



# Determinants of post-operative outcomes in fistula repair surgery: A prospective facility-based study.

## Study Summary:

This will be an observational study, that gathers data prospectively to assess the association of current fistula repair practices at 11 Fistula Care-supported fistula repair sites in Africa and South Asia. The primary objective of the study is to determine predictors of complications and success of fistula repair surgery. The study will look at socio-demographic and other background information, circumstances surrounding development of the fistula (including obstetric history), anatomical and clinical characteristics of the fistula, and pre-, intra- and post-operative techniques used. No new clinical methods or interventions will be introduced as part of the study; however, because pre-operative, intraoperative and post-operative procedures vary between the sites we will be able to examine the association of these different procedures on success of the repair surgery. Staff at the study sites will document client intake and record information on standardized study report forms developed by Fistula Care to ensure consistent data are gathered from all study sites using standard definitions. Data will be gathered at admission to the study, during the clinical exam and the repair surgery, during the hospital stay, and then at a 3 month post-surgery follow-up visit. The results of the study will help answer some of the most pressing clinical research questions in the fistula field, and will inform future interventions and further research in fistula treatment and prevention.

### Projected start and end dates: June 2007-December 2010

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## Background and Need

## Introduction

An obstetric fistula is an abnormal passage/opening between the genital tract and the urinary or intestinal tract. This abnormal opening is usually the result of an injury incurred during delivery, most frequently from prolonged or obstructed labor. The constant pressure of the baby's head against the vaginal and bladder or intestinal wall tissue leads to necrosis, which causes a fistula to develop. The fistula results in the uncontrolled passage of urine and/or feces into the vagina. Less common, fistula results from an injury that occurs due to direct tearing of the vaginal tissues, such as damage during gynecologic surgery, or violent sexual assault, including rape and the forced insertion of objects into a woman's vagina. Fistula as a result of sexual violence has been termed "traumatic gynecologic fistula". Women suffering from fistula live with chronic urinary and/or fecal incontinence, the social effects of which include divorce, abandonment, and even abuse. Many women report feeling shame about their condition and therefore alienate themselves from friends and family.

Obstetric fistula appears to be most common in sub-Saharan Africa and South Asia. There is wide variation in prevalence estimates, not only from country to country, but also from one region to another within any given country. It has been estimated that worldwide, fistula occurs in two to three cases per 1,000 deliveries in areas with high maternal mortality, where access to emergency obstetric care is limited (UNFPA, 2003). Based on the number of women seeking treatment, the World Health Organization (WHO) has estimated that over 2 million women are living with untreated obstetric fistula (UNFPA, 2003), although this is likely a gross underestimation in part because many women with fistula do not seek treatment and most fistula data is facility-based.

In response, Fistula Care is working with national governments and other local partners to strengthen and/or implement fistula programs in the following countries: Bangladesh, Democratic Republic of the Congo, Ethiopia (via IntraHealth), Guinea, Nigeria, Rwanda and Uganda, with regional program in East and West Africa. The Fistula Care fistula project's approach is data-driven, emphasizing the use of data to inform program planning and implementation. This approach helps to identify important needs and opportunities for fistula programming and develop strategies that are clearly adapted to a particular country's context.

## **Research Background**

While work to address fistula has been taking place throughout sub-Saharan Africa and parts of Asia, there still remains a dearth of reliable data around social, demographic and clinical factors that are associated with success of fistula repair surgery. Retrospective record reviews have endeavored to illustrate the "typical" obstetric fistula client looking at variables such as age, parity, cause and type of fistula, and duration of labor. In multiple reports from Ethiopia, Nigeria and Kenya, fistula clients were most often young and primiparous and initially labored at home (Tahzib 1983; Kelly 1993; Hilton 1998; Kabir 2003; Mabeya 2004; Muleta 2004; Wall 2004). A record review in Ghana also showed that the majority of women were primiparous; however, almost 25% of the fistula clients had a parity of five or more (Danso 1996). On the other hand, a record review from Pakistan found that the typical obstetric fistula client was in her early thirties and multiparous (Naru 2004).

