

Identification of Current Practices in Fistula Treatment: A qualitative review Final December 22, 2008

Introduction/Background

USAID/W is interested in funding randomized control clinical trials (RCCTs) on issues which will lead to improved care for women living with fistula. A number of initial descriptive clinical studies are needed to better identify and formulate research questions for the RCCTs.

In late 2007, Fistula Care began discussions with USAID/W about the development of a research agenda to identify needs based on our best assessment of research that would lead, in the shortest time possible, to the largest improvement in safety and in success for the largest number of women possible, while maximizing efficient and cost-effective use of very limited personnel and materials resources. These priorities would also be subject to the local context in the field, expected caseload, availability of service delivery and research expertise, funding and time. Some of the research ideas the Fistula Care team identified were a composite of two or more potential research questions that could be un-bundled for convenience, research feasibility and validity.

USAID and Fistula Care, in consultation with partners at the Accra Partners Meeting in early 2008, and later at a meeting in July 2008 narrowed the field of possible research questions. The following three topics, emerged as priorities since they are not being studied in depth as part of the USAID or UNFPA funded observational studies on fistula care and treatment¹:

- use of prophylactic antibiotics
- role of catheterization in fistula care management,
- and management of stress incontinence post fistula surgery.

Before embarking on the development of randomized controlled clinical trials on these issues, we agreed with USAID/W that Fistula Care would conduct a 'simple', short-duration, multicenter, descriptive clinical review of current practices around these three issues. Findings from this review will have the potential to immediately lead to the formulation of RCCTs. The goal of the qualitative studies is to determine what current practices are in order to better frame questions for RCCTs. The goal of conducting the RCCT studies is that the findings would contribute to influencing policy and practice and lead to improved care for women living with fistula.

For ease and speed in conducting the qualitative review of practices around these three issues, we are developing one study proposal/protocol with one questionnaire divided into three sections.

¹ Fistula Care, with USAID funding is conducting a global observations study in 6 countries: Determinants of post-operative outcomes in fistula repair surgery- A prospective study. UNFPA, in collaboration with WHO and Johns Hopkins University is conducting a similar study in 7 countries: *Prognosis, Improvements in Quality of Life (QOL) and Social Integration of Women with Obstetric Fistula after Surgical Treatments: A Collaborative JHU/UNFPA/WHO Study*. This study, will examine post-operative prognosis, improvement in quality of life, social integration, and rehabilitation of fistula patients after surgical treatments. The study data will be further utilized for developing a standardized classification system that allows for the predictability of prognosis.

We will inform our colleagues at UNFPA, WHO and JHU about the study. We will request a list of possible respondents from UNFPA supported sites. Because of the clinical nature of the study, we will not be soliciting their input on the study questionnaires.

Objectives of study

The overall objective of the study is to collect information about current practices in the care and treatment of fistula which will inform the development of one or more RCCTs. The specific objectives are:

1. **To identify the use of antibiotics before, during and after fistula surgery. Specific issues to address include:**
 - a. Determine current resources at fistula centers regarding access to antibiotics.
 - b. Catalogue current clinical practices with respect to the choice, timing, and duration of prophylactic antibiotic use.
 - c. Explore the rationale that providers use to make choices regarding antibiotic use.

2. **To identify the role of catheterization in fistula management. Specifically to:**
 - a. Determine current resources at fistula centers regarding availability of catheters supplies
 - b. Catalogue current clinical practices with respect to the choice, duration and nature of catheter use (e.g., open vs. closed drainage, pre and post op use of catheters).
 - c. Explore nursing practices with regard to catheter management, including bladder training for patients. .

3. **To review management practices for patients with stress incontinence after fistula repair. Specifically to:**
 - a. Catalogue clinical strategies currently in place for the diagnosis and treatment of stress urinary incontinence after fistula repair.
 - b. Explore which clinical factors that providers believe will predict the incidence of stress urinary incontinence.
 - c. Describe current practices for women whose treatment of stress urinary incontinence fails.

