FISTULA CARE *PLUS*

International Research Advisory Group Meeting Report

July 8-9, 2014

USAID FROM THE AMERICAN PEOPLE

Fistula Care *Plus*

EngenderHealth for a better life

Maternal Health Task Force

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Acknowledgements

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This report was authored by Vandana Tripathi, with contributing material from Karen Beattie, Bethany Cole, and Kacie Dragan.

Photo: K. Dragan/EngenderHealth

IRAG Meeting Participants:
Standing, left to right: Ms. Mary Nell Wegner, Dr. Charlotte Warren, Dr. Steven Arrowsmith, Dr. UnJa Hayes, Ms. Mary Ellen Stanton, Dr. Vandana Tripathi, Dr. Joseph Ruminjo, Ms. Kate Ramsey, Prof. Serigne Magueye Gueye, Ms. Grace Omoni, Ms. Erin Mielke, Ms. Maggie Bangser, Dr. Mark Barone, Ms. Sheena Currie, Ms. Karen Beattie, Ms. Ellen Brazier, Ms. Celia Pett
Seated, left to right: Dr. Ben Bellows, Ms. Erin Anastasi, Dr. Thomas Raassen, Prof.Oladosu Ojengbede, Dr. Suzy Elneil, Dr. Ozge Tuncalp, Ms. Bethany Cole

I. Overview of Report

The Fistula Care *Plus* (FC+) project and the Maternal Health Task Force co-convened the first meeting of the FC+ International Research Advisory Group (IRAG) in July 2014 to examine research needs related to fistula prevention and treatment. This brief report presents research priorities identified through the meeting and an FC+ research action plan, developed in consultation with USAID.

Priorities are organized by the four categories of research noted above. For each topic, key discussion points, illustrative study designs/research questions, and pending issues are noted if available. Topics have been ordered to reflect small group feedback and individual ratings. The report closes with a summary of the topics that the FC+ project anticipates addressing through study development and other activities in the coming year. Appendices provide the meeting agenda and participants and other information from the meeting.

II. Meeting Processes

On July 8-9, the FC+ IRAG, as well as key project partners, met at the Harvard School of Public Health. Appendix A provides the list of participants and Appendix B provides the meeting agenda. Meeting presentations are available on request.

At this meeting, participants heard about the achievements of the previous Fistula Care (FC) project and the priorities of the new FC+ project. Participants also discussed research conducted by the FC project and the resulting publications; this included in-depth review of several studies conducted by FC staff and partners.

Participants then examined future research needs across four categories: 1) clinical/biomedical research, 2) epidemiological research, 3) service delivery improvement research, and 4) community-based/other programmatic research. The group's goal was to propose and prioritize potential research topics for FC+, for consideration by project management in consultation with USAID. The starting list of potential research topics was developed by FC+ staff by synthesizing ideas proposed through forums such as: FC and FC+ project meetings, the publication *Obstetric Fistula in the Developing World*,[1] and prior meetings of the International Obstetric Fistula Working Group and the International Society of Obstetric Fistula Surgeons. Appendix C provides this starting list of topics.

Applying structured criteria (Table 1), participants rated and ranked topics within each of the four research categories individually, in small groups, and in plenary. While complete consensus on priorities was not achieved, there was broad agreement on important issues within each research category. Illustrative research questions within emerging priority topics were also identified in plenary discussions. Of the 28 meeting participants, 17 completed individual surveys rating research topics based on the structured criteria. A summary of individual ratings is provided in Appendix D.

[1] Paul Abrams, Ed. (2012) *Obstetric Fistula in the Developing World*. Montreal: Societe Internationale d'Urologie.