Most of the previously listed studies note that the majority of their fistula cases were due to obstructed labor, and also provide some data concerning the etiology of fistulas due to other causes, usually surgical. However, record reviews of cases of traumatic gynecologic fistula due to sexual violence remain scarce. One such record review has provided information about 91 women and adolescent girls with traumatic gynecologic fistula; 13 were due to rape and the other 78 to sexual intercourse within marriage (Muleta 1999). The review found that 82% of the cases of traumatic gynecologic fistula were young women under the age of 16.

Retrospective record reviews have been useful in supplying information on factors that lead to unsuccessful fistula closure and continued incontinence. Factors that have been found to be associated with unsuccessful closure of fistula include:

previous unsuccessful attempts at repair, complicated fistula, multiple fistulas, fistula size of greater than 10mm, and type II fistula (Kelly 1993; Ayed 2006). Another study found the following risk factors as significant to the development of stress incontinence after obstetric fistula repair: involvement of the urethra, small functional bladder capacity, large diameter of fistula, and the need for vaginal reconstruction (Browning 2006). An uncontrolled observational study found that following fistula repair surgery, 55% of women reported persistent urinary incontinence while 38% reported altered fecal continence (Murray 2002).

The length of wait time between the formation of the fistula and the repair surgery, which many providers suggest should be no earlier than 3 months may play an important role in the likelihood of repair surgery success. However, one study found that there was no significant difference between the rates of successful repair in an early group (surgery within 3 months of the development of the fistula) and a late group (surgery more than 3 months after the development of the fistula)(Melah 2006). Another review presented the results of a surgeon who employed catheterization for possible spontaneous healing and surgical repair in less than 3 months from the formation of the fistula (Waaldijk 2004). The author found that 15% of the patients healed spontaneously with the catheter, with 96% of those women remaining continent. The rest of the women underwent fistula repair as soon as the fistula edge was clean (even with inflammation) with an 87% success rate (success defined as continence).

While these studies present some very useful information, the data gathered from *retrospective* record reviews is by its nature limited to the information available in that record, lacking additional indicators that could provide a more nuanced description of fistula clients or consistent information from multiple sites/countries. For example, the majority of record reviews reported on the age of presentation at the hospital, not on the age of onset of the fistula. Additionally, many of the reviews do not include information on the size, type *and* location of the fistula.

# Objective

The Fistula Care Project proposes a fistula research study that will consist of *prospective* data collection at Fistula Caresupported fistula sites. This will be an observational study looking at the association of current clinical practices at the study sites with the outcome of repair surgery. Because pre-operative, operative and post-operative procedures vary between the sites we will be able to examine the association of these different procedures on success of the repair surgery. The results of the study will help answer some of the most pressing clinical research questions in the fistula field, and will inform future interventions and further research in fistula treatment and prevention.

The primary objective of the fistula research study is to:

- Determine predictors of complications and success of fistula repair surgery. The study will examine the many
  variables that have the potential to impact success and complication rates of fistula repair. The study will look at sociodemographic and other background information, circumstances surrounding development of the fistula (including
  obstetric history), anatomical and clinical characteristics of the fistula, and pre-, intra- and post-operative techniques
  used. Several specific questions that the study will aim to answer include:
  - o What is the association of duration of catheterization post-op on outcome of repair surgery?
  - What is the association of prophylactic antibiotic use (before, during or after the fistula repair) on outcome of repair surgery?<sup>1</sup>
  - o What is the association of provider training/experience/qualification on outcome of repair surgery?
  - What is the association of how fistula repair services are organized (i.e., camp, training event, routine service) on outcome of the repair surgery?

A secondary objectives of the fistula research study is to:

<sup>&</sup>lt;sup>1</sup> Numbers may not be sufficient to examine difference is antibiotic use at the different time points in relation to repair surgery (i.e. before, during and after the repair surgery). If this is the case, we will use prophalyctic antibiotic use vs. no antibiotic use.

Examine socio-structural factors associated with fistula. We will gather socio-demographic and other background
information, details of the circumstances surrounding development of the fistula (including obstetric history, sexual
violence, iatrogenic) and explore issues around availability of and access to obstetric services, helping us to identify
some of the socio-structural factors associated with development of fistula. In addition we will gather information about
female genital cutting and infibulation in fistula clients.

