula repair after 7 day versus 14 day postoperative bladder catheterisation: a randomised, controlled, open-label, non-inferiority trial. *Lancet*. 2015;386(9988):56–62. doi:10.1016/S0140-6736(14)62337-0.
 29. Sjoveian S, Vangen S, Mukwege D, Onsrud M. Surgical outcome of obstetric fistula: a retrospective analysis of 595 patients. *Acta Obstet Gynecol Scand*. 2011;90(7):753–60.
 30. Goh JT, Browning A, Berhan B, Chang A. Predicting the risk of failure of closure of obstetric fistula and residual urinary incontinence using a classification system. *Int Urogynecol J Pelvic Floor Dysfunct*. 2008;19(12):1659–62.
 31. Raassen TJ, Verdaasdonk EG, Vierhout ME. Prospective results after first-time surgery for obstetric fistulas in East African women. *Int Urogynecol J Pelvic Floor Dysfunct*. 2008;19(1):73–9.
 32. Marchal B, Dedzo M, Kegels G. A realist evaluation of the management of a well-performing regional hospital in Ghana. *BMC Health Serv Res*. 2010;10:24. doi:10.1186/1472-6963-10-24.

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Review

Pregnancy and childbirth after repair of obstetric fistula in sub-Saharan Africa: Scoping Review

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Abstract

OBJECTIVE To synthesise the evidence on pregnancy and childbirth after repair of obstetric fistula in sub-Saharan Africa and to identify the existing knowledge gaps.

METHODS A scoping review of studies reporting on pregnancy and childbirth in women who underwent repair for obstetric fistula in sub-Saharan Africa was conducted. We searched relevant articles published between 1 January 1970 and 31 March 2016, without methodological or language restrictions, in electronic databases, general Internet sources and grey literature.

RESULTS A total of 16 studies were included in the narrative synthesis. The findings indicate that many women in sub-Saharan Africa still desire to become pregnant after the repair of their obstetric fistula. The overall proportion of pregnancies after repair estimated in 11 studies was 17.4% (ranging from 2.5% to 40%). Among the 459 deliveries for which the mode of delivery was reported, 208 women (45.3%) delivered by elective caesarean section (CS), 176 women (38.4%) by emergency CS and 75 women (16.3%) by vaginal delivery. Recurrence of fistula was a common maternal complication in included studies while abortions/miscarriage, stillbirths and neonatal deaths were frequent foetal consequences. Vaginal delivery and emergency C-section were associated with increased risk of stillbirth, recurrence of the fistula or even maternal death.

CONCLUSION Women who get pregnant after repair of obstetric fistula carry a high risk for pregnancy complications. However, the current evidence does not provide precise estimates of the incidence of pregnancy and pregnancy outcomes post-repair. Therefore, studies clearly assessing these outcomes with the appropriate study designs are needed.

keywords pregnancy, childbirth, post-repair, obstetric fistula, sub-Saharan Africa

Introduction

Obstetric fistula (OF) is a preventable maternal condition whose eradication 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 [1, 2]. A review by Adler *et al.* [3] and a meta-analysis by Maheu-Girou *et al.* [4] reported similar estimates of the lifetime prevalence of OF in sub-Saharan Africa: between 1.0 and 1.57 per 1000 in women aged 15–49 years. Women living with fistula may suffer not only from other physical impediments but also

psychologically and socially (divorce, isolation or rejection by relatives and community) [5, 6].

In the past decade, an increasing commitment to holistic care of fistula has occurred in sub-Saharan Africa [2, 7]. After international funding of fistula care programmes worldwide [8–10], 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 latter contributed to achieving satisfactory post-operative closure rates for an increased number of women [11–15].

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More research on fistula has resulted in a better understanding of determinants of both fistula development and surgical outcomes [16–18].

As reported in the literature, the fistula occurring during childbirth is, in the majority of cases (over 80%), associated with stillbirth [15, 18–20]. In addition, a recent review shows that the fulfilment of their social roles is a key factor for rehabilitation of women after OF repair [21]. In many countries where fistula incidence is high, becoming a mother is an important component of fulfilling these social roles [20, 22–24]. However, for a repaired woman, becoming pregnant and giving birth might increase the risk of fistula recurrence [22–24]. Also, repair after previous attempts to close the fistula is often technically difficult for the surgeon and exhausting for the woman [25, 26].

As efforts to increase access to treatment of fistula in low-income countries continue [2], pregnancy and childbirth after OF repair are an emerging concern because repaired women remain at high risk of developing either a recurrence of fistula or a complication during pregnancy and childbirth. It is usually recommended to perform an elective caesarean section for subsequent delivery of women repaired for fistula [23, 27, 28], but there is little evidence whether and to what extent this recommendation is followed and implemented. The few data available on pregnancy and childbirth after OF repair and the factors that influence its outcome have not been synthesised in order to guide fistula care programmes and to identify research priority areas. The objectives of this review were to [1] identify and describe studies examining pregnancy and childbirth after repair of OF in sub-Saharan Africa; [2] synthesise the evidence on main outcomes, that is pregnancy and childbirth and factors associated with these outcomes; and [3] identify the existing knowledge gaps along with future research priorities.

Methods

Search strategy

A scoping review of studies reporting on subsequent pregnancy and childbirth in women who underwent repair for obstetric fistula in sub-Saharan Africa was conducted using the guidance for conducting scoping reviews developed by the Joanna Briggs Institute [29]. Our aim was to get a broad overview of the existing evidence, which is consistent with scoping studies [29, 30].

A literature search for relevant articles published between 1 January 1970 and 15 March 2016, without methodological or language restrictions, was carried out in electronic databases PubMed (1970–2016), Popline

(1970–2016), Embase (1970–2016), Web of Science (1973–2016), Global Library-African Index Medicus (2006–2016), general Internet sources (Google Scholar), grey literature and reference lists for primary studies on pregnancy and childbirth after obstetric fistula repair using the following search terms: ‘fistula’, ‘pregnancy’, ‘delivery’, ‘childbirth’, ‘birth’ and ‘reintegration’. The search strategies were designed according to the specifications of each database. There was no difference between the databases in terms of results yielded. We did not include ‘sub-Saharan Africa’ as search term to allow a broad search that would include all papers published on the study topic. The last search was carried out on 15 March 2016.

Inclusion/Exclusion criteria

The review included studies conducted in sub-Saharan Africa, between 1 January 1970 and 15 March 2016 which examined pregnancies and childbirth in women after repair of an OF. We excluded case studies and studies on non-obstetric fistula.

Screening

After removing duplicates and following to the review protocol developed *a priori*, two authors (AD and BU) independently reviewed titles and abstracts of all articles for their relevance and compliance with the selection criteria followed by full-text screening of selected articles. Discrepancies were resolved by discussion between two reviewers with the assistance of an experienced researcher (TD). Reference Manager[®] version 12.01 (Thomson Reuters) was used for screening/checking for duplicates and examining titles and abstracts. We also reported on limitations of the included studies.

Data collection

A standardised data collection form was used to extract study data, and evidence tables were generated to describe and summarise the characteristics of included studies, study outcomes and potential factors associated with study outcomes. Study characteristics including author, year of publication, time period covered by the study, country, setting (whether rural or urban, hospital based or population based or both), study design, sample size and study population were collected. Study outcomes on the maternal side comprised the occurrence of pregnancy (yes/no), pregnancy outcomes for the mother (abortion/miscarriage, term pregnancy with delivery, ongoing pregnancy at the end of the study and maternal death) and recurrence of the fistula. On the child side,

study outcomes were live birth, stillbirth or neonatal death. The potential factors associated with pregnancy (or getting pregnant) included the reported desire for children, reported fear of fistula recurrence, resuming and timing of sexual intercourse, marital status after repair, use of family planning methods. Finally, factors associated with maternal and neonatal outcomes such as the use of antenatal care during pregnancy and delivery mode (at home or at hospital, vaginal delivery or planned *vs.* emergency C-section) were collected.

Results

Description of the studies included

The initial literature search yielded 2717 studies and 29 additional studies were identified through other sources. After removing duplicates, we screened the titles of the remaining 1947 studies and excluded 1767 irrelevant studies. A total of 133 of 180 were excluded based on the abstracts. Of the 47 full texts assessed for eligibility, 31 were excluded and 16 studies were included in the qualitative synthesis. Figure 1 shows the PRISMA flow chart of the study selection process [31].

The 16 studies that met our inclusion criteria were published between 1978 and 2016, mostly in the past 10 years. Studies were conducted in only seven sub-Saharan African countries: five in Nigeria [27, 28, 32–34], four in Ethiopia [5, 22–24], two in Malawi [35, 36], one in Niger [37], one in Mali [38], one in both Mali and Niger [39], one in Sierra Leone [40] and one in Eritrea [41] (Table 1).

Eleven studies were conducted in hospitals, with 10 studies in urban referral hospitals. Five studies were community based. In terms of methods used, 12 of the 16 were cohort studies (seven using a retrospective design and five a prospective design), two used only qualitative methods, one used a mixed-methods approach and one was a cross-sectional mixed-methods survey. Three studies (two qualitative and one cross-sectional mixed method) additionally reported on families and non-repaired women, and one documented pregnancies in women living with non-repaired fistula.

A sample size was available for 15 of 16 studies and ranged from 13 to 390 women. The length of follow-up time post-repair across all studies ranged from 6 months to 10 years, with a median follow-up time of 30 months (interquartile ranges of 12 and 60 months). The outcomes assessed across studies were the occurrence of

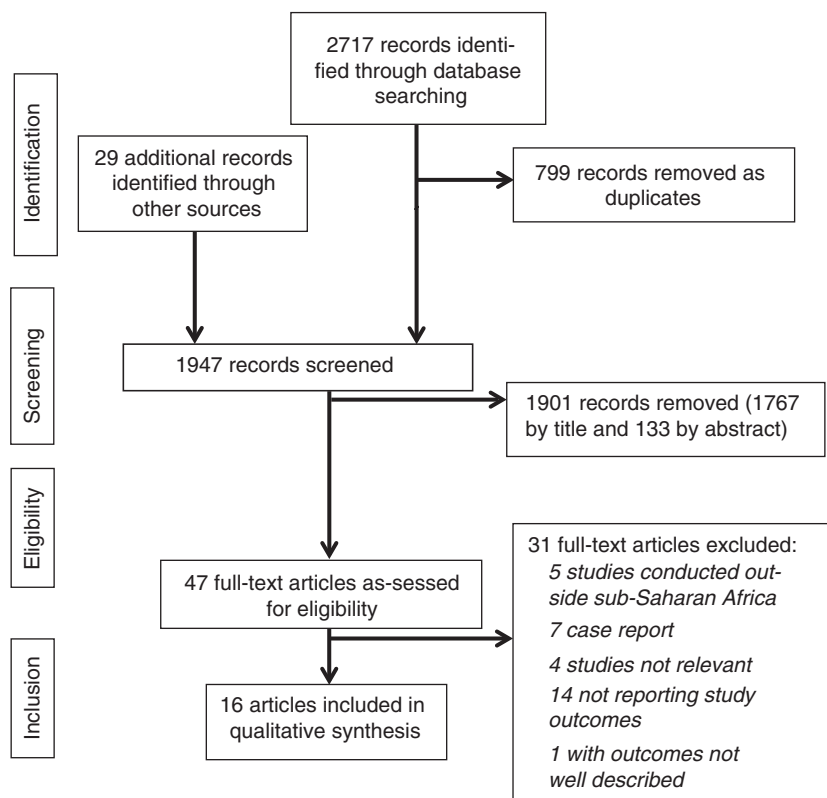


Figure 1 PRISMA flow chart of the studies selection process for the scoping review of pregnancy and childbirth after obstetric fistula repair in sub-Saharan Africa (1970–2016) [31].

A. Delamou *et al.* **Pregnancy post-repair of obstetric fistula****Table 1** Characteristics of 16 studies reporting on pregnancy and childbirth after repair of obstetric fistula in sub-Saharan Africa

Study (Author and Year)	Location and setting	Study design	Study period or follow-up time	Study population and Sample size	Study objectives	Outcomes assessed	
						Pregnancy	Childbirth
Drew <i>et al.</i> , 2016 [35]	Malawi (Urban and Rural, community based)	Qualitative study	1–2 years after fistula repair	20 women from seven health districts Aged between 18 and 76 years	To assess long-term outcomes among women who underwent obstetric fistula repair	Yes	Yes
Lawani, Iyoke & Ezeonu, 2015 [34]	Nigeria (Urban hospitals)	Prospective cohort study	24 months follow-up per woman (January 1, 2011 to December 31, 2013)	188 women followed up among 211 included (23, 10.9% loss to follow-up)	To determine the contraceptive practices of women after successful surgical repair of obstetric fistula and to assess determinants of uptake and the pregnancy rate in the first year of follow-up.	Yes	No
Tembely <i>et al.</i> , 2014 [38]	Mali (Urban referral hospital)	Prospective cohort study	13 months (June 2008–June 2009)	Not provided	To study the sexuality of women victims of obstetric urogenital fistula after surgical management	Yes	No
Ford, Narrainen-Poullé & Mansaray, 2013 [39]	Sierra Leone (Urban hospital)	A retrospective review of electronic and paper databases	2010–2013 (32 months)	82 babies from previous VVF repaired patients among 2735 deliveries. Denominator not reported.*	To examine the obstetric outcomes of women who attended with pregnancies after fistula repair	Yes	Yes
Maulet & Macq, 2012 [41]	Niger, Mali (community based)	Mixed-methods cohort study	18 months (2008–2009)	93 women of reproductive age from 120 fistula patients (quantitative study) and 15 current and former fistula patients (qualitative study)	To explore fistula patients' reproductive health paths and perspectives	Yes	Yes

A. Delamou *et al.* **Pregnancy post-repair of obstetric fistula****Table 1** (Continued)

Study (Author and Year)	Location and setting	Study design	Study period or follow-up time	Study population and Sample size	Study objectives	Outcomes assessed	
						Pregnancy	Childbirth
Wilson <i>et al.</i> , 2011 [36]	Malawi (Rural)	Retrospective Cohort study	2007–2009 with a minimum follow-up time of 6 months	17 women repaired for OF out of 32 women	To evaluate fertility and childbearing outcomes after obstetric fistula repair or in the absence of repair	Yes	Yes
Browning, 2009 [22]	Ethiopia (Fistula referral hospital)	Retrospective cohort study	44 months (February 2005 to September 2008) Average time from fistula repair of 37.5 months (range 7–288 months)	49 pregnant women following repair of OF. Denominator not reported.*	To report on the experience of managing pregnancies from women who underwent repair for obstetric fistula	Yes	Yes
Nielsen <i>et al.</i> , 2009 [21]	Ethiopia (Rural, community based)	Prospective cohort study	14–28 months following fistula repair	38 women who undergone fistula repair	To assess urinary and reproductive health and quality of life following surgical repair of obstetric fistula	Yes	Yes
Browning & Menber, 2008 [23]	Ethiopia (urban hospital)	Prospective cohort study	6 months	240 returning women of 390 index cases	To quantify surgical and quality of life outcomes 6 months after obstetric fistula repair	Yes	No
Muleta <i>et al.</i> , 2008 [5]	Ethiopia (Rural setting)	Cross-sectional mixed-methods survey	No follow-up time reported	13 women with repaired fistula and 39 untreated among 22826 women of reproductive age (15–49 years)	To assess health, social and psychological problems encountered by women with treated and untreated obstetric fistula	Yes	Yes
Turan, Johnson & Polan, 2007 [40]	Eritrea (rural hospital)	Qualitative study	6–10 months (2004)	15 women returning for follow-up after repair of 31 study participants	To present the findings from qualitative interviews with new and returning fistula repair patients and their family members	Yes	No

A. Delamou *et al.* **Pregnancy post-repair of obstetric fistula****Table 1** (Continued)

Study (Author and Year)	Location and setting	Study design	Study period or follow-up time	Study population and Sample size	Study objectives	Outcomes assessed	
						Pregnancy	Childbirth
Emembolu, 1992 [32]	Nigeria (urban hospital setting)	Retrospective cohort study	60 months (January 1986– December 1990)	75 women with repaired VVF are compared to 80 women with a non- repaired VVF. Denominator not reported.*	To determine the factors associated with the improvements in the pregnancy outcome in the VVF patients following successful surgical correction	Yes	Yes
Docquier, 1988 [37]	Niger (urban hospital)	Prospective cohort study	96 months (1977–1984) with a minimal follow-up time of 2 months	200 of reproductive age assessed from 230 returning women of 377 women successfully repaired.	To describe the gynaecological and obstetrical status of women successfully repaired from obstetric fistula	Yes	Yes
Otubu, Kumi & Ezem, 1981 [27]	Nigeria (urban hospital)	Retrospective cohort study	35 months (February 1, 1977– December 30, 1979)	110 pregnant women of 138 following successful repair of VVF. Denominator not reported.*	To examine the complications of pregnancy and labour in pregnant VVF patients following successful repair	Yes	Yes
EvoH & Akinla, 1978 [33]	Nigeria (Urban hospital)	Retrospective cohort study	10 years (1966–1976)	148 women with successful repair of obstetric fistula	To assess how Nigerian women with successfully repaired vesico- vaginal fistulae of obstetric origin fulfilled reproductive function	Yes	Yes
Aimakhu, 1974 [28]	Nigeria (Urban hospital)	Retrospective cohort study	10 years (1957–1966)	246 women successfully repaired	To study the reproductive functions after the successful repair of obstetric vesicovaginal fistulae	Yes	Yes

*Denominator: number of women discharged from hospital with the fistula successfully closed (required for the calculation of the proportion of pregnancies).