Table 1: Structured Criteria for Evaluating and Rating Research Topics

Criterion	Definition
Overall importance	Importance across all criteria
Feasibility	Considerations related to cost, practicality (e.g., manageable sample size) and ethics of research, and FC+ staff/partners/advisors' technical capacity
Technical importance	A topic of interest, debate, and discussion among technical peers and leaders in the field; an area with notable gaps in evidence
Unsaturated topic	A topic on which extensive, high quality, relevant research is not already being conducted by other actors
Potential for impact on FC+ and partner programs	A topic for which FC+ research findings can lead to action (vs. only leading to more research) by helping "settle" questions and change how services or programs are delivered; an area that is relevant to the FC+ results framework

The IRAG meeting was followed by a consultation on the quantification of the burden of fistula. Participant feedback from this meeting is reported separately; however, these inputs also guided the selection of FC+ research priorities described in this report.

III. Meeting Outcomes: Priority Research Topics

Table 2: Priorities Identified by the International Research Advisory Group (IRAG)

Criterion	Definition
Clinical	1. Catheterization for prevention of fistula after obstructed labor and for treatment of "fresh fistula" 2. Residual incontinence, including causes and management 3. Women deemed incurable – definitions, incidence, management strategies 4. Iatrogenic fistula – definition, indications, incidence, management, causes/prevention
Epidemiology	1. Improved measurement and estimation methodologies, starting with the development of a validated diagnostic interview/survey tool. 2. Association of fistula incidence and treatment outcomes with co-morbidities and socio-cultural factors
Service delivery	1. Training/post-training support to ensure competence in and provision of repairs 2. Testing different outreach models to reach different groups of women, particularly women in rural areas 3. Components/cost-effectiveness of reintegration packages/strategies
Community	1. Non-clinical outcomes of fistula repair, particularly post-repair quality of life (e.g., fertility desires, socio-economic needs, integration in family and community) 2. Comprehensive documentation of the costs to patients (social, cultural, economic) related to fistula repair.

A. Clinical/biomedical Research

Emerging Priorities

Topic 1: Catheterization for prevention of fistula after obstructed labor and for treatment of "fresh fistula"

Research into this topic would need to incorporate routine bladder care and proper management of obstructed labor – there are no evidence-based guidelines on proper bladder care before, during, or after labor. The challenges of sample size and powering a study that has fistula as the outcome have been discussed each time this topic has been raised as a priority. Participants suggested that a study of catheterization after obstructed labor could use return to normal bladder function as the outcome. This might dramatically reduce sample size, increase feasibility, and build evidence about the general science of bladder function as well. Such a study could contribute to evidence-based guidelines across settings (not just developing countries).

Topic 2: Residual incontinence, including causes and management

From a woman's perspective, residual incontinence means she still has a problem even if the fistula has been "successfully closed." This topic touches on many clinical areas, including the basic science of voiding and how the bladder functions after a fistula has healed.

Possible research questions include:

- What is the incidence or prevalence of residual incontinence following primary fistula repair?
- What factors are associated with residual incontinence after repair (e.g., socio-demographic)?
- What are the causes of such incontinence and what can be done to treat it?

Possible study designs include a prospective cohort study of consecutive cases to obtain patient-reported incontinence data before and after repair (e.g., 3, 6, and 12 months following). A limitation would be a lack of information on the causes of residual incontinence; causes also determine the type of treatment/management required. A more costly but more informative "gold standard" version of such a study would include urodynamic and clinical exam as well as patient-reported outcomes. Inclusion of urodynamics could enable eventual validation of clinical algorithms or less elaborate/lower cost bedside urodynamic tests.

Topic 3: Women deemed incurable (WDI) – definitions, incidence, and management strategies

Criteria for WDI have been recommended through earlier FC meetings and further discussion is also planned at the next conference of the International Society of Obstetric Fistula Surgeons; however, there is little evidence on the right procedures for managing WDI, particularly incorporating the socio-cultural impacts on women of procedures such as diversions. There are also numerous training and oversight issues. Additionally, the incidence of WDI is unknown; there are possible linkages to the fistula epidemiology research area.

