Background

- There are limited reliable data about the association of clinical, social, and demographic factors with outcomes of fistula repair surgery.

- Most studies have collected data *retrospectively*, so results are limited to information available in the records being reviewed.
  
  - Collection of consistent information from multiple sites/countries is unlikely.
  
  - Additional indicators that could provide a more nuanced description of fistula clients and the care they have received are not available.
Primary study objective

- To determine factors that predict outcomes (closure and complications) of fistula repair surgery
- Factors being examined include:
  - socio-demographic and other background information
  - circumstances surrounding development of the fistula
  - anatomical and clinical characteristics of the fistula
  - pre-, intra- and post-operative techniques (e.g. duration of post-op catheterization, prophylactic antibiotic use), provider training/experience/qualifications, and how fistula repair services are organized
Secondary objective

- To examine socio-structural factors associated with fistula
- To support this objective, we are
  - gathering socio-demographic and other background information
  - collecting details of the circumstances surrounding development of the fistula
  - exploring issues around availability of and access to obstetric services
  - collecting information about female genital cutting and infibulation.
Study design

- Multi-center, multi-country study with a total of 13 study sites in six countries
- Prospective data collection at Fistula Care-supported sites
- Observational study
  - no new clinical methods or interventions introduced
  - Surgeons continue to use their standard procedures for fistula repair
  - Because pre-, intra- and post-operative procedures vary between sites we will be able to examine the association of different procedures on repair outcome
Countries where study sites are located

- Niger (2)
- Guinea (2)
- Nigeria (3)
- Rwanda (1)
- Uganda (2)
- Bangladesh (3)
## Study sites

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<tr>
<th>Bangladesh</th>
<th>Kumudini Hospital</th>
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<td>LAMB Hospital</td>
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<td>Memorial Christian Hospital</td>
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<td>Guinea</td>
<td>Kissidougou Hospital</td>
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<td>Ignace Deen Hospital</td>
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<td>Lamordé Hospital</td>
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<td>Nigeria</td>
<td>Mariamma Abacha Hospital (Sokoto State)</td>
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<td>Faridat Yakubu Hospital (Zamfara State)</td>
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<td>Bernin Kebbi (Kebbi State)</td>
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<td>Rwanda</td>
<td>Central University Hospital of Kigali</td>
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<td>Uganda</td>
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<td>Kitovu Mission Hospital</td>
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Sample size and study participants

- 1439 women with a urinary or recto-vaginal fistula (obstetric or traumatic in origin) seeking fistula repair services at study sites will be recruited into the study.

- The sample size was calculated assuming an overall closure rate of 80% and a loss to follow-up rate of 30%.

- Recruitment numbers vary among study sites and were based on projected caseload at each study site.

- No participant will be recruited into the study until she has given her informed consent.
Data collection methods

- Staff at the study sites are documenting client intake information and details of pre-, intra- and post-operative procedures.

- Data is being collected:
  - at admission to the study
  - during the clinical exam and repair surgery
  - at discharge (includes details about procedures and practices during the period of convalescence)
  - at one follow-up visit 3 months after surgery
  - Information on complications will be gathered at any time they occur.

- Standardized study report forms, developed for the study to ensure consistent data are gathered following standard definitions, are being used.
Study report forms

- 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
Interviews

- Interviews at 3 points during the study
  - Admission
  - Discharge
  - 3-month follow-up

- Interview forms will be in the following languages:
  - English (Uganda)
  - French (Guinea)
  - Bangla (Bangladesh)
  - Hausa (Niger & Nigeria)
  - Kinyarwanda (Rwanda)
  - Zarma (Niger)
Current study status

- Instruments have been field tested & interview forms translated
- Staff from all study sites have received training in the study procedures and interview techniques
- Relevant IRB approvals have been obtained
- Data collection is being done in a phased manner
  - ongoing in Bangladesh, Guinea and Uganda (130 women enrolled as of March 30, 2008)
  - expect to begin in late April/early May at the Nigeria sites
  - Rwanda and Niger sites should begin in June
- Study should be completed by the end of 2009
Use of the study results

- Given the limited previous research on factors affecting fistula repair outcome the study is exploratory in nature.
- The results may directly inform future fistula repair services.
- Ideas for additional clinical research to improve fistula treatment are likely to emerge from the study.
- Data will be useful for discussion, modeling and/or validation of classification systems. We will not be developing a classification system as part of this study.
- Staff at fistula repair sites will gain experience in conducting research, providing a pool of sites for future studies.