Design & Methodology

This study will survey a number of surgeons at fistula repair sites in Africa and Asia. EngenderHealth/Fistula Care will send each respondent a letter of introduction (via email whenever possible) to explain the rationale and design of the study (see Annex 2) Those who agree to participate will be sent a questionnaire by e-mail (or mail); using a web based survey tool such as Survey Monkey was discussed, however because of slow internet connections in many countries, this option was not pursued. The questionnaire is attached . (see Annex 3.. The questionnaire will be divided into three sections and will be designed to allow for completion and return by e-mail as well. The letter of introduction and the questionnaires will be translated into French for Francophone surgeons. When participants have questions or responses are

unclear, they will be contacted by e-mail and/or telephone in order to make necessary clarifications. Participants will be given one month in which to complete and return the questionnaire. We will ask Fistula Care/EngenderHealth staff in countries where we have offices to assist with follow up of respondents and where necessary collect completed questionnaires and mail them to us.

The first draft of the questionnaire was pretested with Fistula Care staff who are fistula surgeons to assess clarity of the questions. No pretesting will be conducted with other surgeons outside of the Fistula Care Project since our pool of possible respondents is very small.

Respondent selection

A list of surgeons and their affiliated institutions has been developed (see Annex 1). We plan to cast a wide net and contact approximately 60 surgeons who provide fistula surgery in Africa and Asia to ask for their participation in the study; potential respondents include surgeons working at USAID/Fistula Care supported sites and non supported sites, as well as visiting surgeons. We will attempt to include surgeons from UNFPA supported sites as well.² Our sample size will simply represent a group of surgeons we have identified who agree to participate after reviewing a letter of introduction, and then actually do complete the questionnaires and return them.

Limitations of design

Obviously the information gleaned from the study would be open to justifiable criticism with regard to the geographic and structural distribution of the sites included in the final sample. Whether the sample of surgeons and their institutions is legitimately “representative” of current practices worldwide will be impossible to document. The selection of surgeons and sites is purposive—it includes sites where Fistula Care is currently working and places where we have professional contacts and/or have worked with in the past. Selection of respondents will not be random, in that our sample list is limited to places where we have relationships. Nor will surgeons and their home institutions be chosen according to any characteristics such as size, funding, locations, level of activity, or organizational affiliations of fistula centers. We are dependent on the willingness of individual providers to participate when there is no immediate tangible benefit to the participants. We do not expect a 100% response rate from those who agree to participate. We expect at least 75 % of the surgeons will agree to participate and perhaps will respond. We will aim to increase the response rate through follow up.

Data analysis

The study is descriptive and does not aim to achieve statistical significance. Rather, the data will be used as a general guide to current practices in the areas of clinical care in question as described above. This information will help guide us in the development of protocols for one or more randomized clinical trials. Therefore the data will be analyzed for broad trends that frame current practices at active fistula care sites.

Report writing

A final technical report will be produced and will include the following:

1. Description of the level of participation among solicited sites.

² The current list of surgeons includes contacts made at recent meetings of the International Society of Obstetric Fistula Surgeons (ISOFS) and Pan African Urological Surgeons Association (PAUSA)

2. Discussion of limitations (if any) imposed on the study by the level of response and suggestions for improvement.
3. Simple tabulation of the responses to the individual items on each questionnaire.
4. Discussion of the current state of practice with regard to our three areas of interest.
5. Discussion of the implications of the survey results to our upcoming randomized clinical trials in these areas.

Informed consent and confidentiality procedures and text

This study will not involve patient care or patient input in any way. The questionnaire includes a statement about informed consent and that all information provided by respondents will be kept confidential. See Annex 3 with the sample questionnaire and the informed consent statement.