Topic 4: Iatrogenic fistula – definitions, incidence, management, and causes/prevention

Is there a set of indications that strongly suggests that a fistula is iatrogenic (e.g., ureteric involvement, vault fistula, size, and/or history and circumstances of medical procedures)? Some indications have been proposed in recent research by Dr. Thomas Raassen; these may be further explored. Should research on iatrogenic fistula focus particularly in areas where there has been rapid expansion of cadres performing C-sections or rapid increase in the numbers of C-sections performed across cadres? What are the morbidity outcomes of C-sections? It is important to keep in mind that iatrogenic fistulas also result from other types of pelvic surgery, such as hysterectomies. To what degree does this topic reflect questions about clinical guidelines and best practices, rather than research questions?

Other Comments

Topics related to C-section (e.g., indications and the safety and efficacy of alternative procedures, such as symphiosotomy) were deemed important, but participants thought that other groups may be addressing these. Classification systems were also considered of high importance, but there may be fatigue around this topic or barriers to consensus and uptake of a single proposed system. It may be possible to do secondary analyses of existing FC study data through partnership with the World Health Organization (WHO), including to examine the classifications that are suggested in the data from the randomized controlled trial (RCT) on non-inferiority of short duration catheterization and observational prospective cohort study on determinants of repair outcomes.

There was high concordance between the clinical research topics that were rated highly in individual surveys and those selected through small group discussions.

B. Epidemiological Research

Emerging Priorities

Topic 1: Improved measurement and estimation methodologies, starting with the development of a validated diagnostic interview/survey tool.

Participants agreed that research on prevalence and incidence must link data from communities and the health system. Resources for validating a diagnostic tool include the Demographic and Health Survey (DHS) fistula module, questionnaires used in other household surveys, and the National Institutes of Health PROMIS system (nihpromise.org). A literature review and subsequent inventory and content mapping of tools that have been used in past studies could be a starting point. Clinical exam follow-up of women identified as having fistula through DHS surveys might be another approach to question validation. It is important to note that predictive value is influenced by prevalence – hence, validation may be sensitive to the settings and populations in which it is conducted. Validity also includes aspects of face validity, such as cultural appropriateness and acceptance by the community of experts.

A possible design for validation of a diagnostic tool would be a multi-arm study of fistula survey/diagnostic questions, including DHS module questions as one arm. A case-control model should be used to minimize sample size, enrolling women who are known to have fistula, known to have other uro-gynecological disorders, and with no known conditions. Different arms could also evaluate different interview/survey approaches (e.g., with/without probes, addressing multiple topics or SRH/uro-gyn only). It would be important to single- or double-blind if possible. It would also be important to conduct validation in multiple geographic regions to ensure generalizeablity and acceptability to end-users.

Topic 2: Association of fistula incidence and treatment outcomes with co-morbidities and socio-cultural factors

Such studies could examine co-morbidities (e.g., HIV/AIDS) as well as socio-cultural factors – for example, while female genital mutilation (FGM) may not be a clinical risk factor for obstructed labor (the constriction and scars affect soft tissue) leading to fistula, the reasons women aren't going to facilities for delivery may be the same reasons they are undergoing FGM. Such research may reveal larger socio-cultural issues that affect fistula prevention and treatment programs.

Other Comments

Good research on both of these topics requires a conceptual framework that illustrates the causal pathways of fistula. This could be a literature-based "think piece" produced by FC+.

Individual ratings were generally concordant with the group priorities noted above. The development of a validated diagnostic interview/survey tool and community mapping of women with fistula were the topics rated most highly by individual respondents.

Additional priorities regarding research related to fistula epidemiology were made at the consultation on measurement and estimation; these are reported separately.

C. Service Delivery Improvement Research

Emerging Priorities

Topic 1: Training/post-training support models to ensure provision of and competence in repairs

Research on this topic should include evaluation of barriers and enablers to providing services after training, as well as models for effective supervision. Such research should also define service outcomes and quality to include the patient perspective, for example adapting recently developed frameworks for respectful maternity care. Such research may be integrated with services for other childbirth injuries (e.g., genital prolapse).