## Statement of Hypothesis

Given the limited previous research examining the variety of factors that may affect fistula surgery outcome, the primary aims of this study are exploratory.

## Study Design & Methodology

## a) Study design

This will be a prospective, observational clinical research study. The primary focus of the data collection will be to explore predictors of success and complications of fistula repair.

No new methods or interventions will be introduced as part of the study. Physicians / surgeons will continue to use their standard procedures for fistula repair. Staff at the study sites will document client intake and record information on standardized study report forms developed by Fistula Care to ensure consistent data are gathered from all study sites using standard definitions.

Data will be collected at admission to the study, during the clinical exam and repair surgery, and then during follow-up (see specific details on pages 5 and 6). Follow-up data will be gathered during the hospital stay (including outcome assessment at discharge) and at 3 months post-surgery to assess for any remaining incontinence. Information on complications among study participants will also be gathered at any time they occur during the study period.

## b) Study sites

A total of 11 sites will be included in the study as follows:

Bangladesh	Kumudini Hospital LAMB Hospital
	Memorial Christian Hospital
Guinea	Kissidougou Hospital
Niger	Maradi Hospital
	Hôpital Lamordé
Nigeria	Birnin Kebbi Fistula Centre
	Faridat Yakubu Hospital
	Mariamma Abacha Hospital
Uganda	Kagando Hospital
	Kitovu Mission Hospital

A local principle investigator (PI), a study coordinator and a social or outreach worker will be identified at each site. For those sites where repairs are generally conducted by providers on staff at the site, the local PI should be the surgeon responsible for the fistula repairs/clients. If repairs are generally conducted by an external trainer/expert then the local PI should be the physician responsible for the clients' clinical care before and after the surgery. The local study coordinator would ideally be a mid- to high-level nurse working at the study site. The social worker or outreach worker will spend time talking with and counseling participants about the importance of the 3 month follow-up while they are recovering from their repair surgery and

can where possible/practical assist with tracking of study participants who do not return to the site for the 3 month follow-up visit. For details of the responsibilities of the local PI and study coordinator see the management, roles and responsibilities section of this proposal.

## c) Study participants

Study participants will include women at the study sites who are scheduled to undergo fistula repair surgery and who agree to participate in the study. Participants should meet all of the inclusion criteria and none of the exclusion criteria listed below.

- Inclusion Criteria
  - o Freely consents to participate in the study and signs an informed consent form<sup>2</sup>
  - Has a urinary fistula or RVF (obstetric or traumatic in origin)
  - o Agrees to attend 1 follow-up visit after discharge from the hospital (at 3 months post-surgery)
  - Able to understand the procedures and study requirements
- Exclusion Criteria
  - Does not consent to participate in the study
  - o Incontinence <u>unrelated</u> to obstetric or traumatic fistula
  - Has a condition, which in the opinion of the site PI, prevents the women from undergoing fistula repair surgery
  - o Has a condition, which in the opinion of the site PI, contraindicates participation in the study

We will recruit 1436 women into the study. The sample size was calculated assuming an overall success rate for fistula repair surgery of 80% and a loss to follow-up rate of 30%. This sample size will enable us to detect a 5% difference between duration of catheterization groups with a confidence level of 95%. Assuming a refusal rate of approximately 10%, we will need to ask approximately 1600 if they are interested in participating in the study. The number of women recruited at each site will vary based on the projected number of clients arriving to each facility during the study period.

d) Data Sources and Study Report Forms

Participating facilities will be required to collect client intake and record information using standard study report forms developed by Fistula Care for this purpose<sup>3</sup>. Fistula Care recognizes that the majority of facilities in which the research will be conducted are already collecting routine intake and client record information; however, the type of information collected (including clinical definitions), and methods of collecting information across facilities varies. Since the success of the study depends on the availability of comparable information, Fistula Care will collect the same data from all sites using identical data collection forms, and will ensure that all clinical definitions are standardized prior to data collection. Study sites may continue to use their own records as well as the study report forms, or may choose, during the duration of the study, to use only the study report forms, making these the official site records for the client. Study report forms will be completed by the responsible study site staff during and/or immediately after each encounter (e.g. initial intake, clinical exam, repair surgery, etc.) with a study participant.