A. Delamou *et al.* **Pregnancy post-repair of obstetric fistula****Table 2** Pregnancy, pregnancy outcomes and factors associated with getting pregnant in 16 studies reporting on pregnancy and child-birth after repair of obstetric fistula in sub-Saharan Africa.

Study (Author, Year and Type)	Number of women followed up	Number of women who became pregnant	Proportion of women who got pregnant	Pregnancy outcome		Factors associated with getting pregnant
				Abortion/Miscarriage	Term pregnancy	
Drew <i>et al.</i> , 2016 [35]	20 women	3 women	15.0%	2/3 pregnancies	1/3 pregnancy (ongoing)	14 women (70%) were sexually active and 2 women using contraception (implant); 9 women desired another child but feared fistula recurrence in a future pregnancy
Lawani, Iyoke & Ezeonu, 2015 [34]	188 women	13 women (12 pregnancies among 118 women not using FP <i>vs.</i> 1 pregnancy in 70 women using)	6.9% (10.2% in women not using FP <i>vs.</i> 1.4% in those using)	Not reported	Not reported	28% of the 188 women commenced sexual activity within 3 months post-discharge despite being counselled on the risk. Family Planning use reduced the risk of pregnancy. 62% of their sample had resumed sexual activity but 60% did not desire another children.
Tembely <i>et al.</i> , 2014 [38]	Not provided	Not reported	13%	Not reported	Not reported	Not reported
Ford, Narrainen-Pouille & Mansaray, 2013 [39]	Not reported	81 women	Not reported	0	81/81 pregnancies	Not reported
Maulet & Macq, 2012 [41]	93 women	18 women	19.4%	6/18 pregnancies	12/18 pregnancies (5 ongoing at the end of study)	Not reported
Wilson <i>et al.</i> , 2011 [36]	17 women	6 women (in total 10 pregnancies)	35.3%	7/10 pregnancies	3/10 pregnancies (2 ongoing)	Not reported
Browning, 2009 [22]	Not reported	49 women	Not reported	0	49/49 pregnancies	Not reported

A. Delamou *et al.* **Pregnancy post-repair of obstetric fistula****Table 2** (Continued)

Study (Author, Year and Type)	Number of women followed up	Number of women who became pregnant	Proportion of women who got pregnant	Pregnancy outcome		Factors associated with getting pregnant
				Abortion/ Miscarriage	Term pregnancy	
Nielsen <i>et al.</i> , 2009 [21]	38 women	5 women	13.2%	0/5 pregnancy	5/5 pregnancies (1 ongoing)	27 (71%) were married and sexually active, 11 (41%) used contraception
Browning & Menber, 2008 [23]	240 women	6 women	2.5%	0	6 pregnancies	Only 84/240 women had resumed sexual intercourse (35%)
Muleta <i>et al.</i> , 2008 [5]	13 women	2 women	15.4%	0	2/2 pregnancies	7 had resumed sexual activity Fear from fistula recurrence and incontinence identified as factors delaying the resuming of sexual activity
Turan, Johson & Polan, 2007 [40]	15 women	0	0.0%	Not reported	Not reported	Women who desired another child were sexually active while divorced and widowed women were not
Emembolu, 1992 [32]	Not reported	75 women (3 outcome unknown)	Not provided	3/72 pregnancies	69/72	Not reported
Docquier, 1988 [37]	200 women	80 women (Mean time between repair and pregnancy: 10 months)	40%	5/80 pregnancies	75/80 (36 ongoing at the end of study)	87% had resumed with menstruation (were of reproductive age)
Otubu, Kumi & Ezem, 1981 [27]	Not reported	110 women	No reported	0	110 pregnancies (100%)	Among the 110 pregnant women, there were more women with juxta-urethral (39%) and mid-vaginal fistula (37%) than women with other types of fistula

Table 2 (Continued)

Study (Author, Year and Type)	Number of women followed up	Number of women who became pregnant	Proportion of women who got pregnant	Pregnancy outcome		Factors associated with getting pregnant
				Abortion/Miscarriage	Term pregnancy	
Evoth & Akinla, 1978 [33]	148 women	31 women (in total 38 pregnancies) Time to pregnancy varied from 2–24 months	20.9%	1/38 pregnancies	37/38	There were more pregnant women with juxta-cervical (N = 18) and juxta-urethral (N = 12) fistula than with all other types of fistula (N = 8)
Aimakhu, 1974 [28]	246 women	48 women (in total 65 pregnancies)	19.5%	5/65 pregnancies	60/65	Not reported
Total	1218 women From 11 studies that reported on women followed up	212 women (with 240 pregnancies) from the 11 studies that reported the number of women followed up) 527 women (in total 555 pregnancies) from 15 studies	17.4% (from the 11 studies reporting the number of women followed up)	29 cases from 15 studies reporting the number of pregnancies	510 pregnancies (45 ongoing) from 15 studies reporting the number of pregnancies	

OF, obstetric fistula; FP, family planning methods.

pregnancy (all studies), mode of delivery (vaginal delivery, emergency or elective C-section), perinatal outcomes (12 studies), recurrence of fistula (nine studies), abortion/miscarriage (eight studies) (Tables 2 and 3). Maternal complications (during pregnancy and at delivery) were documented in nine studies. Ten studies reported on the predictors of pregnancy, 14 studies documented the outcome of the pregnancy for the mother (Table 2) and 10 reported on the factors associated with the birth outcomes (Table 3).

Occurrence of pregnancy post-repair of obstetric fistula

The occurrence of pregnancy and the factors associated with getting pregnant across studies are summarised in Table 2. Fifteen of these 16 studies reported on numbers and recorded 555 pregnancies in 527 women with three studies including multiple pregnancies (28 additional pregnancies). Only 11 studies reported on the number of women followed up after repair. In these studies, 212 of

1218 followed up women became pregnant after repair (in total 240 pregnancies), corresponding to an overall proportion of 17.4% (range 2.5–40%). Of the 555 pregnancies reported in the included studies, the outcome of 539 pregnancies was known: 29 (5.4%) ended in abortion or miscarriage, 465 were term pregnancies (86.3%) and 45 pregnancies were ongoing at the time of the study (8.3%). Overall, 465 term pregnancies resulted in 463 deliveries with two reported maternal deaths.

Only six studies reported that women included were successfully repaired at discharge from hospital. None of the studies stratified data on pregnancies after repair and pregnancy outcomes by fistula repair status at discharge.

Factors associated with getting pregnant post-obstetric fistula repair

Ten studies reported on the predictors of pregnancy after repair (Table 2). As expected, married women and those

A. Delamou *et al.* Pregnancy post-repair of obstetric fistula**Table 3** Maternal and neonatal outcomes and factors associated with these outcomes in 16 studies reporting on pregnancy and childbirth after repair of obstetric fistula in sub-Saharan Africa.

Study (Author, Year and Type)	Number of deliveries (out of term pregnancies)	Elective CS		Emergency CS		Vaginal deliveries		Factors associated with maternal and neonatal outcomes
		Live births	Stillbirths/ neonatal death	Live births	Stillbirths/ neonatal death	Live births	Stillbirths/ neonatal death	
Drew <i>et al.</i> , 2016 [35]	0/1	0	0	0	0	0	0	No delivery was reported Miscarriage was frequent Not reported
Lawani, Iyoke & Ezeonu, 2015 [34]	Not reported	Not reported	Not reported	Not reported	Not reported	Not reported	Not reported	Not reported
Tembelly <i>et al.</i> , 2014 [38]	Not provided	Not provided	Not provided	Not provided	Not provided	Not provided	Not provided	Not provided
Ford, Narrainen-Pouille & Mansaray, 2013 [39]	81/81 (with 82 babies)	22/81 deliveries	Not reported	57/81 deliveries	Not reported	3/81 deliveries	Not reported	Elective CS improves maternal/neonatal outcomes Foetal size at delivery was small (mean birth weight of 2.8 kg) No recurrence of fistula No maternal death
Maulet & Macq, 2012 [41]	7/12	3/7 deliveries	0	0	0	3/7 deliveries (2 medically assisted and 1 not)	1/7 deliveries not medically assisted	Delivery without medical assistance appeared to be associated with worse maternal and neonatal outcomes
Wilson <i>et al.</i> , 2011 [36]	1/3	0	0	0	0	1/1 delivery	0	Perinatal mortality high among women becoming pregnant post-repair. Recurrence of fistula is associated with vaginal delivery

A. Delamou *et al.* **Pregnancy post-repair of obstetric fistula****Table 3** (Continued)

Study (Author, Year and Type)	Number of deliveries (out of term pregnancies)		Elective CS		Emergency CS		Vaginal deliveries		Factors associated with maternal and neonatal outcomes
	Live births	Stillbirths/neonatal death	Live births	Stillbirths/neonatal death	Live births	Stillbirths/neonatal death	Live births	Stillbirths/neonatal death	
Browning, 2009 [22]	49/49 (with 50 neonates)	0	5/49 deliveries	0	41/49 deliveries	1/49 deliveries	1/49 deliveries	2/49 deliveries	No recurrence of fistula No maternal death
Nielsen <i>et al.</i> , 2009 [21]	3/5 (and 1 death in labour)	0	1/3 deliveries (Elective CS planned for all women)	0	0	1/3 deliveries	0	1/3 deliveries	1 maternal death in labour 1 fistula recurrence (emergency CS)
Browning & Member, 2008 [23]	6/6	Not reported	Not reported	Not reported	Not reported	Not reported	Not reported	Not reported	Not reported
Muleta <i>et al.</i> , 2008 [5]	2/2	Not reported	2/2 deliveries	Not reported	Not reported	Not reported	Not reported	Not reported	Not reported
Turan, Johnson & Polan, 2007 [40]	0/0	Not reported	Not reported	Not reported	Not reported	Not reported	Not reported	Not reported	N/A

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Table 3 (Continued)

Study (Author, Year and Type)	Number of deliveries (out of term pregnancies)	Elective CS		Emergency CS		Vaginal deliveries		Factors associated with maternal and neonatal outcomes
		Live births	Stillbirths/ neonatal death	Live births	Stillbirths/ neonatal death	Live births	Stillbirths/ neonatal death	
Emembolu, 1992 [32]	69/69	19/69 deliveries (51/75 pregnant women were planned for elective CS)	Not reported	35/69 deliveries	Not reported	15/69 deliveries	Not reported	4 women who did not attend their elective appointment got early perinatal deaths Obstructed labour, vaginal delivery and emergency CS associated with recurrence of fistula; Early referral and acceptance of elective CS and multiparity had positive impact on the outcomes for mother and child.
Docquier, 1988 [37]	39/75	14/39 deliveries	Not reported	Not reported	Not reported	25/39 deliveries	Not reported	9 perinatal deaths 4 women with anaemia; no maternal death but 8 recurrences of fistula

A. Delamou *et al.* **Pregnancy post-repair of obstetric fistula****Table 3** (Continued)

Study (Author, Year and Type)	Number of deliveries (out of term pregnancies)	Elective CS		Emergency CS		Vaginal deliveries		Factors associated with maternal and neonatal outcomes
		Live births	Stillbirths/neonatal death	Live births	Stillbirths/neonatal death	Live births	Stillbirths/neonatal death	
Otubu, Kumi & Ezem, 1981 [27]	110/110	75/110 deliveries (Elective CS planned for all women)	5/110 deliveries	14/110 deliveries	8/110 deliveries	3/110 deliveries	6/110 deliveries	Antenatal complications: anaemia (11.8%) and urinary tract infection (15.4%), 1 uterus rupture and 1 maternal death; 5 recurrence of fistula
Evoh & Akimla, 1978 [33]	37/37	30/37 deliveries (CS planned for all women)	2/37 deliveries	Not reported	Not reported	3/37 deliveries	2/37 deliveries	5 recurrence of fistula after delivery and 1 uterine rupture No maternal death but 2 women with stress incontinence after CS

A. Delamou *et al.* **Pregnancy post-repair of obstetric fistula****Table 3** (Continued)

Study (Author, Year and Type)	Number of deliveries (out of term pregnancies)	Elective CS		Emergency CS		Vaginal deliveries		Factors associated with maternal and neonatal outcomes
		Live births	Stillbirths/ neonatal death	Live births	Stillbirths/ neonatal death	Live births	Stillbirths/ neonatal death	
Aimakhu, 1974 [28]	59/60 deliveries (and 1 death during labour)	30/58 deliveries	0/58 deliveries	17/58 deliveries	2/58 deliveries	5/58 deliveries	4/58 deliveries	Elective CS increased neonatal survival; Vaginal delivery associated with bad maternal and neonatal outcomes, especially with recurrence of fistula
Total	463/510 in 14 studies	201 live births (in 13 studies)	7 Stillbirths/ neonatal death	164/201 live births	12 Stillbirths/ neonatal death	59/201 live births	16 Stillbirths/ neonatal death	2 recurrence of fistula and 2 maternal deaths (1 in labour and 1 CS) 23 recurrence of fistula 4 maternal death 2 uterine ruptures

CS, C-section; N/A, not applicable.

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women who said they wanted more children at discharge were more likely to resume sexual activity [22, 24, 35, 37]. More women with juxta-cervical, juxta-urethral or mid-vaginal fistula became pregnant post-repair than women with other types of fistula [27, 33]. Inversely, multiparous women, women who reported having a fear of fistula recurrence or those using family planning methods, were less likely to become pregnant [5, 34, 36]. In one study, for instance, there was only one pregnancy among 70 women using family planning (FP) methods (1.4%) while 12 pregnancies were recorded in 118 women who were not using a FP method (10.2%) after 24 months follow-up [34]. Even after being counselled on the risk of sexual activity at the time of their surgery, more than one-quarter of women resumed sexual activity within 3 months of repair [34].