Possible research questions include:

- What are barriers and enablers to provision of fistula services after training?
- What is the benefit of post-training support?

- What factors are associated with provision of fistula services after training (e.g., provider selection criteria, financial incentives for training participation, cost recovery, post-training supervision, patient volume, provider confidence/competence, provider motivation, availability of simulation learning packages)?
- What are effective audit and record-keeping systems for fistula services?

Topic 2: Testing different outreach models to reach different groups of women, particularly women in rural areas

To what degree is this research topic part of the service delivery improvement category vs. community/other programmatic research or even epidemiological research, if evidence contributes to better measurement of the fistula burden? Is information about the effectiveness of different outreach methods already available in the literature? Is evidence from outreach for other health issues/services relevant? Can research on this topic have global utility – how much context-specificity is there to outreach strategies and their effectiveness?

Possible research questions include:
- What are the response rates to different outreach methods? How "far" do different outreach strategies reach, particularly as catchment areas very close to treatment sites are saturated with awareness regarding availability of treatment?
- What are the costs of different outreach strategies, including input/output ratio?
- What proportion of the total estimated prevalent cases are reached/identified/brought into care through different outreach strategies?

Topic 3: Components/cost-effectiveness of reintegration packages/strategies

Participants discussed whether reintegration services (and research on these services) should be anchored within the health system, or be "held" by community groups? Are there potential harms of focusing reintegration just on women with fistula or women who had fistula? Do they have more needs than other women who have delivered, who are poor, etc.? Can well-intentioned efforts that are "fistula-only" produce stigma? Should research on this topic focus exclusively on WDI (with or without urinary diversions)? Do other factors contribute to a higher need for reintegration (e.g., duration of fistula pre-repair, self-efficacy, and/or level of family support)? Considering the treatment backlogs believed to exist in many areas, do services for reintegration provide additional services those who have been able to reach care at the expense of those who are in need of support to even access treatment? To what degree are these issues being addressed by recent/ongoing research (e.g., in Tanzania and Uganda)? To what degree should this topic be in the community/other programmatic research category vs. in services delivery improvement?

Other Comments

All quality of care research needs to consistently include women's perspectives. The service delivery improvement research group felt there was significant overlap between the topics it considered and those examined by the clinical/biomedical group and the community/other programmatic research groups. Members identified topics within other categories (e.g., bladder/care and catheterization for prevention of fistula) as research priorities that would also improve service delivery. The group felt that an examination of barriers to treatment must use a

population-based lens; the location of fistula cases must be better understood to identify context-specific barriers.

Topics related to provision of quality fistula services following training were the most highly rated by individual respondents – these included barriers to post-training service provision and supervision after training. Individuals also rated testing the effectiveness of outreach models highly. However, reintegration topics were not highly rated in the individual surveys.

D. Community-based/Other Programmatic Research

Emerging Priorities

Topic 1: Non-clinical outcomes of fistula repair, particularly post-repair quality of life (e.g., fertility desires, socio-economic needs, integration in family and community)

Research on this topic may contribute to the design both of measures of quality of life (QoL) and evidence-based models for reintegration and support services. Such research must consider gender equity as well as the differences between groups of women: those who can't or don't want to go back to their communities, those who can and want to go back but need a lot of support, and finally those who can and want to go back and do not need support. Relevant information may be available in ongoing (e.g., Johns Hopkins) and published (e.g., Tanzania) studies using tools to measure reintegration and QoL. Relevant measures may also be available or adaptable from existing tools, such as the World Health Organization (WHO) QoL and/or disability indicators (http://www.who.int/substance_abuse/research_tools/whoqolbref/en/, http://www.who.int/classifications/icf/whodasii/en/). A literature review may be the starting point on this topic, in part to determine whether others have already adequately addressed the issues. However, there may be insights not in the literature; a consultative expert interview process may be required to map existing knowledge. Research should evaluate the difference in QoL between women who are leaking and those who are not, and between those who are post-repair and those of comparable age in the same communities without a history of fistula.