Management

Dr. Joseph Ruminjo, Clinical Director, and Ms. Evelyn Landry, Senior M&E/Research Advisor will work with Dr. Steven Arrowsmith, consultant to carry out this study. Roles and responsibilities are as follows:

Dr. Arrowsmith will:

- Design questionnaires
- Develop study protocol following EngenderHealth research SOPs
- Respond to questions and concerns of respondents considering participation in the study.
- Distribute questionnaires to study participants
- Follow-up to encourage completion and return of questionnaires
- Follow-up with individual participants to answer questions and clarify responses after questionnaires are returned
- Tabulate data and perform simple statistical analysis
- Generate final project report

Joseph Ruminjo will:

- Formulate and distribute a letter explaining the study to potential sites and soliciting participation
- Review and provide input on study protocol.
- Review and edit questionnaires prior to distribution
- Provide liaison for EngenderHealth support of the project in areas such translation of project materials, provision of budget, and other logistical support.
- Assist in review and editing of final report

Evelyn Landry will:

- Review and edit questionnaires prior to distribution
- Review and revise study protocol
- Provide liaison for EngenderHealth support of the project in areas such translation of project materials, provision of budget, and other logistical support.
- Ensure compliance of study design with EngenderHealth and USAID research standards
- Assist in provision of EngenderHealth support of the project in areas such translation of project materials, provision of budget, and other logistical support.

- Assist in review and editing of final report

Description of how results will be disseminated

The primary goal of the study is to provide information to USAID and Fistula Care to help in the decision making as to whether to pursue the development of one or more RCCTs. A realistic understanding of current clinical practices is crucial to planning for subsequent studies to provide an evidence base for rational care in these areas. Results of this initial survey are not intended for scientific publication, however depending on the results, we will consider identifying a venue for presentation of the findings. All surgeons who participated in the study will be provided with a copy of the final report (or a summary report).

Data collection tools. See Annex 3.

Timeline: September 2008 to April 2008

	Sept				Oct				Nov				Dec				Jan				Feb				March				April			
	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Contract with consultant	x	x																														
Develop study proposal				x	x																											
Develop questionnaire				x	x																											
USAID review											x	x	x	x	x																	
Translate letter & questionnaire into French															x	x	x	x														
Finalize questionnaires															x	x																
Contact UNFPA, WHO, JHU to inform about study																x																
EEmail letters																	x	x														
EEmail questionnaire																			x	x	x	x										
Questionnaires Returned																					x	x	x	x	x							
Data Analysis/report Writing																											x	x	x			
Draft report																																x

Annex 1. List of Possible Respondents (REVISED DRAFT)

Country	FC supported Site	Participant
Bangladesh	X	Dr. Felicity Mussel, Lamb Hospital
	X	Dr. Ahsan Kabir, Kumudini Hospital
		Prof Sayeba Akher, Dakha University Hospital
		Dr. Hasina Afroz, National Fistula Center, Dhaka Medical College Hospital
Benin		Dr Rene Hodonou, urologist, Cotonou, Benin
		Rene Xavier Perrin, PAUSA, Cotonou
Burkina Faso		Dr Kambou Timothee, urologist, Bobo Diolosso,
Congo		Dr Severin Anani Odzebe, urologist, Congo Brazzavile
		Bouya PA, PAUSA, Congo
DRC	X	Dennis Mukwege, Panzi Hospital
		Prof Ahuka Longombe
	X	Prof Pascal Manga Okenge
Ethiopia		AAFH
		Mekele (AAFH)
		Andrew browning , Bahir Dar
		Dr. Mulu (formerly with AAFH)
		Dr. Ambaye (formerly with AAFH)
		Dr. Biruk (formerly with AAFH)
Guinea ³	X	Dr Thierno Hamidou Barry, Kissidougou Hospital
	X	Professeur Mamadou Bobo Diallo, Ignase Deen University Hospital
	X	Dr Magassouba Malick, Kissidougou
	X	Dr Mamadou Barry, Kissidougou
	X	Dr Mandian Camara, Jean Paul II
	X	Dr Fodé Camara, Jean Paul II
	X	Dr Ibrahima Baldé Jean Paul II
		Dr Kindy Diallo, urologist
		Dr Ibrahima Sory Diallo, urologist
		Kante Daouda, urologist
		Cisse Demba, urologist
		Dr. Charles Rochat, point person GFMER

³ We are conferring with EH Guinea office about their suggested list of respondents from supported sites. This list may be shortened.