Maternal and neonatal outcomes post-fistula repair

Maternal and neonatal outcomes as reported in the 16 included studies are summarised in Table 3. Overall 463 deliveries were recorded in the included studies but for only 459 the mode of delivery was reported. A total of 208 women (45.3%) delivered by elective caesarean section (CS), 176 (38.4%) by emergency CS and 75 (16.3%) by vaginal delivery.

In three studies [27, 32, 33], only 131 of 198 pregnant women (66.2%) appointed for an elective CS respected the appointment. The most common maternal complications were the recurrence of a fistula (23/463 deliveries; 5.0%), maternal death (four cases; 0.9%) and two uterine ruptures (0.4%). One study [27] included antenatal complications such as anaemia (13/110 women, 11.8%) and urinary tract infections (17/110 women; 15.4%).

Overall the proportion of stillbirths across studies was 7.6% (35/459 neonates). However, considering the perinatal outcome by mode of delivery across studies, there were more stillbirths associated with a vaginal delivery (16/75 neonates, 21.3%) than emergency CS (12/176 neonates, 6.8%) and elective CS (7/208 neonates, 3.4%).

Factors associated with maternal and neonatal outcomes post-fistula repair

Most of the studies (12 of 16) identified elective CS as the main mode of delivery resulting in a better maternal and neonatal outcome of pregnancies after successful repair of an obstetric fistula. Delays in seeking care or refusal to deliver with skilled birth attendants [23, 27, 32], non-use of antenatal care [27], were identified as factors that contributed to delaying delivery at a hospital. Vaginal delivery without medical assistance and

emergency CS were listed as factors increasing the risk of recurrence of a fistula post-repair. One study [33] reported that the resumption of sexual activity within 3 months was associated with the recurrence of fistula.

Discussion

Our scoping review on pregnancy and childbirth post-repair of an obstetric fistula in sub-Saharan Africa found that many women still desire to become pregnant after the repair of their OF [22, 24, 33, 36, 41]. However, the incidence of pregnancies was not reported in the reviewed studies, and the overall incidence could not be estimated in this review. The overall estimate of the proportion of women who became pregnant during the follow-up was low but varied widely across studies. Even though evidence is scarce [42], return to fertility has been reported to be difficult in women after OF repair in a number of studies [5, 28, 30, 43]. It has been stated that women with a previous traumatic birth experience had fewer pregnancies post-repair than women without such an experience [44]. Women treated for OF are usually advised to wait for 3–6 months before resuming sexual intercourse [45, 46] to allow for complete healing. In addition, the fear of fistula recurrence might delay the resuming of sexual activities [43, 45, 47]. Divorce and mental trauma, but also urinary infections or iatrogenic amenorrhoea, which are common among fistula women, might reduce the probability of getting pregnant [27, 28, 30].

The low proportion of pregnancies and the wide range across studies observed in this review might be explained by (i) the limited number of studies reporting the number of women followed up over time; (ii) the heterogeneity of follow-up time across studies (two-fifth of the studies included had a follow-up time of <2 years); (iii) the use of purposive and small samples using qualitative or cross-sectional designs which are not representative of all repaired women; (iv) the lack of information on the proportion of women of reproductive age across one-third of the included studies and (v) the fear of recurrence of the repaired fistula or formation of a new fistula following a pregnancy [33].

Women who get pregnant after repair of OF carry a high risk of pregnancy and childbirth complications [22]. Across studies, the mode of delivery was an important determinant of pregnancy outcomes. Stillbirths, recurrence of the fistula or even maternal death were more likely to occur with vaginal delivery and emergency CS than with a scheduled CS [22, 27, 28, 32, 33, 36, 39, 40]. Therefore, delivery with

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a skilled birth attendant, especially through elective C-section (CS) was identified across all studies as a key factor to achieve good maternal and child health outcomes.

Our review reveals that many women are encouraged by healthcare providers to attend antenatal care and deliver in a hospital by elective CS. However, for various reasons, none of the women could follow these recommendations [27, 32, 33]. The reasons were poverty, refusal due to cultural reasons, husband or family opposition [22]. The experience of women who fear that their husbands refuse to send them to the hospital if they become pregnant has been reported by Donnely *et al.* [47]. Studies generally described women suffering from obstetric fistula being poor and living in rural areas with insufficient access to emergency obstetric care [45, 46]. It is therefore important to ensure transportation and free care are offered as facilitators of access to women planned to deliver in health facilities [46]. If barriers to a delivery in a health facility are not removed, access to elective C-section for women pregnant after successful repair of OF might be insufficient.

Our findings suggest that recurrence of fistula is a common maternal complication of pregnancy after the repair of OF; abortions/miscarriage, stillbirths and neonatal deaths are frequent foetal consequences. As reported in some studies on fistula outcomes [14, 18, 43], for up to 90% of women who develop an OF, the delivery ends in a stillbirth. This emphasises the need to strengthen and extend follow-up of women post-repair in order to preserve the health of the mother and her future babies. Post-repair counselling about fistula and the risk factors for OF recurrence, such as early resuming of sexual intercourse, as well as the implementation of a community-based follow-up care have been recommended [21, 33, 47]. However, questions remain on how these recommendations can be realised and integrated into routine maternal and child health programmes that involve husbands and families [22].

Finally, although a few studies specified if women were successfully repaired for their OF, in most studies information was missing whether women followed up had their fistula closed or were continent at discharge from the repair hospital. In addition, none of the included studies reported on pregnancies and pregnancy outcomes by fistula repair status (closed *vs.* continent at discharge).

Our review has some limitations: (i) missing information in studies did not permit good estimates of the study outcomes; (ii) it included qualitative studies that did not focus on providing the estimates of study outcomes; (iii) the geographical distribution of studies included was rather narrow and might therefore affect the external

validity of the findings; (iv) there was heterogeneity of recruitment strategies and follow-up of women included in studies. Nonetheless, this review forms the basis for more research on the life of women successfully repaired for OF in sub-Saharan Africa.

Conclusion

Pregnancy and childbirth after repair of obstetric fistula carry a high risk of adverse outcomes in sub-Saharan Africa. Current evidence does not provide precise estimates of the incidence of pregnancy and pregnancy outcomes post-OF repair. We need to set up a data collection and reporting system for women after OF repair that could be integrated into the existing system, and studies assessing outcomes by repair status and providing more precise estimates of their incidence.

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References

1. Miller S, Lester F, Webster M, Cowan B. Obstetric fistula: a preventable tragedy. *J Midwifery Womens' Health* 2005; 50: 286–294.
2. Osotimehin B. Obstetric fistula: ending the health and human rights tragedy. *Lancet* 2013; 381: 1702–1703.
3. Adler AJ, Ronsmans C, Calvert C, Filippi V. Estimating the prevalence of obstetric fistula: a systematic review and meta-analysis. *BMC Pregnancy Childbirth* 2013; 13: 246.
4. Maheu-Giroux M, Filippi V, Samadoulougou S *et al.* Prevalence of symptoms of vaginal fistula in 19 sub-Saharan Africa countries: a meta-analysis of national household survey data. *Lancet Glob Health* 2015; 3: e271–e278.
5. Muleta M, Hamlin EC, Fantahun M, Kennedy RC, Tafesse B. Health and social problems encountered by treated and untreated obstetric fistula patients in rural Ethiopia. *J Obstet Gynaecol Can* 2008; 30: 44–50.
6. Siddle K, Mwambingu S, Malinga T, Fiander A. Psychosocial impact of obstetric fistula in women presenting for surgical care in Tanzania. *Int Urogynecol J* 2013; 24: 1215–1220.
7. Donnay F, Ramsey K. Eliminating obstetric fistula: progress in partnerships. *Int J Gynaecol Obstet* 2006; 94: 254–261.
8. MacDonald P, Stanton M. USAID program for the prevention and treatment of vaginal fistula. *Int J Gynaecol Obstet* 2007; 99 (Suppl. 1): S112–S116.

A. Delamou *et al.* **Pregnancy post-repair of obstetric fistula**

9. Fistula C. *Project Report: October 2007 to December 2013, Part I: Global Accomplishments*. Fistula Care/EngenderHealth: New York, 2013.
10. Osotimehin B. Ending fistula within a generation. Statement on the International Day to End Obstetric Fistula. 23 May 2016. (Available at: <http://www.endfistula.org/news/ending-fistula-within-generation>) [30 May 2016].
11. De Bernis L. Obstetric fistula: guiding principles for clinical management and programme development, a new WHO guideline. *Int J Gynaecol Obstet* 2007; **99** (Suppl. 1): S117–S121.
12. Ruminjo JK, Frajzyngier V, Bashir AM *et al.* Clinical procedures and practices used in the perioperative treatment of female genital fistula during a prospective cohort study. *BMC Pregnancy Childbirth* 2014; **14**: 220.
13. Tayler-Smith K, Zachariah R, Manzi M *et al.* Obstetric Fistula in Burundi: a comprehensive approach to managing women with this neglected disease. *BMC Pregnancy Childbirth* 2013; **13**: 164.
14. Hawkins L, Spitzer RF, Christoffersen-Deb A, Leah J, Mabeya H. Characteristics and surgical success of patients presenting for repair of obstetric fistula in western Kenya. *Int J Gynaecol Obstet* 2013; **120**: 178–182.
15. Delamou A, Diallo M, Beavogui AH *et al.* Good clinical outcomes from a 7-year holistic programme of fistula repair in Guinea. *Trop Med Int Health* 2015; **20**: 813–819.
16. Creanga AA, Ahmed S, Genadry RR, Stanton C. Prevention and treatment of obstetric fistula: Identifying research needs and public health priorities. *Int J Gynaecol Obstet* 2007; **99** (Suppl. 1): S151–S154.
17. Barone MA, Frajzyngier V, Ruminjo J *et al.* Determinants of postoperative outcomes of female genital fistula repair surgery. *Obstet Gynecol* 2012; **120**: 524–531.
18. Frajzyngier V, Ruminjo J, Barone MA. Factors influencing urinary fistula repair outcomes in developing countries: a systematic review. *Am J Obstet Gynecol* 2012; **207**: 248–258.
19. Muleta M, Rasmussen S, Kiserud T. Obstetric fistula in 14,928 Ethiopian women. *Acta Obstet Gynecol Scand* 2010; **89**: 945–951.
20. Landry E, Frajzyngier V, Ruminjo J *et al.* Profiles and experiences of women undergoing genital fistula repair: Findings from five countries. *Glob Public Health* 2013; **8**: 926–942.
21. Lombard L, de St Jorre J, Geddes R, El Ayadi AM, Grant L. Rehabilitation experiences after obstetric fistula repair: systematic review of qualitative studies. *Trop Med Int Health* 2015; **20**: 554–568.
22. Nielsen HS, Lindberg L, Nygaard U *et al.* A community-based long-term follow up of women undergoing obstetric fistula repair in rural Ethiopia. *BJOG* 2009; **116**: 1258–1264.
23. Browning A. Pregnancy following obstetric fistula repair, the management of delivery. *BJOG* 2009; **116**: 1265–1267.
24. Browning A, Menber B. Women with obstetric fistula in Ethiopia: a 6-month follow up after surgical treatment. *BJOG* 2008; **115**: 1564–1569.
25. Gupta P, Mishra S, Mishra A, Seth A, Anand A. Outcome of repeat supratrigonal obstetric vesicovaginal fistula repair after previous failed repair. *Urol Int* 2012; **88**: 259–262.
26. Maulet N, Keita M, Macq J. Medico-social pathways of obstetric fistula patients in Mali and Niger: an 18-month cohort follow-up. *Trop Med Int Health* 2013; **18**: 524–533.
27. Otubu JA, Kumi GO, Ezem BU. Pregnancy and delivery after successful repair of vesicovaginal fistula. *Int J Gynaecol Obstet* 1982; **20**: 163–166.
28. Aimakhu VE. Reproductive functions after the repair of obstetric vesicovaginal fistulae. *Fertil Steril* 1974; **25**: 586–591.
29. Peters MD, Godfrey CM, Khalil H, McInerney P, Parker D, Soares CB. Guidance for conducting systematic scoping reviews. *Int J Evid Based Healthc* 2015; **13**: 141–146.
30. Arksey H, O'Malley L. Scoping studies: towards a methodological framework. *Int J Soc Res Methodol* 2005; **8**: 19–32.
31. Moher D, Liberati A, Tetzlaff J, Altman DG, PRISMA Group. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. *PLoS Med* 2009; **6**: e1000097.
32. Emembolu J. The obstetric fistula: factors associated with improved pregnancy outcome after a successful repair. *Int J Gynaecol Obstet* 1992; **39**: 205–212.
33. Evoh NJ, Akinla O. Reproductive performance after the repair of obstetric vesico-vaginal fistulae. *Ann Clin Res* 1978; **10**: 303–306.
34. Lawani LO, Iyoke CA, Ezeonu PO. Contraceptive practice after surgical repair of obstetric fistula in southeast Nigeria. *Int J Gynaecol Obstet* 2015; **129**: 256–259.
35. Drew LB, Wilkinson JP, Nundwe W *et al.* Long-term outcomes for women after obstetric fistula repair in Lilongwe, Malawi: a qualitative study. *BMC Pregnancy Childbirth* 2016; **16**: 2.
36. Wilson AL, Chipeta E, Kalilani-Phiri L, Taulo F, Tsui AO. Fertility and pregnancy outcomes among women with obstetric fistula in rural Malawi. *Int J Gynaecol Obstet* 2011; **113**: 196–198.
37. Docquier J. Urogenital fistulas of obstetrical origin. Apropos of 421 cases. *Acta Urol Belg* 1988; **56**: 535–544.
38. Tembely A, Diarra A, Berthé H. Sexuality and fertility of women operated for obstetric urogenital fistulae. *Prog Urol* 2014; **24**: 876.
39. Maulet NBE, Macq J. Obstetric fistula patients' reproductive health paths and perspectives. *Int J Gynaecol Obstet* 2012; **119**(S2): S841.
40. Ford CCM, Narrainen-Pouille T, Mansaray TG. Pregnancy outcomes following obstetric fistula repair in Sierra Leone. Abstracts of the RCOG World Congress 2013, 24–26 June 2013, Liverpool, UK. *BJOG* 2013; **120** (S1):332.
41. Turan JM, Johnson K, Polan ML. Experiences of women seeking medical care for obstetric fistula in Eritrea:

A. Delamou *et al.* **Pregnancy post-repair of obstetric fistula**

- implications for prevention, treatment, and social reintegration. *Glob Public Health* 2007; **2**: 64–77.
42. Andreucci CB, Bussadori JC, Pacagnella RC *et al.* Sexual life and dysfunction after maternal morbidity: a systematic review. *BMC Pregnancy Childbirth* 2015; **15**: 307.
43. Benfield N, Kinsindja RM, Kimona C, Masoda M, Ndume J, Steinauer J. Fertility desires and the feasibility of contraception counseling among genital fistula patients in eastern Democratic Republic of the Congo. *Int J Gynaecol Obstet* 2011; **114**: 265–267.
44. Gottvall K, Waldenström U. Does a traumatic birth experience have an impact on future reproduction? *BJOG* 2002; **109**: 254–260.
45. Khisa W, Wakasiaka S, McGowan L, Campbell M, Lavender T. Understanding the lived experience of women before and after fistula repair: a qualitative study in Kenya. *BJOG* 2016; doi:10.1111/1471-0528.13902. [Epub Ahead of print].
46. Delamou A, Delvaux T, Utz B *et al.* Factors associated with loss to follow-up in women undergoing repair for obstetric fistula in Guinea. *Trop Med Int Health* 2015; **20**: 1454–1461.
47. Donnelly K, Oliveras E, Tilahun Y, Belachew M, Asnake M. Quality of life of Ethiopian women after fistula repair: implications on rehabilitation and social reintegration policy and programming. *Cult Health Sex* 2015; **17**: 150–164.