The data to be gathered from each client include:

<sup>&</sup>lt;sup>2</sup> It is possible that at some study sites young women/girls who are minors will present for fistula repair, with or without a guardian. A person will be determined to be a "minor" in accordance with the legal age of adulthood in the country in which the research is being conducted, and in accordance with local legal definitions of an "emancipated minor" (e.g. a minor who is married or has children). Proxy consent will not be required for "emancipated minors." Proxy consent for non-emancipated minors will be sought in accordance with host country legislation and, where appropriate, will be obtained from a relevant legal authority (i.e. parent, guardian or others with parental responsibility). Proxy consent will not substitute for the minor's own consent, but will supplement it.

<sup>&</sup>lt;sup>3</sup> Study report forms developed by Fistula Care are based on forms developed by GFMER, WHO, AAFH, and forms used by various experienced fistula surgeons in the field, as well as on DHS data collection instruments.

- Participant intake / sociodemographic information: Participant demographic information will include items such as client
  age, marital status, parity, and rural vs. urban residence, and education status.
- Circumstances related to the development of the fistula, including obstetric history. Participants will be asked the cause
  of their fistula. A through basic obstetric history will be gathered including age and parity at time of fistula and
  participants will be questioned regarding the details of the causative delivery. Participants with traumatic fistula
  (iatrogenic or sexual in origin) will be asked to provide details about the cause of the fistula.
- Anatomical and clinical characteristics of the fistula(s). Anatomical and clinical characteristics of the fistula(s) including
  the presence of scarring, location and type of the fistula, length and width of the fistula, duration of the fistula and
  previous attempts at repairing the fistula. As part of the analysis, we will classify fistula into simple and complex based
  on the following criteria (taken from the WHO's Obstetric Fistula: Guiding principles for clinical management and
  programme development).

Criteria based on the degree of anticipated difficulty of the repair				
Defining Criteria	Simple	Complex		
Number of fistula	■ single	<ul> <li>multiple</li> </ul>		
Site	<ul> <li>vesico-vaginal (VVF)</li> </ul>	<ul> <li>All non-VVF urinary fistula</li> <li>recto-vaginal (RVF)</li> <li>mixed VVF/RVF</li> <li>involvement of cervix</li> </ul>		
Size (diameter)	■ <4cm	■ >4cm		
Involvement of the urethra/continence mechanism	<ul> <li>absent</li> </ul>	<ul> <li>present</li> </ul>		
Scarring of vaginal tissue	<ul> <li>absent</li> </ul>	<ul> <li>present</li> </ul>		
Presence of circumferential defect*	absent	<ul> <li>present</li> </ul>		
Degree of tissue loss	<ul> <li>minimal</li> </ul>	<ul> <li>extensive</li> </ul>		
Ureter/bladder involvement	<ul> <li>ureters are inside the bladder, not draining into the vagina</li> </ul>	<ul> <li>one or both ureters are draining into the vagina</li> <li>one or both ureters are at the edge of the fistula</li> </ul>		
Number of previous repair attempts	<ul> <li>no previous attempt</li> </ul>	<ul> <li>failed previous repair attempts</li> </ul>		

\* the complete separation of the urethra from the bladder

- *Details of pre-operative care:* The specifics of pre-operative care provided, if any.
- Details regarding the surgical procedure: Aspects of the surgical procedures including administration of antibiotics (including type administered, dose, and duration of administration), the type of anesthesia, the type of procedure (e.g. VVF repair, RVF repair), surgical route, and the technique used to close the fistula. The occurrence of intra-operative complications will also be assessed. Information on who performed the surgery (so we can look at outcome relative to provider training and experience) and the circumstances under which the repair was carried out (e.g. camp, training event, routine service) will be recorded.
- Details of post-operative care: Details of post-operative care including the administration of antibiotics for prophylaxis or treatment, type and duration of catheterization, length of hospital stay, and duration of bed rest / timing of ambulation.
  - o Duration of catheterization will be divided into several categories for example:
    - 2 weeks 10-17 days
    - 3 weeks 18-24 days