Country	FC supported Site	Participant
Kenya		Dr Julius Kiiru, Jamaa Mission Hospital OB/GYN (
		Dr Weston Khisa, AMREF surgeon OB/GYN
		Jennifer Merry Othigo, Coast General Hospital, Mombasa, Kapanga, Machakos Hospital
		Dr Hillary Mabeya Moi University Hospital head of dept OB/GYN (
Liberia		John Mulbah, PAUSA, Monrovia,
Mali		Dr. Kalilou Quattara
		Ali Tembeley, PAUSA, Bamako
Mozambique		Dr Igor Jose Vaz, urologist, university hospital Maputo
Mauritania		Dr Moustapha Cheikh Abdallahi, Nouakchott, Mauritania (PAUSA)
Niger	X	Dr Sanda Ganda, urologist, Lamorde Hospital
	X	Dr Idris Abdoulaye chef de service National Hospital Niamey
		?point person maradi hospital
		Danja?
Nigeria	X	Dr Sa'ad Idris, Fistula Surgeon, Yakubu Faridat Hospital, Gusau, Zamfarah
	X	Dr Abbas A. Walli, Fistula Surgeon, Mariamu Abacha Women and Children's Hospital, Sokoto
	X	Mohammed, Birnin Kebbi fistula center
	X	Hassan Wara, Birnin Kebbi fistula Center,
	X	Dr Mustapha Lawal, Fistula Surgeon, Bernin Kebbi Fistula Hospital, Kebbi
Rwanda	X	Dr Theobald Hategekatheos, urologist and hospital director CHUK
	X	Dr Laurent Head of OB/GYN CHUK
		Dr Tekle Geziabher, OBGYN Kanombe military hospital Kigali
	X	Dr Felix Kaigamba director Ruhengeri Hospital
		Dr Tom Raassen, visiting surgeon from AMREF, workshops twice a year
Senegal		Prof Sheikh Cisse, O/G,
		Prof Serigne Magueye Gueye, urologist, University Hospital
		Baye Assane Diagne, (PAUSA) Dakar,

Country	FC supported Site	Participant
		Papa Ndiaye,(PAUSA), Dakar
Sudan		Dr Adam Mohammedin, Darfur Hospital
		Dr Ali Altayeb Elfak, Abbo Center Khartoum
		Prof Abbo, Abbo center, Khartoum
Tanzania		Dr Marietta Mahendeka
		Maranga ,ISOFS, CCBRT center, Dar es Salaam
		Dr Perelis, Dar Es Salaam
		Balthazar Gumodoka, Bugando Medical Center,
Uganda	X	Dr John Kelly consultant fistula surgeon Kitovu hospital
	X	Dr Maura Lynch, Kitovu Hospital, hospital director
	X	Dr Frank Asiimwe, Kagando Hospital
		Justus Baragaine, Mulago
		Brian Hancock
Zambia		Michael Breen,(visiting surgeon Uganda)
Zimbabwe		Alex Danso, (PAUSA),Harar
Mercy Ships		Africa Mercy: Steve/Ineke
	X	Freetown: Dr. Dave Lyth
others (including visiting surgeons to countries in Africa/Asia)		
USA		Catherine R. deVries (PAUSA)
Australia		Judith Goh (visiting surgeon, Sierra Leonewith Mercy Ships)
		Suzie De Nil, (ISOFS), Queen's Hospital UK (visiting fistula surgeon Sudan)
		Gloria Esegbon, (ISOFS), (visiting surgeon Nigeria)
		Mike Bishop, (visiting surgeon Uganda/Gambia)
		Christine Edwards (visiting surgeon Bangladesh)
		Rochat Henry
		Dr Mark Morgan, gyn-oncologist, Philadelphia (visiting surgeon Eritrea) (ISOFS)
Total	83	note: several persons still need to be identified for known fistula sites (e.g. Ethiopia, Niger)

Annex 2. Letter of Introduction to the study (REVISED draft)

October XX 2008

Dear Prof/Dr/Mr/Ms....