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STUDY PROTOCOL

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A descriptive longitudinal study protocol: recurrence and pregnancy post-repair of obstetric fistula in Guinea

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Abstract

Background: Obstetric fistula is a serious medical condition which affects women in low income countries. Despite the progress of research on fistula, there is little data on long term follow-up after surgical repair. The objective of this study is to analyse the factors associated with the recurrence of fistula and the outcomes of pregnancy following fistula repair in Guinea.

Methods: A descriptive longitudinal study design will be used. The study will include women who underwent fistula repair between 2012 and 2015 at 3 fistula repair sites supported by the Fistula Care Project in Guinea (Kissidougou Prefectoral Hospital, Labé Regional Hospital and Jean Paul II Hospital of Conakry).

Participants giving an informed consent after a home visit by the Fistula Counsellors will be interviewed for enrolment at least 3 months after hospital discharge. The study enrolment period is January 1, 2012 – June 30, 2015. Participants will be followed-up until June 30, 2016 for a maximum follow up period of 48 months. The sample size is estimated at 364 women.

The cumulative incidence rates of fistula recurrence and pregnancy post-repair will be calculated using Kaplan-Meier methods and the risk factor analyses will be performed using adjusted Cox regression. The outcomes of pregnancy will be analysed using proportions, the Pearson's Chi Square (χ^2) and a logistic regression with associations reported as risk ratios with 95 % confidence intervals. All analyses will be done using STATA version 13 (STATA Corporation, College Station, TX, USA) with a level of significance set at $P < 0.05$.

Discussion: This study will contribute to improving the prevention and management of obstetric fistula within the community and support advocacy efforts for the social reintegration of fistula patients into their communities. It will also guide policy makers and strategic planning for fistula programs.

Trial registration: ClinicalTrials.gov Identifier: NCT02686957. Registered 12 February 2016 (Retrospectively registered).

Keywords: Recurrence, Pregnancy, Risk factors, Obstetric fistula, Post-repair, Guinea

Background

Obstetric fistula (OF) is a serious medical condition in which a perforation develops between vagina, bladder and/or rectum, most commonly after prolonged labour when the head of the unborn child compresses the birth canal and leads to tissue necrosis [1, 2]. A recent study

in 5 countries showed that women suffering from OF are generally married young, have little formal education and for most of them the fistula occurred after the first pregnancy, at a median age of 20 years [3]. The condition hardly exists in the developed world, but remains prevalent in sub-Saharan Africa, especially in countries where access to quality emergency obstetric care is low [4, 5]. Guinea for instance has a high maternal mortality ratio (724 per 100 000 live births) and a prevalence of OF among women of reproductive age estimated to be

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0.6 %, which represents a total number of 15 – 18 thousands women living with an OF [6].

Thanks to the international mobilization against fistula in recent years, the holistic care of OF (prevention, treatment and reintegration) in many sub-Saharan African countries has improved [7, 8]. As a result, immediate post-operative closure rates of OF have increased [9–12]. In addition, the number of repaired women has increased worldwide with more than 30,000 fistula repairs supported by the Fistula Care Project in 15 countries since 2005 [13] and more than 57,000 repairs funded by the UNFPA over the past decade [14]. Furthermore, new evidence has shown that women's hospital stay can be shortened and costs lowered, allowing more women to be treated [15]. In Guinea, about 3,000 fistulas were repaired between 2007 and 2013 by the Fistula Care Project (a USAID-funded project managed by EngenderHealth) [13, 16].

Despite these improvements, gaps still exist, especially in the long term follow-up of women after successful fistula repair [17]. In fact, data currently available show that delivery leading to fistula usually ends up with a stillbirth [10–12] and that women are relatively young at the time their fistula is repaired [3]. Therefore, when successfully repaired, women return to their community with the desire to resume social and sexual life, and have children [18–20]. However, this return to sexuality exposes repaired woman to pregnancy and childbirth, which increases the risk of recurrence of a previously repaired fistula or the formation of a second, new fistula [18, 19]. Fear of recurrence of fistula is a constant worry for women successfully repaired of OF [21–23] and, given the cost of fistula care and the lower success of repairing [24], these women might need more attention to prevent recurrence of fistula and adverse pregnancy outcomes.

There is no precise estimate of the recurrence of fistula or pregnancy after OF repair. In Ethiopia, Nielsen et al [18] observed 2.63 % re-occurrence of fistula among 38 women in a 21 months' post-repair median follow up and Browning and Menber [19] recorded 4.26 % in 141 women successfully repaired after 6 months' follow-up. In Malawi, Wilson et al [20] reported 3.85 % of re-occurrence in 26 women after 9 – 24 months' follow-up post-repair.

The same authors found a proportion of pregnancies of respectively 13.16 % [18] and 4.26 % [19] in Ethiopia and 23.10 % in Malawi [20]. Delivery outcomes were poor with only 1 live birth reported in both Ethiopia and Malawi [18, 20]. Heavy work, sexual intercourse, and delivery have been reported to be associated with the recurrence of fistula [25–28]. Because sexuality and desire of children are part of women's life after successful OF repair [18, 19, 21, 29]

and recurrence of fistula and stillbirth are very common complications of delivery post OF repair [18, 20], there is a need for more well powered long term follow-up studies that could fill the existing gap of knowledge. The need to collect long-term follow-up data about fistula recurrence, subsequent pregnancies and their outcomes has already been identified among current research priorities on fistula [17]. Since, there has been no major comprehensive and well powered study initiated in a sub-Saharan African country involving women after OF repair, and for the status of the fistula at discharge is not always specified in the existing studies, we initiated this study with the following objectives:

- Analyse the incidence rate and risk factors of fistula recurrence up to 48 months follow up.
- Analyse the incidence rate and factors associated with pregnancy and pregnancy outcomes (maternal and perinatal) up to 48 months' follow-up;

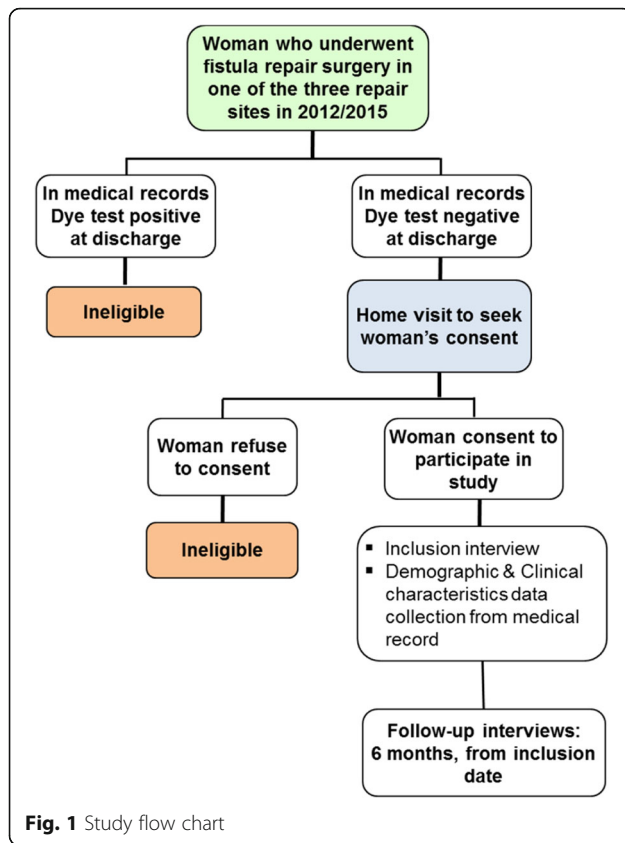
The endpoints will be recurrence of fistula, pregnancy, abortion or miscarriage, maternal, perinatal and child death at any time from hospital discharge.

Methods

Study design

This is a longitudinal follow-up study over a period of 4 years conducted among women underwent fistula repair at 3 sites supported by Engenderhealth in Guinea. A cohort will be constituted. Participants who have been repaired at OF treatment sites before the study has started will be included retrospectively and then followed up prospectively (Fig. 1).

The primary outcome is the incidence rate of the recurrence of fistula. For the purpose of this study, recurrence of fistula includes the breakdown of a repaired fistula or the occurrence of a new fistula in study participants. At the study sites, the closure of fistula was determined at hospital discharge by a pelvic exam using a dye test. During follow-up visits, women will first be asked about current medical status using the question “does the woman have continuous and uncontrolled leakage of urine?”. If the answer is “YES” then women will be scheduled for a pelvic exam with a dye test for confirmation, at the nearest health facility (health centre or health post). This question is always used at EngenderHealth supported sites to assess women at reception, before further pelvic exam. In addition, the presence of “continuous and uncontrolled leakage of urine” is commonly used as a screening question for fistula in circumstances in which a pelvic exam is not possible (e.g. Demographic and Health Surveys, DHS); it differentiates between fistula and other forms of



incontinence, which are unlikely to be continuous and uncontrolled. In some cases, it might not be feasible to perform the dye test if for instance the woman refuses to go to a health facility. This might lead to a misclassification which can bias the estimate towards a null. However, misclassification is unlikely, since women with continued urinary leakage are eager to report their experiences in order for the condition to be rectified.

The secondary outcomes include pregnancy and pregnancy and outcomes (miscarriage or abortion or term pregnancy). Pregnancy and pregnancy outcomes will be documented by a positive pregnancy test from discharge (done at recruitment or during follow-up visit or given at any time by a result from medical records such as antenatal (ANC) card) or by a self-reporting corroborated by 2 witnesses. Maternal status at delivery and mode of delivery (dead or alive; caesarean section or normal delivery; no complication or any complication) will be assessed by looking at the ANC & Delivery card or hospital records or self-reporting. Child outcome at delivery (stillbirth, neonatal death or alive) will be assessed by looking at the ANC & Delivery card or hospital records or self-reporting corroborated by 2 witnesses.

Our predictors of interest will include patient characteristics, fistula characteristics, context of repair and

context of reintegration. Because women will be recruited and followed-up to record the occurrence of the study outcomes over a period of time, the longitudinal follow-up study design is the most suitable design.

Study setting

General setting

Guinea is a coastal West African country with an estimated population of 12 million people [6]. The population is largely rural (65 %) and poor [30]. The Guinean health care system faces many challenges, including chronic shortage of qualified physicians and nurses, and poor clinical infrastructure, particularly in rural and mountainous areas. According to the national action plan for repositioning family planning in Guinea 2014–2018 [20], only 16 % of health professionals (doctors, state midwives and state nurses) work in rural areas where they serve 65 % of the population. Guinea has an estimated lifetime prevalence of obstetric fistula of 0.6 % among women aged 15–49 which ranges regionally from 0.2 to 1.2 % [6], although this figure is likely underestimated. Challenging contextual factors in maternal health include low modern contraceptive prevalence (6 %), concurrent high fertility rate of 5.1, and high maternal mortality (724 deaths per 100,000 live births) [6]. Over the period 2007–2012, the majority of births (54.7 %) were assisted by untrained individuals, and occurred at home (58.8 %) [6]. Since 2012, the Ministry of Health has elaborated a national strategic plan (2012–2016) for the prevention and treatment of fistula [16]. This strategic plan emphasizes the importance of reintegration and support to victims of OF and advocates for more operational and action research that can inform policy.

Specific setting

Fistula repair services are available in 4 sites across the country but the study will be conducted with women successfully repaired at the 3 Engenderhealth supported hospitals. From 2007 to 2013, about 3000 OF repairs have been conducted at the 3 Engenderhealth supported sites (Jean Paul II Hospital in Conakry, the Regional Hospital of Labé and the Prefectural Hospital of Kissidougou), where 16 physicians have been trained in obstetric fistula repair, 55 nurses/midwives have been trained in fistula management and 400 – 450 fistula repairs per year have been performed [13].

Study population

The study population includes all women who underwent successful repair of OF from January 1, 2012 – June 30, 2015 at the 3 above described fistula repair sites.

Sample size calculation

For the estimation of the incidence rate of the recurrence of fistula, we used the 2-Sided Confidence Intervals for 1 Proportion Confidence Interval Formula [31]. Using the existing data [19] and considering a $\pm 2\%$ margin of error and 95 % confidence interval, we estimate the sample size of the cohort to be 280. We anticipate 20 % loss to follow-up and 10 % refusal rate and accordingly increase the sample size to 364. The same formula provides an estimation of the sample size for the incidence rate of pregnancy [31]. If we estimate the rate of pregnancy to be around 20 % at 24 months' follow-up among successfully repaired women [20], a sample size of 264 women produces a 2-sided 95 % confidence interval with 10 % precision. Therefore, the sample size of 364 women will be sufficient to describe the objective on pregnancy and its outcomes.

Participants' recruitment and follow-up

All women who underwent successful repair of OF from January 1, 2012 to June 30, 2015 at the 3 study sites are eligible for inclusion in study. However, only women with a unique obstetric fistula that was closed at discharge, as measured by a dye test, who provide written informed consent, reside in Guinea and agree with follow-up visits will be included in the study (Fig. 1). Eligible participants who refuse informed consent, who got repair outside the study sites or whose medical records are incomplete will be excluded.

Individual medical records of all women who benefited fistula repair at the 3 sites in 2012–2015 will be screened by the study team to identify those who were discharged with a close fistula (Fig. 1). After locating them through their medical records, the study team (that includes nurses called “Fistula Counsellors” who are involved in the management of women at the fistula repair sites) will contact women by home visit in their community to obtain informed consent.

Once the informed consent is obtained, the woman will be interviewed for 30 – 60 min by the study team and examined in an isolated place for inclusion in the study. Later, her medical records will be used at the fistula repair site where she got the surgery to collect her sociodemographic and clinical characteristics at the time of surgery. For all women recruited in the study, most retrospectively, new fistula or recurrence of the repaired fistula, pregnancies and their outcomes (miscarriage, stillbirth, live birth, early new-born death, maternal death, and type of maternal complication) will be documented. Health Centres and Health posts around which the study participants live will be used by the study team to perform the dye test in women who report “Continuous and uncontrolled leaking” since discharge or at the follow up visit.

Study procedures

The study team will retrospectively screen individual medical records of all women who benefited fistula repair at the 3 sites from January 1, 2012 to June 30, 2015 to identify those who were discharged with a close fistula (Table 1 and Fig. 2).

A home visit will then be conducted within the community to seek informed consent with the repaired women. After obtaining the consent, women will be interviewed. Women who report “Continuous and uncontrolled leaking” since the last follow-up visit will be scheduled for a pelvic exam and a dye test at the nearest health centre or health post. If the case is confirmed as fistula (by a dye test of clinical exam), the woman will be counselled and referred to the nearest fistula repair centre. By this approach, we think that any misclassification of outcome (recurrence of fistula) will be minimal, since women with any continuous and uncontrolled leakage of urine following repair are likely to report it, and any reported incontinence will be evaluated by a dye test.

If a woman reports pregnancy, she will be asked to show her antenatal care (ANC) & delivery card on which pregnancy test result is routinely reported. If possible, a pregnancy test will be performed. Otherwise, investigators will rely on woman self-reporting.

Sociodemographic and clinical characteristics of women will be collected from individual medical records at each participating fistula repair site.

All investigators will receive appropriate training at the Maferinyah National Research and Training Centre before they go in the field.