- Greater than 3 weeks more than 24 days
- Outcomes of the fistula surgery. The primary point to assess success of the repair surgery will be at the 3 month postrepair surgery visit. The time point for assessing success is complicated by the fact that it is not possible to evaluate success until the catheter is removed and given that this is an observational study the time of catheter removal relative to the date of surgery will vary from site to site (or even from women to women at any particular site).
  - o Success: the fistula is closed and the woman is dry (i.e. she has no remaining incontinence of any kind)
  - Failure: the fistula is still open and the women remains incontinent (i.e. she still has continuous leakage of urine and/or feces)<sup>4</sup>
  - o The fistula is closed but the woman has urge or stress incontinence<sup>5</sup>

Complications of fistula surgery will also be assessed, at any time they occur during the period of the study, and include, for example, catheter blockage, wound infection, hemorrhage, urinary tract infections and death. We will also gather details in cases where more than one surgery is required to complete the repair.

Study report forms will include the following:

- Participant eligibility checklist
- Admission/patient history interview form
- Admission examination and pre-op form
- Clinical examination under anesthesia or sedation form
- Surgery form
- Discharge clinical exam form
- Discharge interview form
- Complications form
- 3 month post-surgery follow-up clinical exam form
- 3 month post-surgery follow-up interview form
- Final status form
- Provider profile form
- e) Data collection and monitoring

Data will be collected at the sites over an 18 month period. The local (PI) will routinely monitor data collection to ensure that forms are accurate and complete.

Prior to data collection, Fistula Care will train staff from each facility. The main objectives of the training will be as follows:

- Present the study objectives
- Orient facility staff to the study report forms and the importance of filling out the forms completely and accurately
- Orient facility staff to study procedures, including informed consent procedures

In addition, after the first two women have been enrolled in the study at a site and undergone their fistula repair surgery, the site PI will fax a copy of the study report forms to the Fistula Care office in New York. The purpose of this effort is to find any systematic errors in completion of the study report forms or problems with the forms such as confusing skip patterns. After careful review, any problems with how the forms are being completed will be clarified with study site staff. These data will not be entered into the database; it will be entered when the actual copies of the forms from these participants arrive in NY (see below).

<sup>&</sup>lt;sup>4</sup> Fistulas that are irreparable and those that require additional surgery to close will be included in this category.

<sup>&</sup>lt;sup>5</sup> Urge incontinence involves a strong, sudden need to urinate, followed by a bladder contraction, which results in leakage. Stress incontinence is an involuntary loss of urine that occurs during physical activity, such as coughing, sneezing, laughing, or exercise.

Fistula Care staff will make regular monitoring visits to each study site every 3-4 months. To the greatest extent possible these monitoring visits will be conducted by the local fistula coordinators and consultants and occur during regular program visits to the fistula sites. During these visits staff will review completed study report forms and attempt to resolve any problems such as incomplete forms. They will also check a random sample of the forms against any source documents that may exist such as the sites records for the study participant or records women bring from visits to previous facilities. They will discuss conduct of the study with site staff and help to resolve any problem they may be experiencing. Study report forms will be printed on two-ply carbonless paper. Staff conducting monitoring visits will take the original of the study report form and leave the one copy in the participant's folder at the study site (see below).

# f) Data management

## Data transfer

The original study report forms will be collected by Fistula Care staff during monitoring visits. It will be sent via express courier to the Fistula Care office in New York for data entry.

## Data storage

Within each facility, study report forms will be stored in a locked cabinet. Documents linking participant names with participant study numbers will be stored in a separate locked cabinet. All study documents with the participant's name should remain at study sites at all times.

## Data entry

Data will be entered into an ACCESS (or SPSS) database. Data entry screens will be created for each form used in the study. For each question on the forms, the data entry screen will contain a variable name, description, type, and code list if appropriate. The data will be entered at Fistula Care headquarters in New York and one-third of the data will be re-entered by another person to check reliability. Any inconsistencies in data entry will be resolved with the help of the data analyst.