Topic 2: Comprehensive documentation of the costs to patients (social, cultural, economic impact) related to fistula repair.

Cost documentation may flag equity issues in terms of who is able to reach and access repair services. Research should consider the different models of repair – many sites absorb fees for medical care, but there may be hidden/opportunity costs faced by patients that reduce access even if surgery is free or heavily subsidized. There may be socio-cultural dimensions of exclusion that might not be well understood for women who are not accessing services. Participants suggested that aspects of this topic are already covered by the desk review being conducted in collaboration with the Population Council to identify barriers to treatment access.

Other Comments

Gaining a better understanding of and ability to measure QoL before and after fistula repair was highly rated in individual surveys. However, individual ratings of other community research topics

were somewhat different from the priorities that emerged from small group discussions. Upon discussion in plenary, some of these differences were resolved. For example, evaluating social reintegration and the impact of village safe motherhood committees were highly rated by individuals. However, upon further discussion, it was suggested that these topics might be locally important but not rise to the top of a global research agenda. Similarly, some topics rated highly in individual surveys were deemed to be more general, rather than fistula-specific – e.g., women's motivation for care-seeking for safe delivery and emergency obstetric services.

Cross-cutting Issues

Meeting participants and FC+ staff identified some cross-cutting issues to keep in mind when ultimately selecting research topics for examination by the project.

- There is a difference between topics that require the definition or selection of clinical best practices or guidelines and topics that require the kind of evidence that comes from research. In developing an FC+ research agenda, it is necessary to refine the clinical research topics to focus on the latter.
- The group discussing clinical research topics was mostly composed of experts on fistula repair; the lack of clinicians who primarily focus on prevention in this small group may have skewed the resulting priorities, which did not include prevention topics or focus on issues such as C-section safety and quality. On the other hand, other safe motherhood initiatives may be conducting research that would also generate evidence for fistula prevention.
- The lines between different research categories were occasionally blurred – for example, the topics addressed by the service delivery group had relevance to the clinical research group as well as the community/programmatic research group. Thus, it is important to look at priorities from all categories together, to identify areas of complementarity and overlap.
- It is useful for the FC+ project to identify "quick wins" – for example, some of the research topics could be partly addressed through mapping existing evidence, compiling and reviewing existing tools, supporting secondary analyses of existing data, and producing conceptual pieces to guide further research.
- While the aim of this meeting was to identify global priorities for FC+ research, there will also be parallel country needs and areas of strong local interest that the project may wish to support; e.g., the presence of local political will or pilot programs may make it possible to generate a large national or regional impact through small-scale studies implemented in specific countries.

IV. FC+ Research Agenda – Near-Term Action Plan

FC+ has selected several topics and activities for near-term research activity based on:

- Priorities that emerged from the IRAG meeting and the July 10-11 consultation on measurement and estimation.
- Internal assessment of feasibility, partnerships, likelihood of impact, and representation of objectives across the FC+ project framework (e.g., prevention, identification/engagement of fistula clients, and treatment)
- Discussion with USAID.

The implementation of studies on these topics is subject to factors including resource availability and USAID Mission priorities. Selection of topics for the action plan does not guarantee that resources will be adequate to implement research studies or that studies can be conducted in specific FC+ countries of work.

A. Selected Research Topics

In 2014-2015, FC+ will develop research protocols and assess the availability of adequate financial resources related to up to three research topics:

- *Prevention*: Catheterization for prevention of fistula following obstructed labor, including coordination with research planned by the Royal College of Obstetricians and Gynecologists.
- *Identification & referral into care*: Testing different outreach models to evaluate their reach for different types of women, case finding effectiveness (including for calculation of prevalence), and effectiveness at getting women into care.
- *Treatment*: Evaluation of barriers to and enablers of provision of quality fistula services after training.

These topics or others identified by the IRAG may also be the focus of literature reviews to better understand the current state of evidence.