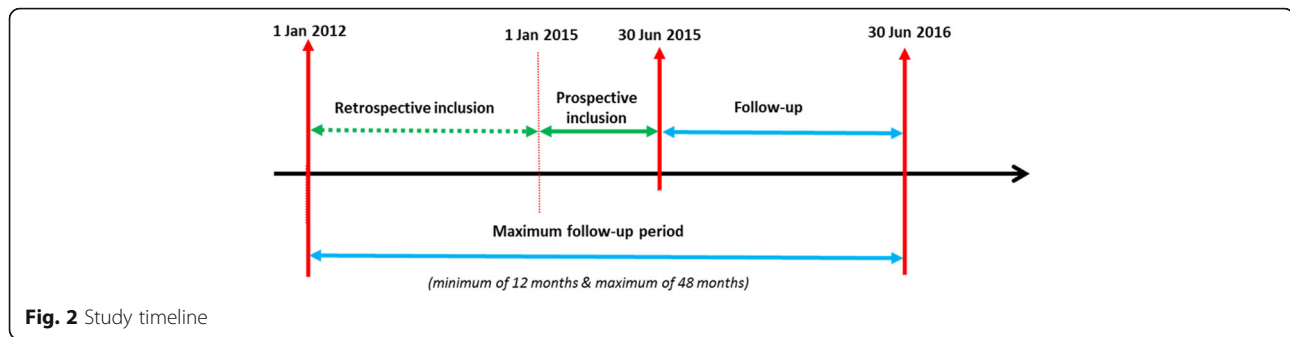
Data collection

Recruitment and follow-up visit

The enrolment and follow up data are collected using structured and pre tested standardised questionnaires. Both questionnaires will include participants' current fistula status (fistula close and continent/closed but not

Table 1 Study schedule of assessment

Study steps	Procedures
Screening	<ul style="list-style-type: none"> Retrieving of medical records Identification of women closed at discharge
Enrolment	<ul style="list-style-type: none"> Home visit to seek informed consent Administering of inclusion questionnaire Dye test at nearest health post/centre Appropriate referral when needed Collection of demographic and clinical data from medical records
Follow up visits	<ul style="list-style-type: none"> Home visit to administer follow up questionnaire Dye test at nearest health post/centre Appropriate referral when needed



continent), post-operative social and reproductive life (marital status, occupation, sexuality, use of modern contraceptive methods, pregnancy, childbirth), and any fistula related complication. Participants' current full address is also collected to facilitate communication, referral and follow-up visits.

Sociodemographic and clinical characteristics

After obtaining the informed consent during the recruitment visit, a standardised questionnaire called Baseline form is used to collect the demographic and clinical characteristics of women from hospital records in the hospitals where they were discharged from. This questionnaire includes age at presentation at hospital, marital status, age at marriage, occupation, level of education, residence (rural/urban), number of pregnancies, parity, number of previous repairs, and duration of fistula. Clinical characteristics include mode of delivery related to development of the fistula, neonatal outcome at causal delivery, type of fistula (VVF, RVF or both), status of the bladder neck, nature of the fistula according to the surgeon (simple versus complex), duration of catheterization after repair, status of the operating surgeon (expatriate, local trainer, local trainee), postoperative complications, context of repair (routine repair or pooled repair) and the status of the fistula at discharge (close and continent/Close but not continent).

Data management

Study forms will be checked after data collection before sending to the Maferinyah Training and Research Centre in a sealed envelope where they will be stored in a locked cabinet. Data will be double entered by 2 independent encoders into a data entry file created using EpiData Entry software (EpiData Association, Odense, Denmark). Reliability will be checked and any inconsistencies in data entry will be resolved. It is planned to perform data entry on a continuous basis from the start of enrolment so that discrepancies are addressed while data collection is ongoing. Data entry screens will be created for each form used in the study. The database will be password protected and only authorized users will be

given access. All data will be stored in a GCP compliant server, and data management will respect patient confidentiality.

All study documents with the participant's name (i.e. participants' contact form) will be kept in a strict confidentiality.

Data analysis

Categorical data and treatment outcomes will be summarized as frequencies (%) and compared using χ^2 or Fisher's exact tests as appropriate. Continuous data will be presented using median (interquartile range) and compared using the Wilcoxon rank-sum test. Follow-up will be calculated from the date of hospital discharge. The date of fistula recurrence or the estimated date of pregnancy will be selected as the date of events. Patients who do not experience recurrence of fistula or pregnancy will be censored at the last follow up visit. For patients who are reported dead (by the relatives), the date of death will be used to determine their follow-up time in the study. For patients who are lost to follow up (i.e. who move from their village without any address to joint them after inclusion) the date of the last visit will be used.

Socio-demographic and clinical differences between those women who remain in the study and those who are lost-to-follow-up will be estimated to check for any imbalances at inclusion.

The incidence of fistula recurrence and that of pregnancy will be estimated using the method of cumulative incidence. The cumulative incidence rate will be compared across risk factors using Kaplan-Meier methods. Exposure variables with a P -value <0.2 in the univariate analysis will be included in multivariate models. Exposure variables with a P -value <0.2 in the univariate analysis will be included in multivariate models. A risk factor analysis will be performed using adjusted Cox regression. Associations will be reported as adjusted hazard ratios with 95 % CIs. Analysis will be done using STATA version 12 (STATA Corporation, College Station, TX, USA) with a level of significance will be set at $P < 0.05$.

For the outcomes of pregnancy (miscarriage or abortion, mother and child status at delivery), Pearson's Chi square (χ^2) will be used to compare proportions of these outcomes between potential exposure variables (age group, previous repair (Yes/No), fistula status at hospital discharge, use of antenatal care, delivery by caesarean section, etc.). Logistic regression analysis and models will be used and associations will be reported as risk ratios with a level of significance set at $P = 0.05$ and a 95 % confidence intervals.

Discussion

This longitudinal study will generate long-term follow-up data on fistula recurrence, subsequent pregnancies and their outcomes among women who underwent successful fistula repair in order to guide policy making and strategic planning in Guinea. This will improve current and future programmes for fistula management and care. The findings will also contribute towards improving programme performance and support advocacy efforts for better reintegration of fistula patients in Guinea and beyond.

This study has a number of strengths. First the protocol employs appropriate design and analytical methods, and a well powered sample size. Second, it will take advantage of the large collection of long term data assessing the recurrence of fistula and the outcomes of pregnancy. Third, it will add to previous studies examining fistula recurrence and reproductive outcomes after obstetric fistula repair by assessing a wide variety of variables, and by adjusting for potential confounding factors.

The results of this study and its potential implications will be made known to health care staff in the study sites, as well as the national level. National and international platforms will be used to disseminate study findings and the results will be presented at international conferences and published in peer reviewed journals. Since the findings might be applicable to other fistula care and management programmes in neighbouring countries, the lessons learnt might have wider benefit.

Abbreviations

ANC: Antenatal care; CI: Confidence intervals; DHS: Demographic and health survey; GCP: Good clinical practice; IRB: Institutional Review Board; ITM: Institute of Tropical Medicine; OF: Obstetric fistula; RVF: Rectovaginal fistula; UNFPA: United Nations Population Fund; USA: United States of America; USAID: United States Agency for International Development; VF: Vesicovaginal fistula

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Availability of data and materials

The data collected as part of this study will be kept in an anonymous file at the Maferinyah Training and Research Centre according to regulations stated by the Guinean National Ethics Committee for Health Research.

Authors' contributions

Alexandre Delamou (AD) initiated the study as principal investigator. All authors were involved in the design of the study. Therese Delvaux (TD), Abdoul Habib Beavogui (AHB), Alain Levêque (AL), Wei-Hong Zhang (WHZ) and Vincent De Brouwere (VDB) developed the study protocol. VDB is senior advisor to the project. AD, TD and AHB drafted this manuscript which was reviewed by AL, WHZ and VDB. All authors read and approved the final manuscript.

Competing interests

The authors declare that they have no competing interests.

Consent for publication

The protocol does not include any individual person's data; hence consent to publish is not applicable.

Ethics approval and consent to participate

This study was approved by the Institutional Review Board of the Institute of Tropical Medicine (ITM) of Antwerp (IRB# 948/14), the Ethics committee of the University Hospital of Antwerp (Ref# 14/22/238), (Belgium), and the National Ethics Committee for Health Research of Conakry, Guinea (Ref# 10/CNERS/14). Before enrolment, all participants provide written informed consent. The study is carried out according to the principles stated in the Declaration of Helsinki, all applicable regulations and according to established international scientific standards.

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References

1. Capes T, Ascher-Walsh C, Abdoulaye I, Brodman M. Obstetric fistula in low and middle income countries. *Mt Sinai J Med.* 2011;78(3):352–61.
2. Wall LL. A framework for analyzing the determinants of obstetric fistula formation. *Stud Fam Plann.* 2012;43(4):255–72.
3. Landry E, Frajzyngier V, Ruminjo J, Asiiimwe F, Barry T, Bello A, et al. Profiles and experiences of women undergoing genital fistula repair: Findings from five countries. *Glob Public Health.* 2013;8(8):926–42.
4. Adler AJ, Ronsmans C, Calvert C, Filippi V. Estimating the prevalence of obstetric fistula: a systematic review and meta-analysis. *BMC Pregnancy Childbirth.* 2013;13:246.
5. Lozano R, Wang H, Foreman K, et al. Progress towards Millennium Development Goals 4 and 5 on maternal and child mortality: an updated systematic analysis. *Lancet.* 2011;378:1139–65.
6. Institut National des Statistiques. Guinea demographic and health survey 2012. Conakry: Institut National des Statistiques and Mesures DHS; 2014.
7. Osotimehin B. Seizing the moment to end obstetric fistula. *Lancet Glob Health.* 2014;2(7):e381–2. doi:10.1016/S2214-109X(14)70251-7.
8. Osotimehin B. Obstetric fistula: ending the health and human rights tragedy. *Lancet.* 2013;381(9879):1702–3. doi:10.1016/S0140-6736(13)61001-6.
9. Tayler-Smith K, Zachariah R, Manzi M, van den Boogard W, Vandeborne A, Bishinga A, et al. Obstetric Fistula in Burundi: a comprehensive approach to managing women with this neglected disease. *BMC Pregnancy Childbirth.* 2013;13(1):164.
10. Hawkins L, Spitzer RF, Christoffersen-Deb A, Leah J, Mabeya H. Characteristics and surgical success of patients presenting for repair of obstetric fistula in western Kenya. *Int J Gynaecol Obstet.* 2013;120(2):178–82.

11. Delamou A, Diallo M, Beavogui AH, Delvaux T, Millimono S, Kourouma M, et al. Good clinical outcomes from a 7-year holistic programme of fistula repair in Guinea. *Trop Med Int Health*. 2015;20(6):813–9.
12. Barone MA, Frajzyngier V, Ruminjo J, Asiimwe F, Barry TH, Bello A, et al. Determinants of postoperative outcomes of female genital fistula repair surgery. *Obstet Gynecol*. 2012;120(3):524–31.
13. *Fistula Care/EngenderHealth*. Final Project Report: October 2007 to December 2013, Part 1I: Country Accomplishments. New York: Engenderhealth; 2013.
14. Osotimehin B. Statement on the International Day to End Obstetric Fistula – Assessed March 15, 2016. Available at: <http://www.unfpa.org/press/statement-international-day-end-obstetric-fistula-dr-babatunde-osotimehin-united-nations-under>
15. Barone MA, Widmer M, Arrowsmith S, Ruminjo J, Seuc A, Landry E, Barry TH, Danladi D, Djangnikpo L, Gbawuru-Mansaray T, Harou I, Lewis A, Muleta M, Nembunzu D, Olupot R, Sunday-Adeoye I, Wakasiaka WK, Landoulsi S, Delamou A, Were L, Frajzyngier V, Beattie K, Gülmezoglu AM. Breakdown of simple female genital fistula repair after 7 day versus 14 day postoperative bladder catheterisation: a randomised, controlled, open-label, non-inferiority trial. *Lancet*. 2015;386(9988):56–62. doi:10.1016/S0140-6736(14)62337-0.
16. Ministry OHoG. National Strategy for the prevention and treatment of Obstetric fistula, 2012–2016. Conakry: Ministry of Health of Guinea, UNFPA; 2012.
17. De Rider D, Abubakar K, Raassen T, Waaldijk K, Stanford E. Surgical treatment of obstetric fistula. In: Abrams P, De Ridder D, Devries C, Elneil S, Esegbona G, Mourad S, editors. *Obstetric fistula in the developing world*. Montreal (QC): Societe Internationale d'Urologie (SIU); 2012. p. 87–122.
18. Nielsen H, Lindberg L, Nygaard U, Aytenfisu O, Sorensen B, Rudnicki M, et al. A community-based long-term follow up of women undergoing obstetric fistula repair in rural Ethiopia. *BJOG*. 2009;116(9):1258–64.
19. Browning A, Menber B. Women with obstetric fistula in Ethiopia: a 6-month follow up after surgical treatment. *BJOG*. 2008;115(12):1564–9.
20. Wilson AL, Chipeta E, Kalilani-Phiri L, Taulo F, Tsui AO. Fertility and pregnancy outcomes among women with obstetric fistula in rural Malawi. *Int J Gynaecol Obstet*. 2011;113(3):196–8.
21. Drew LB, Wilkinson JP, Nundwe W, Moyo M, Mataya R, Mwale M, Tang JH. Long-term outcomes for women after obstetric fistula repair in Lilongwe, Malawi: a qualitative study. *BMC Pregnancy Childbirth*. 2016;16(1):2. doi:10.1186/s12884-015-0755-1.
22. Khisa W, Wakasiaka S, McGowan L, Campbell M, Lavender T. Understanding the lived experience of women before and after fistula repair: a qualitative study in Kenya. *BJOG*. 2016 19. doi: 10.1111/1471-0528.13902.
23. Donnelly K, Oliveras E, Tilahun Y, Belachew M, Asnake M. Quality of life of Ethiopian women after fistula repair: implications on rehabilitation and social reintegration policy and programming. *Cult Health Sex*. 2015;17(2):150–64. doi:10.1080/13691058.2014.964320.
24. *Fistula C*. Estimating Costs to Provide Fistula Services in Nigeria and Ethiopia: Key Findings. New York: Engenderhealth; 2012.
25. Bishinga A, Zachariah R, Hinderaker S, Tayler-Smith K, van den Boogard W, Tamura M, et al. High loss to follow-up following obstetric fistula repair surgery in rural Burundi: is there a way forward? *Public Health Action*. 2013;3(2):113–7.
26. Aimakhu VE. Reproductive functions after the repair of obstetric vesicovaginal fistulae. *Fertil Steril*. 1974;25(7):586–91.
27. Emembolu J. The obstetric fistula: factors associated with improved pregnancy outcome after a successful repair. *Int J Gynaecol Obstet*. 1992;39(3):205–12.
28. Evoh NJ, Akinla O. Reproductive performance after the repair of obstetric vesico-vaginal fistulae. *Ann Clin Res*. 1978;10(6):303–6.
29. Benfield N, Kinsindja RM, Kimona C, Masoda M, Ndume J, Steinauer J. Fertility desires and the feasibility of contraception counseling among genital fistula patients in eastern Democratic Republic of the Congo. *Int J Gynaecol Obstet*. 2011;114(3):265–7. doi:10.1016/j.ijgo.2011.02.024.
30. Institut National des Statistiques G. Pauvreté et inégalités en Guinée de 1994 à 2012: analyse à partir d'enquêtes auprès des ménages. Conakry: INS; PAM; BM; BAD; PNUD; EU; 2013.
31. Fleiss J, Levin B, Paik M. *Statistical Methods for Rates and Proportions*. Third ed. New York: John Wiley & Sons, Editors; 2003.

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Fistula recurrence, pregnancy, and childbirth following successful closure of female genital fistula in Guinea: a longitudinal study



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Summary

Background Female genital fistula is a devastating maternal complication of delivery in developing countries. We sought to analyse the incidence and proportion of fistula recurrence, residual urinary incontinence, and pregnancy after successful fistula closure in Guinea, and describe the delivery-associated maternal and child health outcomes.