Re: Survey of Practices Important for the Improvement of Fistula Management

(note: the letter and questionnaires will be translated into French for Francophone respondents)

EngenderHealth is an international NGO working worldwide to improve the lives of families by making reproductive health services safe, available and sustainable. We provide technical assistance, training and information, with a focus on practical solutions that improve services where resources are scarce.

Fistula Care, a project managed by EngenderHealth and supported by USAID, is collaborating with in-country partners to explore knowledge gaps regarding care for women living with fistula which. Before proceeding with the development of any studies to address any gaps, it is useful to take a look at some of the current practices in order to formulate future research questions. Finding from such research could then be used to inform policy, practice and evidence-based programming. The initial list of clinical areas we are interested in includes:

- 1. Use of antibiotics in fistula management*
- 2. Role of catheterization in fistula management*
- 3. Stress incontinence associated with urinary fistula repair*

We are hoping to benefit from your expertise in these and related areas and would greatly appreciate your sharing your knowledge with Fistula Care. Dr. Steve Arrowsmith is serving as a consultant for us on this study. If you agree to participate in our short survey of these three issues, Dr. Arrowsmith will contact you via email with the three questionnaires. We estimate it should take you 30-45 minutes to complete the three short questionnaires. If you agree to participate in this review, we would ask that you please complete the questionnaires and return them via email to Dr. Arrowsmith by XX 2008.

The survey seeks only to describe the current state of fistula care in the three areas described above. Our selection of respondents for the survey is designed to obtain as broad a spectrum as possible of fistula surgeons. This information will be kept in strict confidence and will not be used for individual peer-review. Individual respondents are not accountable in any way for the quality their responses. We pledge to keep individual responses in the strictest confidence. The individual responses will be known only to EngenderHealth staff and consultants involved in the study and will not be shared with anyone else.

Once again, only aggregate results and not individual responses will be disseminated in a technical report early 2009. The results will be used to develop proposals for future research in consultation with our partners.

Please contact Dr. Arrowsmith arrow@wfmic.org and me to let us know if you are interested in collaborating in this survey. We will be happy to send you the survey questionnaires. Do not hesitate to contact us if you have any concerns or need to discuss this further.

Yours sincerely,

Joseph Ruminjo, MD

Clinical Director

EngenderHealth/Fistula Care Project

440 ninth avenue, New York, New York 10001, U.S.A.

Tel 1-212-561-8000 Fax 1-212-561-8067, e-mail: jruminjo@engenderhealth.org

Annex 3. Questionnaires (DRAFT)

Identification of Current Practices in Fistula Treatment: A qualitative review

DRAFT

Informed Consent

This survey is for a study that is being done by Fistula Care, a USAID supported project, managed by EngenderHealth.

This study will gather information on current practices in the care and treatment of women who have fistula.

This questionnaire includes three sections: 1) use of prophylactic antibiotics 2) role of catheterization in fistula management; and 3) management of stress incontinence following fistula repair. It will take you about 45 minutes to answer the questions.

The study seeks only to describe the current state of fistula care in the three areas described above. Our selection of respondents for the study is designed to obtain as broad a spectrum as possible of fistula care providers. This information will not be used for individual peer-review. Individual respondents are not accountable in any way for the quality their responses. We pledge to keep individual responses in the strictest confidence. We will not identify individuals or sites in our summary of responses. The individual responses will be known only to EngenderHealth staff and consultants involved in the study and will not be shared with anyone else.

Instructions for Completion of Questionnaire

The questionnaire is divided into three sections. Please answer each question based on your current practices. Return the completed questionnaire by email to Dr. Steven Arrowsmith [arrow@wfmic.org] by XX 2008. If you do not have email, please return the completed questionnaire in a sealed envelope to the Fistula Care/EngenderHealth staff person in country.