

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



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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



Study sites

Bangladesh	Kumudini Hospital LAMB Hospital Memorial Christian Hospital
Guinea	Kissidougou Hospital Ignace Deen Hospital
Niger	Dosso Regional Hospital Lamordé Hospital
Nigeria	Mariamama Abacha Hospital (Sokoto State) Faridat Yakubu Hospital (Zamfara State) Bernin Kebbi (Kebbi State)
Rwanda	Central University Hospital of Kigali
Uganda	Kagando Hospital Kitovu Mission Hospital

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 .