Methods We did a longitudinal study in women discharged with a closed fistula from three repair hospitals supported by EngenderHealth in Guinea. We recruited women retrospectively (via medical record review) and prospectively at hospital discharge. We used Kaplan-Meier methods to analyse the cumulative incidence, incidence proportion, and incidence ratio of fistula recurrence, associated outcomes, and pregnancy after successful fistula closure. The primary outcome was recurrence of fistula following discharge from repair hospital in all eligible women who consented to inclusion and could provide follow-up data.

Findings 481 women eligible for analysis were identified retrospectively (from Jan 1, 2012, to Dec 31, 2014; 348 women) or prospectively (Jan 1 to June 20, 2015; 133 women), and followed up until June 30, 2016. Median follow-up was 28.0 months (IQR 14.6–36.6). 73 recurrent fistulas occurred, corresponding to a cumulative incidence of 71 per 1000 person-years (95% CI 56.5–89.3) and an incidence proportion of 18.4% (14.8–22.8). In 447 women who were continent at hospital discharge, we recorded 24 cases of post-repair residual urinary incontinence, equivalent to a cumulative incidence of 23.1 per 1000 person-years (14.0–36.2), and corresponding to 10.3% (5.2–19.6). In 305 women at risk of pregnancy, the cumulative incidence of pregnancy was 106.0 per 1000 person-years, corresponding to 28.4% (22.8–35.0) of these women. Of 50 women who had delivered by the time of follow-up, only nine delivered by elective caesarean section. There were 12 stillbirths, seven delivery-related fistula recurrences, and one maternal death.

Interpretation Recurrence of female genital fistula and adverse pregnancy-related maternal and child health outcomes were frequent in women after fistula repair in Guinea. Interventions are needed to safeguard the health of women after fistula repair.

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Introduction

Female genital fistula generally occurs after prolonged obstructed labour, resulting in continuous and uncontrolled leakage of urine or faeces, among other debilitating sequelae.^{1,2} Over the past decade, substantial international mobilisation towards achievement of a fistula-free generation has resulted in improved management of fistula cases,³ with high incidence of closure at time of hospital discharge^{4–6} and accomplishment of more than 100 000 surgical fistula repairs in sub-Saharan Africa and south Asia.^{7,8}

As more women access fistula treatment worldwide,⁹ attention during the post-repair period is important to ensure health after surgery. Fistula recurrence is of particular interest if the surgical site breaks down or if the woman develops a new, second fistula following

mismanaged obstructed labour after previous fistula repair.^{10–13} After successful fistula repair, many women of reproductive age⁶ return to their communities with the hope of resuming their social roles, including conceiving again, possibly to compensate for the traumatic loss they experienced during the delivery that led to the fistula.^{10,14–17}

Although there are many data for residual fistulas or failed repairs, few data exist for recurrent fistulas after a successful repair—this paucity might be for various reasons, including varying study designs and case definitions or length of follow-up.^{10,11,18,19} Similarly, data for fertility or pregnancy and childbirth after successful fistula repair are scarce, especially from robust studies that are able to provide a precise estimate of pregnancy and delivery outcomes.^{10,14,18,20–22} A review²³ in sub-Saharan Africa found that the risk of adverse maternal

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Research in context

Evidence before this study

Recurrence of fistula and pregnancy after repair of female genital fistula is not well documented in Guinea and sub-Saharan Africa. We searched PubMed for articles published between Jan 1, 1970, and March 31, 2017, with no language restrictions using the terms “post-repair”, “fistula”, “leakage”, “recurrence”, “pregnancy”, “delivery”, “childbirth”, “birth”, and “reintegration”. We found two recent reviews and two additional original studies reporting on fistula recurrence and pregnancy after repair of female genital fistula. The major findings were that most women who become pregnant after fistula surgery deliver either by emergency caesarean section or vaginally, which increases the risk of adverse maternal and neonatal outcomes, including stillbirths, recurrence of the fistula, or maternal death. However, studies do not provide a clear estimate of post-repair fistula recurrence and pregnancy rates. Additionally, most studies used small samples, were done at hospitals, and had short follow-up time.

Added value of this study

Our study fills a gap in knowledge about the health of women after fistula surgery. As far as we know, this study is the first of its kind from Guinea to report on the recurrence of fistula,

pregnancy, and childbirth after repair of female genital fistula, with a sufficient sample size recruited across the country and a relatively long follow-up time. The study adds to the existing body of knowledge on this topic and supports the feasibility of community follow-up in our context. The results provide evidence to guide the design and implementation of interventions that target post-repair reintegration.

Implications of all the available evidence

Combining evidence from this study with existing evidence suggests that women who undergo female genital fistula surgery in Guinea are still at high risk of fistula recurrence and adverse maternal and neonatal outcomes during their reintegration process. Overall, recurrence of female genital fistula was more frequent in Guinea than noted in previous reports from other sub-Saharan African countries. Pregnancy occurrence was relatively low compared with what would be expected and adverse maternal and neonatal outcomes were very common, particularly among women who delivered vaginally or by emergency caesarean section. Our findings underscore the need to rapidly identify locally suitable interventions to safeguard the health of women and that of their babies when they become pregnant after repair.

and neonatal health outcomes was elevated in women after fistula surgery, and that post-surgical fistula recurrence was the most common maternal complication, occurring in 5% of deliveries.²³ Although the general recommendation to women after fistula repair is to seek care at health-care facilities and deliver via scheduled caesarean section for any post-repair pregnancies,^{13,21,22} the proportion of women delivering via elective caesarean section is low (45%).²³

It is not known when or under what circumstances recurrence of fistula unrelated to acute, postoperative surgical site breakdown is most likely to occur. Furthermore, data for pregnancy and management of delivery after repair are lacking. Such data are needed to inform holistic fistula prevention and management programmes in countries in which female genital fistula is still prevalent and incident.²⁴ Guinea has high maternal mortality (724 maternal deaths per 100 000 livebirths) and a lifetime prevalence of self-reported obstetric fistula symptoms that is double that reported in sub-Saharan Africa as a whole (6·0 [95% CI 3·9–7·4] per 1000 women of reproductive age in Guinea *vs* 3·0 [1·3–5·5] per 1000 women of reproductive age in sub-Saharan Africa).^{25,26} In 2013, the fistula care project implemented by EngenderHealth, funded by the US Agency for International Development, supported three of the four repair hospitals in the country: Jean Paul II Hospital (Conakry), Labé Regional Hospital (Labé), and Kissidougou Prefectural Hospital (Kissidougou). About 3000 fistula repairs were done at the sites between

2007 and 2013.⁷ Additional funding was secured by EngenderHealth to support fistula repairs in 2014–15. Therefore, we did a longitudinal study¹⁹ among women discharged with a closed female genital fistula from Guinean repair hospitals, with the aim to estimate the incidence of fistula recurrence, residual urinary incontinence, and pregnancy after successful closure of the fistula, estimate the relative contribution of associated factors, and describe delivery-associated maternal and child health outcomes.

Methods

Study design and participants

We did a longitudinal observational study among women who underwent fistula repair between Jan 1, 2012, and June 30, 2015, at the three hospitals in Guinea supported by EngenderHealth (Conakry, Guinea). A detailed description of the study setting and methods has been previously published.¹⁹

We included women with a single genital fistula confirmed to be closed via dye test at the time of discharge from one of the three repair hospitals supported by EngenderHealth, who resided in Guinea.²⁷ We excluded women with incomplete medical records, and those who had fistula repair at other sites or who declined consent. Costs for surgery, transportation, and hospital stay for women were fully covered by EngenderHealth. Women were recruited both retrospectively and prospectively. Information on the status of the fistula at discharge was obtained through medical records review (retrospective

inclusion) or directly at discharge (prospective inclusion). Ethics approval was obtained from the Institute of Tropical Medicine (ITM) of Antwerp (IRB#948/14), the Ethics Committee of the University Hospital of Antwerp (Ref#14/22/238), and the National Ethics Committee for Health Research of Conakry, Guinea (Ref#10/CNERS/14). Eligible women provided written informed consent.

Procedures

The study procedures are described in detail elsewhere.¹⁹ Briefly, the study team contacted eligible women by phone or home visit in their communities across Guinea to obtain informed consent. The study team included nurses involved in the management of women at the fistula repair hospitals, doctors, and final year medical students. According to the protocol, data collection

follow-up visits were intended to be done every 6 months. However, because of the ongoing Ebola virus outbreak with its associated community reluctance and resistance, this was not possible. We expected most women to receive one follow-up data collection visit, but depending on timing of participant recruitment some could receive two follow-up data collection visits to maximise length of

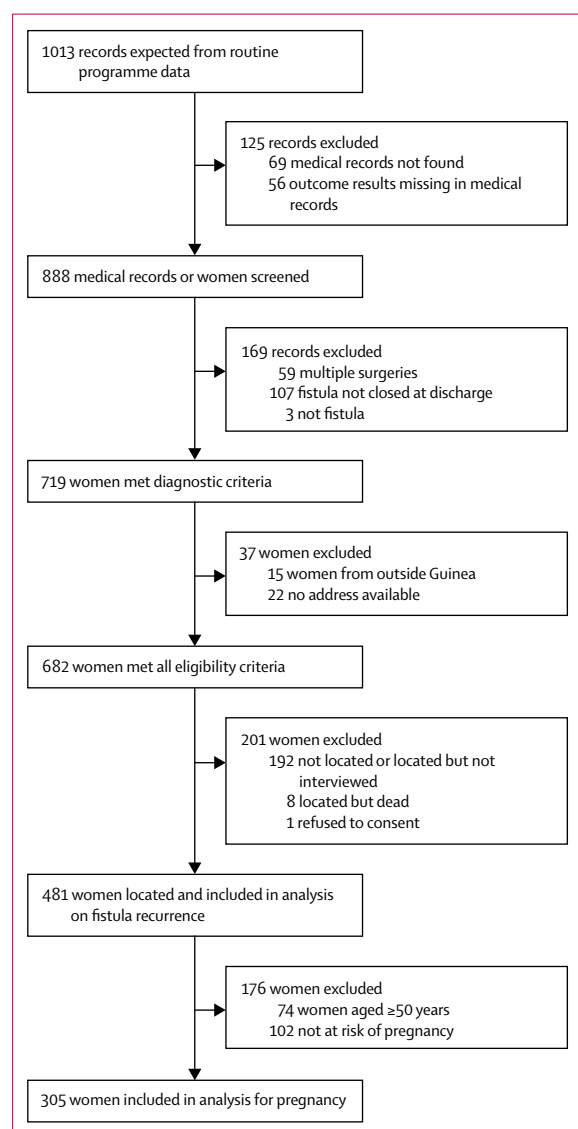


Figure 1: Study profile

	Non-participants (n=201)	Study participants (n=481)	p value
Mean age at surgery, years (SD)	36.3 (12.6)	34.4 (12.4)	0.077
Residence	0.089
Available data	200 (>99%)	479 (>99%)	..
Rural	180 (90%)	449 (94%)	..
Urban	20 (10%)	30 (6%)	..
Mean duration of fistula symptoms, months (SD)	119.1 (11.7)	112.5 (11.6)	0.518
Marital status at surgery	0.838
Available data	195 (97%)	472 (98%)	..
Married or union	146 (75%)	339 (72%)	..
Other*	49 (25%)	133 (28%)	..
Occupation at surgery	0.922
Available data	198 (99%)	474 (99%)	..
Housewife	187 (94%)	445 (94%)	..
Other†	11 (6%)	29 (6%)	..
Level of education at surgery	0.769
Available data	192 (96%)	471 (98%)	..
None	179 (93%)	442 (94%)	..
Primary or higher	13 (7%)	29 (6%)	..
Mean parity (SD)	3.6 (2.7)	3.6 (2.5)	0.857
Location of delivery	0.183
Available data	200 (>99%)	478 (99%)	..
Home	69 (35%)	191 (40%)	..
Health structure	131 (66%)	287 (60%)	..
Method of delivery	0.555
Available data	201 (100%)	479 (>99%)	..
Vaginal	127 (63%)	314 (66%)	..
Caesarean section	74 (37%)	165 (34%)	..
Neonatal outcome	0.027
Available data	196 (98%)	471 (98%)	..
Alive	24 (12%)	33 (7%)	..
Stillborn	172 (88%)	438 (93%)	..
Type of obstetric fistula	0.063
Available data	201 (100%)	480 (>99%)	..
Vesicovaginal fistula	184 (92%)	457 (95%)	..
Other‡	17 (8%)	23 (5%)	..
Number of previous repairs	0.105
Available data	192 (96%)	479 (>99%)	..
None	102 (53%)	298 (62%)	..
One or more	90 (47%)	181 (38%)	..
Urethral involvement	0.916
Available data	181 (90%)	465 (97%)	..
No	105 (58%)	274 (59%)	..
Yes	76 (42%)	191 (41%)	..

(Table 1 continues on next page)

	Non-participants (n=201)	Study participants (n=481)	p value
(Continued from previous page)			
Status of bladder neck	0.873
Available data	187 (93%)	462 (96%)	..
Normal	109 (58%)	266 (58%)	..
Damaged	78 (42%)	196 (42%)	..
Vaginal scarring	0.521
Available data	168 (84%)	439 (91%)	..
No	74 (44%)	177 (40%)	..
Yes	94 (56%)	262 (60%)	..
Route of repair	0.663
Available data	200 (>99%)	481 (100%)	..
Vaginal	195 (98%)	466 (97%)	..
Abdominal	5 (3%)	15 (3%)	..
Continence status at discharge	0.006
Available data	196 (98%)	481 (100%)	..
Closed and continent	169 (86%)	447 (93%)	..
Closed and not continent	27 (14%)	34 (7%)	..

*Single, widowed, divorced, or separated. †Office worker, farming, market vendor, or student. ‡Rectovaginal fistula or both vesicovaginal fistula and rectovaginal fistula.

Table 1: Demographic and clinical characteristics at time of fistula surgery among eligible female study participants and eligible female non-participants, 2012–16 in Guinea

	In hospital at surgery (n=481)	At follow-up visit (n=481)	p value
Residence	<0.0001
Rural	449 (93%)	419 (87%)	..
Urban	30 (6%)	62 (13%)	..
Unknown	2 (<1%)	0	..
Marital status	0.370
Married or union	339 (70%)	360 (75%)	..
Other*	133 (28%)	121 (25%)	..
Unknown	9 (2%)	0	..
Occupation	<0.0001
Housewife	445 (93%)	311 (65%)	..
Other occupation†	29 (6%)	170 (35%)	..
Unknown	7 (1%)	0	..

*Single, widowed, divorced, or separated. †Office worker, farming, market vendor, or student.

Table 2: Selected demographic characteristics of study participants at surgery and follow-up

follow-up. The maximum possible study follow-up was 4.5 years (Jan 1, 2012, to June 30, 2016).¹⁹

Outcomes

The primary outcome was recurrence of fistula following discharge from the repair hospital. For this study, recurrence of fistula was defined as the breakdown of a repaired fistula or the occurrence of a new fistula. During follow-up visits, women were first asked about their current continence status with the question, “Do you have continuous and uncontrolled leakage of urine

and/or faeces?” If the answer was yes, a dye test for confirmation of fistula (vs residual urinary incontinence) was performed at the nearest health-care centre or health post by a member of the research team. The secondary outcomes were time to pregnancy, pregnancy outcome, maternal and neonatal outcomes at first delivery after repair, and residual urinary incontinence among women continent at discharge. Pregnancy was documented by a positive pregnancy test or self-report, and time to pregnancy was calculated from the time of hospital discharge. Residual incontinence was confirmed by a dye test. We also evaluated number of pregnancies per woman, and antenatal care receipt, location of delivery, and method of delivery for each subsequent pregnancy.