## g) Data analysis

Aggregate data (for all study sites) will be analyzed at Fistula Care headquarters. Socio-demographic and client history data will be summarized by frequencies and percentages (categorical variables) or by means, standard deviations, median, and appropriate percentiles (continuous variables). These descriptive statistics will be calculated for the overall sample as well as by site. Predictors of fistula surgery outcome will be assessed through univariate and multivariate logistic regression analysis. All analyses will be conducted using SPSS.

h) Reports, publications and presentation of study results

No data collected in this study will be published without prior written approval from Fistula Care / EngenderHealth and USAID will have the opportunity to review reports and manuscripts prior to completion/publication. A study report will be prepared and submitted to USAID within 5-6 months of the completion of data collection. A presentation for USAID staff and other interested parties will be organized at a mutually convenient time once the data analysis and report writing is complete.

There will be a primary publication of the study, which must precede any publication or presentation of the results by the participating investigational sites. The primary publication will present aggregate data from all the sites, however no individual data will be linked to any specific study site and study sites will only be identified in relation to the affiliation of the local principal investigators (PIs). Local PIs will have the opportunity to review the primary paper and other papers written presenting the aggregate data collected in this study prior to publication. Individual local PIs will not be listed as authors on publications of aggregate data, given limitations to the number of authors allowed per publication. Instead one of the authors listed will be the "fistula study investigator group" with a footnote listing each of the local PIs and their affiliation.

As per EngenderHealth authorship guidelines, an author should be someone who meets the criteria for both responsibility and substantial contribution. Only those whose contribution to the published work can be deemed *substantial* should receive authorship credit. To be considered substantial, a contribution should include *more than one* of the following:

- Conceiving the central idea(s) for the work
- Designing experiments or research necessary to the work
- Analyzing and interpreting data
- Drafting the article or revising it critically for important intellectual content
- Approving and taking responsibility for the contents of the finished work

The following contributions are *not* considered substantial:

- Approving the idea for the work
- Collecting data, if data collection involves no analysis
- Providing administrative support
- Performing data processing
- Providing research support as a routine part of one's job
- Copyediting, no matter how extensive
- Rewriting, if the rewrite is performed merely to clarify the original author's writing and the rewriter undertakes no
  original research and adds no original ideas to the work
- Critically reviewing the finished work, if the reviewer makes no significant alterations
- Verifying data or fact checking
- Typing or typesetting the finished work

### **Protection of Human Subjects**

### a) Ethical Review

The study proposal will be submitted for review by EngenderHealth's Monitoring and Evaluation team according to EngenderHealth's standard operating procedures, as well as to any national research institutes or local IRBs, as specified by the study site or Ministry of Health regulations.

### b) Informed Consent

### No participant may be admitted to this study until the study staff has obtained her informed consent.

Women coming to study sites for fistula repair surgery will be invited to participate in the study. Before any study procedures take place each potential participant will be given detailed information about the study. If she is interested and willing to participate, she will be asked to sign an informed consent form. The individual administering the informed consent will explain in the local language the informed consent process to participants. They will inform prospective participants of the purpose of the study, and the rights of and possible risks associated with participating. Participants will be informed that their names will not appear in any written documentation about the study. Participants will also be informed that they may refuse to participate in the study without jeopardizing in any way their access to health services. An inclusion/exclusion criteria checklist will be completed to ensure that all inclusion/exclusion criteria are met prior to enrollment. Women will not be paid to participate in the study, since their clinical care will be the same whether or not they are taking part in the study. In an attempt to reduce loss to follow-up, women will be given money to cover transport costs to the clinic and then back to their home for the visit 3months after your discharge. This money will be given to the women when they return for the follow-up visit. They will also be given a small gift (e.g. soap, a blanket, fabric to make a dress)—to determined by the staff at each study site—at that time in appreciation for their participation in the study.

# c) Participant Confidentiality

The confidentiality of all participants admitted to this study will be protected to the fullest extent possible. EngenderHealth staff may audit participant's clinic records or may ask other individuals authorized in writing by EngenderHealth to audit the study. A master record will be maintained under lock and key at each study site which will contain participant's name and contact information as well as their study participant number. This record should never leave the study site. All study report forms will contain only the participant's study number. Study participants will not be identified by name on any documentation sent to Fistula Care and will not be reported by name in any report or publication resulting from data collected in this study.

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