Enrolment and follow-up data were collected by trained data collectors by use of structured and pre-tested standardised questionnaires. Sociodemographic data captured at enrolment included age at fistula surgery, level of education, marital status, occupation, and residence (rural or urban). Clinical characteristics at enrolment included number of pregnancies, parity, duration of fistula symptoms, number of previous repairs, mode of delivery during the birth when the fistula occurred, neonatal outcome at this delivery, type of fistula (vesicovaginal fistula, rectovaginal fistula, or both), and continence status at the time of discharge (continent or not continent). The follow-up questionnaire evaluated participants’ current fistula and continence status (fistula closed and continent, closed but not continent, or not closed), self-reported circumstances of fistula recurrence, postoperative and sociodemographic and reproductive characteristics, such as current residence (urban or rural), marital status, occupation, post-repair pregnancies (ongoing, aborted or miscarried, delivered), neonatal outcomes at first delivery post-repair (livebirth, stillbirth, neonatal death), and sex of the child at first delivery post-repair. For individuals who received two follow-up data collection visits, data from the second visit only (to avoid double reporting) was included in the analysis.

Statistical analysis

We estimated that the minimum sample size required determined by specified precision level (2% margin of error and 95% CI) was 364 women receiving surgical fistula repair.¹⁹

All women who met eligibility criteria and who were able to be located and interviewed were used in fistula recurrence-related analyses, whereas pregnancy-related analyses were restricted to women of reproductive age who were considered at risk of pregnancy by self-report of sexual activity after repair. We present categorical data as n (%) and compared them with χ^2 or Fisher’s exact tests. We present continuous data as means with SD (and compared them with Student’s *t* test) and medians with IQR (Mann-Whitney *U* test). *p*<0.05 was regarded as significant. Among eligible women, we compared

sociodemographic and clinical characteristics between women included in our analytical sample and women not included to check for differences at inclusion. We calculated follow-up time from the date of hospital discharge. For calculation of person-time at risk, fistula recurrence, post-repair residual urinary incontinence, or first post-repair pregnancy cumulative incidence and proportion, we considered the self-reported date of onset of recurrent incontinence symptoms or the self-reported first date of last menses as dates of event. Patients who did not experience fistula recurrence or pregnancy, or who died, were censored at the date of last follow-up visit. For all time-related variables, the 15th of the month was used when an exact date was not provided. The study outcomes were estimated as cumulative incidence with Kaplan-Meier survival analysis methods or as proportions. Additionally, we derived incidence ratios of study outcomes and compared them for selected variables using Fisher's exact test. We carried out an analysis that takes the competing event (one death) into account²⁸ but found no difference because of the small number of competing events for fistula recurrence and pregnancy. Study data were managed by EpiData software version 3.1 (EpiData Association, Odense, Denmark) and the analyses were performed using Stata 13 software (Stata Corporation, College Station, TX, USA). This study was registered with ClinicalTrials.gov, number NCT02686957.

Role of the funding source

The funder of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Results

Women were recruited both retrospectively (Jan 1, 2012, to Dec 31, 2014) and prospectively (Jan 1 to June 30, 2015), with follow-up ending on June 30, 2016. Overall, the medical records of 888 women were screened (figure 1), of whom 481 (70%) were locatable and consented to inclusion in the analysis for the primary outcome. Of these women, 305 (75%) of reproductive age reported being sexually active after surgery and were considered in the pregnancy-related analyses. Included women came from across the country (appendix). 327 (68%) women received one follow-up visit and 154 (32%) received two.

Table 1 shows sociodemographic and clinical characteristics at time of fistula surgery for eligible women included in the study and eligible women who did not participate. Characteristics were similar in both groups: most women were married or in union, were housewives, and had vesicovaginal fistulas. Most women were continent at hospital discharge, but a small number had residual incontinence. Eligible study participants had experienced more stillbirths during the delivery

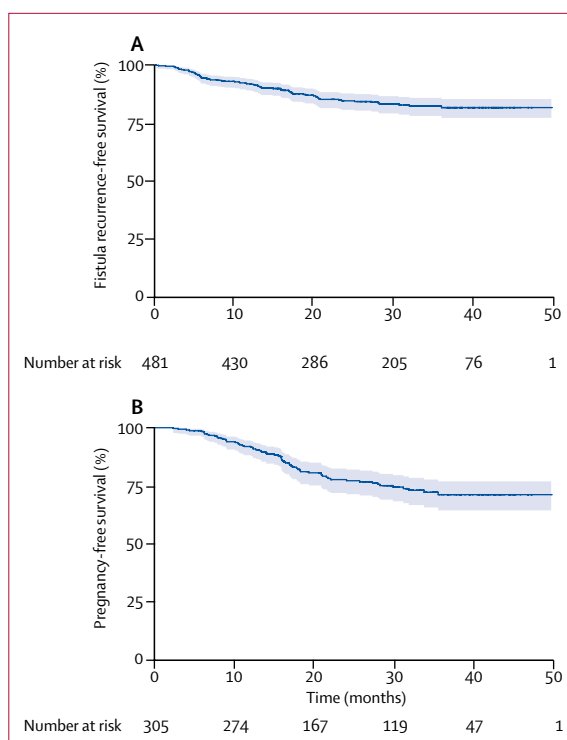


Figure 2: Kaplan-Meier curves for overall recurrence-free survival (A) and first post-repair pregnancy-free survival (B)
Shaded regions are 95% CIs.

leading to the fistula than had eligible women not participating in the study.

At follow-up, some sociodemographic characteristics of women included in the study had changed. The proportion of women reporting urban residence had doubled and the percentage of women reporting an occupation other than housewife had increased (table 2).

Median follow-up was 28.0 months (IQR 14.6–36.6). The cumulative incidence of fistula recurrence was 71.0 per 1000 person-years (95% CI 56.5–89.3), corresponding to 18.4% (14.8–22.8) of women (figure 2, table 3). 39 (53%) of the 73 recurrences of fistula occurred during the first 12 months after discharge (27 [37%] during the first 6 months; figure 3). 14 (19%) women self-reported that the recurrence of fistula occurred during farm work, nine (12%) when walking, seven (10%) after sexual intercourse, and seven (10%) after pregnancy and delivery that occurred after the index fistula repair surgery.

We recorded 24 cases of post-repair residual urinary incontinence among 447 women who were continent at hospital discharge, which is equivalent to a cumulative incidence of 23.1 per 1000 person-years (95% CI 14.0–36.2) or 10.3% (5.2–19.6) of women (table 3). Of these 24 cases, eight (33%) occurred during the first 12 months after discharge (figure 3).

Cumulative incidence of residual urinary incontinence did not differ by pregnancy status, sexual activity, urethral involvement, status of the bladder neck, or vaginal

See Online for appendix

	Fistula recurrence post-repair		Residual urinary incontinence		First pregnancy after repair	
	Events	Incidence (95% CI)	Events	Incidence (95% CI)	Events	Incidence (95% CI)
Cumulative incidence per 1000 person-years						
Total	73	71.0 (56.5–89.3)	24	23.1 (14.0–36.2)	67	106.0 (83.2–134.3)
Cumulative incidence by 6 month study period						
6 months	27	5.6% (3.9–8.1)	4	0.8% (0.3–2.2)	5	1.7% (0.7–3.9)
12 months	12	8.2% (6.1–11.1)	4	1.7% (0.9–3.4)	19	8.1% (5.5–11.8)
18 months	17	12.4% (9.7–15.9)	7	3.4% (2.1–5.6)	24	17.6% (13.5–22.7)
24 months	10	15.5% (12.3–19.4)	1	3.7% (2.3–6.0)	9	21.9% (17.3–27.6)
30 months	4	16.9% (13.5–21.0)	1	4.1% (2.5–6.5)	6	25.2% (20.2–31.2)
≥36 months	3	18.4% (14.8–22.8)	7	10.3% (5.2–19.6)	4	28.4% (22.8–35.0)

Table 3: Incidence of fistula recurrence, residual urinary incontinence, and pregnancy

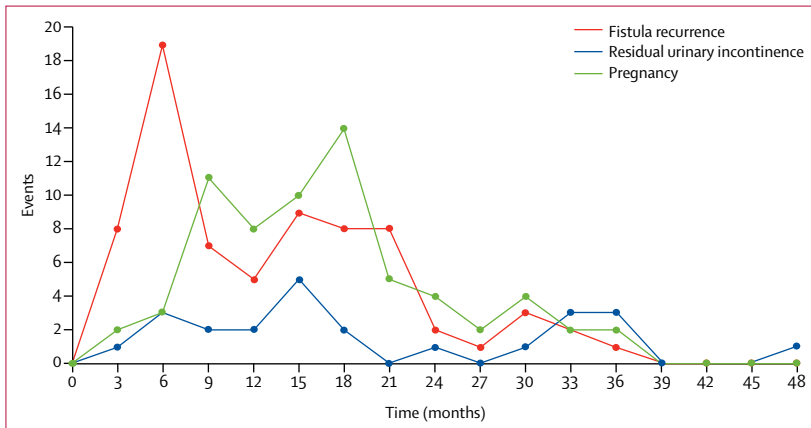


Figure 3: Incidence of fistula recurrence (n=73), first post-repair pregnancy (n=67), and residual urinary incontinence (n=24) over time in study participants

scarring (table 4). However, incidence of fistula recurrence was increased in women not sexually active at follow-up, those who had a damaged urethra at fistula surgery, those who had a damaged bladder neck at fistula surgery, and those who had vaginal scarring at fistula surgery (table 4).

Cumulative incidence of pregnancy was 106.0 per 1000 person-years (95% CI 83.2–134.3), corresponding to 28.4% (22.8–35.0) of women (figure 2, table 3). First post-repair pregnancies occurred between 3 months and 36 months after hospital discharge, with 48 (72%) of the first post-repair pregnancies occurring within the first 18 months, and 57 (85%) within the first 24 months (figure 3). Cumulative incidence of pregnancy did not differ according to urethral involvement, status of the bladder neck, vaginal scarring, or fistula status at the time of hospital discharge (table 4). Of the 67 women with at least one post-repair pregnancy, 51 (76%) achieved at least one antenatal care visit for the first post-repair pregnancy. 50 women had delivered by the time of follow-up, of whom only nine (18%) delivered by elective caesarean section (figure 4). Among these 50 deliveries, we recorded 12 (24%) stillbirths,

seven (14%) delivery-related fistula recurrences, and one (2%) maternal death.

Discussion

This study found that fistula recurrence was quite frequent among women who underwent fistula repair in Guinea, with a higher incidence than expected. Low recurrence rates were expected given the counselling done before surgery and at hospital discharge, and also women’s knowledge of the devastating effects of fistulas. Existing literature does not provide cumulative incidence for fistula recurrence. However, by 24 months’ follow-up, we recorded a cumulative incidence of 15.5% (95% CI 12.3–19.4) of women compared to 3.9% reported in a small study¹⁰ of 26 women followed up for 9–24 months post-repair in Malawi and 2.6% during a 21 month community-based follow-up¹⁸ of 38 repaired women in Ethiopia. Even by 6 months’ follow-up, we recorded a higher proportion (5.6%) than noted among 233 women discharged with a closed fistula in Ethiopia (2.6%).¹¹ The notable differences observed might be related to several factors, including the different follow-up periods, sample sizes, participant recruitment or diagnostic methods, fistula recurrence case definition, or the differences in sample characteristics across studies. Furthermore, most of the previously mentioned studies cited did not do a physical exam or dye test. More than half of the recurrences documented in our study occurred within the first 12 months following hospital discharge, with the maximum risk of recurrence within the first 6 months after discharge (37% of all recurrences). These findings indicate the need to identify and implement interventions that go beyond repair, which might be challenging given the barriers to engaging women after discharge, such as geographical distribution, transportation costs, and the absence of supportive priorities or resources in many fistula programmes.^{29–31} To our knowledge, although patients are often encouraged to return for a follow-up visit, most services provided by fistula treatment programmes are limited to hospital stay, including sexual and reproductive health counselling at discharge,

psychological counselling, skill empowerment, literacy classes, or support groups before discharge.^{14,15,20,32} A rethink of fistula programming to include locally adapted follow-up mechanisms to prevent post-repair recurrence is needed to safeguard the health of women after fistula repair.²⁹

More fistula recurrences were recorded in women with a damaged urethra or bladder neck and vaginal scarring at time of fistula surgery. Periurethral fistulas are more delicate and more likely to break down than are higher fistulas, and the role of vaginal scarring and status of bladder neck has already been described in the African context.^{33,34}

Women reported that fistula recurrences happened during farming activities, walking, or sexual intercourse, confirming what has already been reported.^{11–13,35} However, the association between absence of sexual activity after repair and fistula recurrence should be interpreted with caution. First, the information was collected at the time of follow-up and therefore the directionality of the association cannot be established, and this characteristic might have changed because of fistula recurrence or residual incontinence (reverse causality). Second, divorce or abandonment might lead to socioeconomic precariousness, resulting in differential risk for recurrence. Third, some women were simply unable to have intercourse after fistula repair or only with great difficulty because of vaginal scarring or vaginal stenosis. Whatever the explanation, the findings contrast with the existing literature identifying sexual intercourse as a potential causative factor for fistula recurrence^{11,13,23,35} and warrant further research.³⁶

More than a fifth of sexually active women of reproductive age in our study became pregnant at least once during the study follow-up. The observed pregnancy incidence was lower than what would be expected from women who have not experienced fistula. The low pregnancy incidence observed in our study might be related to infrequent sexual activity structuring differential risk of pregnancy during the follow-up period due to fear of fistula recurrence, lack of partner following hospital discharge, gynaesthesia, intrauterine scarring, upper urinary tract infection, or biological and physiological dysfunctions reported to be frequent after fistula surgery, such as amenorrhoea.^{10,37,38} Wilson and colleagues¹⁸ reported that women repaired for genital fistula frequently complained of infertility, which might be the explanation behind our findings. Furthermore, a study³⁹ done in the African context has reported decreased fertility in women following a caesarean delivery, particularly in those undergoing emergency caesarean sections.

Most pregnancies occurred between 3 months and 24 months after discharge. Early pregnancies and their associated adverse neonatal outcomes observed in this study suggest that either childbearing desire is high among women after surgery or women are not empowered enough to make decisions about the timing of

	Cumulative incidence	Cumulative incidence per 1000 person-years (95% CI)	Rate ratio	p value
Fistula recurrence				
Pregnancy status	1.2 (0.8–1.7)	0.3061
No	63	73.0 (57.0–93.4)
Yes	10	60.7 (32.7–112.9)
Sexual activity				
No	43	142.6 (105.7–192.2)	3.4 (2.1–5.7)	<0.0001
Yes	30	41.3 (28.9–59.1)
Urethral involvement	2.7 (1.6–4.6)	<0.0001
No	25	42.2 (28.5–62.5)
Yes	45	113.8 (85.0–152.5)
Status of bladder neck	1.9 (1.2–3.2)	0.0032
Normal	29	51.1 (35.5–73.5)
Damaged	41	98.7 (72.7–134.0)
Vaginal scarring	1.7 (1.0–3.0)	0.0291
No	19	49.9 (31.8–78.2)
Yes	47	82.7 (62.1–110.1)
Residual incontinence				
Pregnancy status	1.9 (0.6–4.9)	0.1011
No	18	18.8 (11.9–29.9)
Yes	6	35.2 (15.8–78.5)
Sexual activity	1.2 (0.9–1.5)	0.3557
No	7	18.8 (9.0–39.5)
Yes	17	22.5 (14.0–36.2)
Urethral involvement	1.6 (0.6–3.8)	0.1431
No	11	17.8 (9.9–32.2)
Yes	13	27.8 (16.1–47.9)
Status of bladder neck	1.8 (0.7–4.5)	0.0847
Normal	10	16.5 (8.9–30.8)
Damaged	14	29.4 (17.4–49.6)
Vaginal scarring	1.6 (0.6–4.5)	0.1612
No	7	17.2 (8.2–36.1)
Yes	17	27.0 (16.8–43.5)
Pregnancy				
Urethral involvement	1.3 (0.8–2.1)	0.1603
No	36	95.1 (68.6–131.8)
Yes	29	122.0 (84.8–175.6)
Status of bladder neck	1.0 (0.9–1.1)	0.4668
Normal	38	102.4 (74.5–140.7)
Damaged	24	99.9 (67.0–149.1)
Vaginal scarring	1.0 (0.6–1.8)	0.4256
No	24	99.2 (66.5–148.1)
Yes	37	104.5 (75.7–144.2)
Fistula status at discharge	2.2 (0.6–5.9)	0.0798
Closed and dry	63	102.3 (79.9–130.9)
Closed with residual incontinence	4	224.7 (84.3–598.7)

Some variables are missing data as these could not be collected from certain women.

Table 4: Cumulative incidence of study outcomes for selected study variables among women discharged with a closed fistula, 2012–16 in Guinea

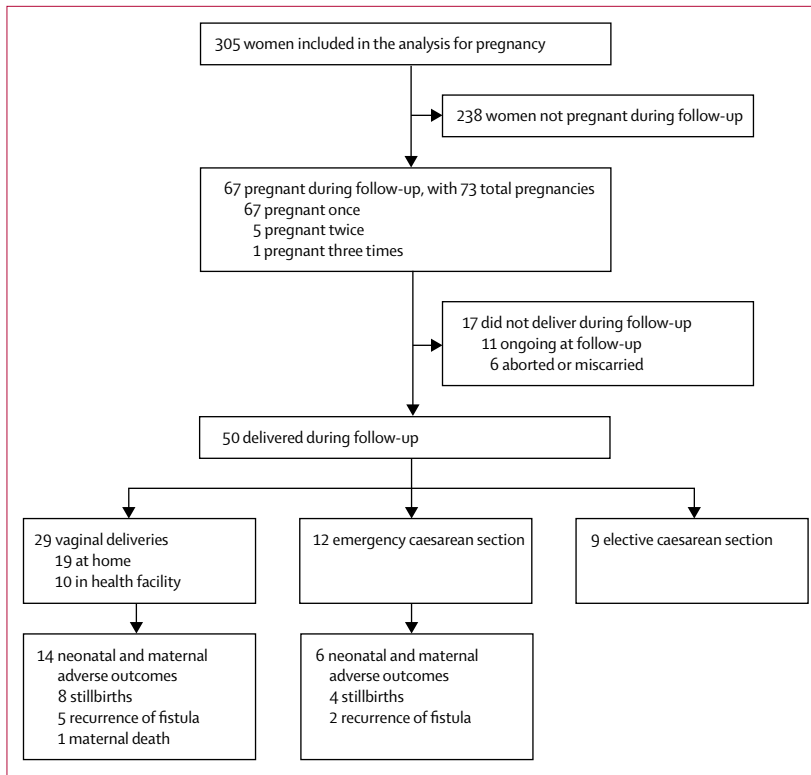


Figure 4: Post-repair pregnancy and delivery outcomes among sexually active study participants of reproductive age

pregnancy, specifically regarding planning for delivery. At many repair hospitals, providers spend a lot of time counselling patients and people accompanying them that they will need a scheduled caesarean section and delivery in a hospital, and to use family planning methods to delay pregnancy after repair. However, this outcome is very challenging for providers and women to achieve.⁴⁰ Therefore, a need exists to ensure that women and their partners are well informed of the need for elective caesarean section, given that caesarean section and obstetric care are free of charge in Guinea. Furthermore, current and future fistula programmes should include locally suitable post-discharge follow-up and management mechanisms for these women.

At first pregnancy after repair, we observed high rates of adverse maternal and neonatal outcomes (fistula recurrence, stillbirth, and maternal death), which are consistent with other reports from different African contexts, albeit with small sample sizes.^{10,23,41} In an 18-month longitudinal study in Niger and Mali,⁴¹ post-repair pregnancy-related adverse outcomes (two stillbirths and one suspicion of fistula recurrence) were recorded only in women who delivered without medical assistance. Furthermore, a review²³ showed that after fistula surgery, women who delivered vaginally or by emergency caesarean section were at greatest risk of having adverse maternal and child health outcomes. In this study, all delivery-related fistula recurrences and stillbirths

occurred in women who had vaginal delivery or emergency caesarean section. That women who already developed and lived with genital fistula had subsequent high incidences of stillbirth and fistula recurrence in a following pregnancy is very concerning. Loss of a child during the delivery associated with fistula is a traumatic experience;^{16,17} a repeated infant loss after repair is even more of a human and public health tragedy.^{9,17} Our findings show the need for interventions that will prevent occurrence of female genital fistula in women of childbearing potential and improve the health of those who receive treatment.

Our study has several limitations. First, follow-up time was short for some women who had undergone a fistula repair in 2015 and part of the sample was included retrospectively. Second, we did not identify cause(s) of urinary incontinence in women with residual incontinence.^{11,42} Third, the circumstances of fistula recurrence relied on women self-reporting the date of onset of severe urinary or faecal incontinence symptoms and preceding activity. Fourth, we did not use any fistula classification system to stratify by type of fistula in the analysis. Finally, because more women were living in urban areas at follow-up than at time of surgery, it is possible that they were at lower risk of having fistula recurrence, which would have underestimated the incidence rate.

Despite these limitations, this is the first study from Guinea to report on the recurrence of fistula, pregnancy, and childbirth after repair of female genital fistula with a sufficient sample size and a relatively long follow-up. This study adds to the existing body of knowledge on the topic and supports the feasibility of community follow-up in our context.^{10,11}

Recurrence of female genital fistula seemed to be more frequent in Guinea than noted in previous reports from other sub-Saharan African countries. Women who undergo fistula surgery are still at risk of having adverse maternal and child health outcomes in Guinea. This risk underscores the need to rapidly identify locally suitable interventions to safeguard the health of these women so that, at a minimum, they do not develop a second fistula or lose their babies when they become pregnant after repair.

Contributors

AD, TD, AHB, W-HZ, AL, and VDB conceived the research question and developed the protocol. AD, BSC, PB, MC, THB, KD, MD, and TD oversaw study implementation. AD analysed the study data and was assisted by AMEA, TD, and VDB. AD, AMEA, VT, LR, BC, TD, and VDB contributed to the writing of the draft manuscript. MD, BSC, PB, MC, THB, KD, W-HZ, and AL interpreted the data and critically reviewed the manuscript. All authors read and approved the final manuscript.

Declaration of interests

We declare no competing interests.

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References

- 1 Wall LL. A framework for analyzing the determinants of obstetric fistula formation. *Stud Fam Plann* 2012; 43: 255–72.
- 2 Arrowsmith S, Hamlin EC, Wall LL. Obstructed labor injury complex: obstetric fistula formation and the multifaceted morbidity of maternal birth trauma in the developing world. *Obstet Gynecol Surv* 1996; 51: 568–74.
- 3 Osotimehin B. Seizing the moment to end obstetric fistula. *Lancet Glob Health* 2014; 2: e381–82.
- 4 Tayler-Smith K, Zachariah R, Manzi M, et al. Obstetric fistula in Burundi: a comprehensive approach to managing women with this neglected disease. *BMC Pregnancy Childbirth* 2013; 13: 164.
- 5 Hawkins L, Spitzer RF, Christoffersen-Deb A, Leah J, Mabeya H. Characteristics and surgical success of patients presenting for repair of obstetric fistula in western Kenya. *Int J Gynaecol Obstet* 2013; 120: 178–82.
- 6 Delamou A, Diallo M, Beavogui AH, et al. Good clinical outcomes from a 7-year holistic programme of fistula repair in Guinea. *Trop Med Int Health* 2015; 20: 813–19.
- 7 US AID, Fistula Care, Engender Health. Fistula Care Associate Cooperative Agreement GHS-A-00-07-00021-00. Final Project Report: October 2007 to December 2013. Part II: Country Accomplishments. New York: Fistula Care/EngenderHealth, 2014.
- 8 Osotimehin B. Statement on the International Day to End Obstetric Fistula. May 23, 2015. <http://www.unfpa.org/press/statement-international-day-end-obstetric-fistula-dr-babatunde-osotimehin-united-nations-under> (accessed March 4, 2017).
- 9 Osotimehin B. Obstetric fistula: ending the health and human rights tragedy. *Lancet* 2013; 381: 1702–03.
- 10 Nielsen HS, Lindberg L, Nygaard U, et al. A community-based long-term follow up of women undergoing obstetric fistula repair in rural Ethiopia. *BJOG* 2009; 116: 1258–64.
- 11 Browning A, Member B. Women with obstetric fistula in Ethiopia: a 6-month follow up after surgical treatment. *BJOG* 2008; 115: 1564–59.
- 12 Bishinga A, Zachariah R, Hinderaker S, et al. High loss to follow-up following obstetric fistula repair surgery in rural Burundi: is there a way forward? *Public Health Action* 2013; 3: 113–17.
- 13 Aimakhu VE. Reproductive functions after the repair of obstetric vesicovaginal fistulae. *Fertil Steril* 1974; 25: 586–91.
- 14 Lombard L, de St Jorre J, Geddes R, El Ayadi AM, Grant L. Rehabilitation experiences after obstetric fistula repair: systematic review of qualitative studies. *Trop Med Int Health* 2015; 20: 554–68.
- 15 Landry E, Vera F, Ruminjo J, et al. Profiles and experiences of women undergoing genital fistula repair: findings from five countries. *Glob Public Health* 2013; 8: 926–42.
- 16 Roka ZG, Akech M, Wanzala P, Omolo J, Gitta S, Waiswa P. Factors associated with obstetric fistulae occurrence among patients attending selected hospitals in Kenya, 2010: a case control study. *BMC Pregnancy Childbirth* 2013; 13: 56.
- 17 Ahmed S, Anastasi E, Laski L. Double burden of tragedy: stillbirth and obstetric fistula. *Lancet Glob Health* 2016; 4: e80–82.
- 18 Wilson AL, Chipeta E, Kalilani-Phiri L, Taulo F, Tsui AO. Fertility and pregnancy outcomes among women with obstetric fistula in rural Malawi. *Int J Gynaecol Obstet* 2011; 113: 196–98.
- 19 Delamou A, Delvaux T, Beavogui AH, Leveque A, Zhang W-H, De Brouwere V. A descriptive longitudinal study protocol: recurrence and pregnancy post-repair of obstetric fistula in Guinea. *BMC Pregnancy Childbirth* 2016; 16: 299.
- 20 Degge HM, Hayter M, Laurenson M. An integrative review on women living with obstetric fistula and after treatment experiences. *J Clin Nurs* 2017; 26: 1445–57.
- 21 Browning A. Pregnancy following obstetric fistula repair, the management of delivery. *BJOG* 2009; 116: 1265–67.
- 22 Otubu JA, Kumi GO, Ezem BU. Pregnancy and delivery after successful repair of vesicovaginal fistula. *Int J Gynaecol Obstet* 1982; 20: 163–66.
- 23 Delamou A, Utz B, Delvaux T, et al. Pregnancy and childbirth after repair of obstetric fistula in sub-Saharan Africa: scoping review. *Trop Med Int Health* 2016; 21: 1348–65.
- 24 De Ridder D, Abubacar K, Raassen T, Waaldijk K, Stanford E. Surgical treatment of obstetric fistula. In: Abraham P, De Ridder D, Devries C, et al, eds. *Obstetric fistula in the developing world*. Montreal: Société Internationale d'Urologie, 2012: 87–122.
- 25 Institut National des Statistiques. Enquête Démographique et de Santé et à Indicateurs Multiples (EDS-MICS), 2012. Conakry: Institut National de la Statistique, 2014.
- 26 Maheu-Giroux M, Filippi V, Samadoulougou S, et al. Prevalence of symptoms of vaginal fistula in 19 sub-Saharan Africa countries: a meta-analysis of national household survey data. *Lancet Glob Health* 2015; 3: e271–78.
- 27 Barone M, Frajzyngier V, Arrowsmith S, et al. Non-inferiority of short-term urethral catheterization following fistula repair surgery: study protocol for a randomized controlled trial. *BMC Pregnancy Childbirth* 2012; 12: 5.
- 28 Andersen PK, Geskus RB, de Witte T, Putter H. Competing risks in epidemiology: possibilities and pitfalls. *Int J Epidemiol* 2012; 41: 861–70.
- 29 Donnelly K, Oliveras E, Tilahun Y, Belachew M, Asnake M. Quality of life of Ethiopian women after fistula repair: implications on rehabilitation and social reintegration policy and programming. *Cult Health Sex* 2015; 17: 150–64.
- 30 Delamou A, Delvaux T, Utz B, et al. Factors associated with loss to follow-up in women undergoing repair for obstetric fistula in Guinea. *Trop Med Int Health* 2015; 20: 1454–61.
- 31 Murray C, Goh JT, Fynes M, Carey MP. Urinary and faecal incontinence following delayed primary repair of obstetric genital fistula. *BJOG* 2002; 109: 828–32.
- 32 Alio AP, Merrell L, Roxburgh K, et al. The psychosocial impact of vesico-vaginal fistula in Niger. *Arch Gynecol Obstet* 2011; 284: 371–78.
- 33 Delamou A, Delvaux T, Beavogui AH, et al. Factors associated with the failure of obstetric fistula repair in Guinea: implications for practice. *Reprod Health* 2016; 13: 135.
- 34 Barone MA, Frajzyngier V, Ruminjo J, et al. Determinants of postoperative outcomes of female genital fistula repair surgery. *Obstet Gynecol* 2012; 120: 524–31.
- 35 Emembolu J. The obstetric fistula: factors associated with improved pregnancy outcome after a successful repair. *Int J Gynaecol Obstet* 1992; 39: 205–12.
- 36 Lawani LO, Iyoke CA, Ezeonu PO. Contraceptive practice after surgical repair of obstetric fistula in southeast Nigeria. *Int J Gynaecol Obstet* 2015; 129: 256–59.
- 37 Tang JH, Steiner A, Bengtson A, et al. Cross-sectional study of the ultrasonographic and hormonal characteristics of obstetric fistula patients with and without secondary amenorrhea. *Int J Gynaecol Obstet* 2017; 136: 238–40.
- 38 Anzaku SA, Lengmang SJ, Mikah S, Shephard SN, Edem BE. Sexual activity among Nigerian women following successful obstetric fistula repair. *Int J Gynaecol Obstet* 2017; 137: 67–71.
- 39 Filippi V, Ganaba R, Calvert C, Murray SF, Storeng KT. After surgery: the effects of life-saving caesarean sections in Burkina Faso. *BMC Pregnancy Childbirth* 2015; 15: 348.
- 40 Pope R, Moyo M, Wilkinson J. She did the right thing: the high price of poor access to obstetric care. *BJOG* 2015; 122: 182.
- 41 Maulet N, Macq J. Obstetric fistula patients' reproductive health paths and perspectives. *Int J Gynaecol Obstet* 2012; 119: S841.
- 42 Goh JT. A new classification for female genital tract fistula. *Aust NZ J Obstet Gynaecol* 2004; 44: 502–04.