In the area of fistula epidemiology, FC+ has also selected a set of activities to advance research on topics identified as priorities by participants at the July measurement and estimation consultation and through discussion with USAID. These include content mapping and comparative assessment of existing tools to estimate fistula prevalence, developing a validation study for an interview-based diagnostic tool, documenting the process of incorporating fistula indicators into country Health Management Information Systems (HMIS), and collaboration with other actors engaged in activities to better measure or estimate fistula prevalence.

B. Other Research Activities

In addition to the topics outlined above, FC+ will conduct additional research activities that were already defined in the project framework or are the result of previous FC project activities:

- Barriers to treatment access: In collaboration with the Population Council, the FC+ project will continue a desk review and formative research process focusing on barriers experienced by women seeking fistula treatment. The findings of this research will contribute, in 2014-2015, to the design of a research strategy testing potential interventions to address these barriers. This research is expected to target Bangladesh, Nigeria, and Uganda.
- Secondary analyses: In 2014-2015, FC+ and the WHO will continue our collaboration, with WHO leading secondary analyses of data from the previous FC project's RCT on shorter duration catheterization and observational prospective cohort study on determinants of repair outcomes. These data may be useful in generating a fistula classification system based on cluster analysis and prognostic value. FC+ and WHO will consult with the fistula community to share findings and determine the best approach to further dissemination of recommendations in 2016.

While research related to C-section quality and safety did not emerge as a near-term priority for FC+ from this consultative agenda-setting process, FC+ will continue to work with USAID to map research on these topics being conducted by other safe motherhood partners. Opportunities to examine this topic, particularly as related to iatrogenic fistula, may be identified in specific countries or future years. Similarly, other local priorities may be identified in specific FC+ areas of activities, for targeted implementation or operations research to strengthen programs and services.

Finally, FC+ will also support research-to-practice activities that emerge from past and new research efforts. An example of this is training materials and guidelines to implement shorter duration catheterization based on the findings of the RCT.

Appendix A: List of Meeting Participants

IRAG Participants
Ms. Erin Anastasi, United Nations Population Fund/Campaign to End Fistula
Dr. Steven Arrowsmith, Fistula Foundation
Ms. Maggie Bangser, Consultant
Dr. Mark Barone, EngenderHealth
Ms. Karen Beattie, Fistula Care Plus (FC+)
Dr. Ben Bellows, Population Council
Ms. Ellen Brazier, EngenderHealth
Ms. Bethany Cole, FC+
Ms. Sheena Currie, Maternal and Child Survival Program
Ms. Kacie Dragan, FC+
Dr. Suzy Elneil, International Federation of Gynecology and Obstetrics
Prof. Serigne Magueye Gueye, University of Cheikh Anta Diop
Dr. UnJa Hayes, United States Agency for International Development (USAID)
Dr. Ana Langer, Maternal Health Task Force (MHTF)
Dr. Susan Meikle, National Institutes of Health
Ms. Erin Mielke, USAID
Prof. Ojengbede Oladosu, University of Ibadan
Prof. Grace Omoni, University of Nairobi
Ms. Celia Pett, Consultant
Dr. Thomas Raassen, International Society of Obstetric Fistula Surgeons
Ms. Kate Ramsey, Columbia/Averting Maternal Death and Disability
Dr. Joseph Ruminjo, FC+
Ms. Mary Ellen Stanton, USAID
Dr. Vandana Tripathi, FC+
Dr. Özge Tunçalp, World Health Organization
Dr. Charlotte Warren, Population Council
Ms. Mary Nell Wegner, MHTF

Appendix B: IRAG Meeting Agenda – July 8-9, 2014

MEETING OBJECTIVE

- To propose and prioritize potential research topics for the Fistula Care *Plus* (FC+) project, for consideration by project management in consultation with USAID.

TUESDAY, 8 JULY 2014

Time	Session	Speaker/Facilitator
8:30am	Breakfast	
9:00am	Welcome, introductions, and review of agenda and expectations	Ms. Karen Beattie, FC+
9:30am	Setting the stage	Ms. Mary Ellen Stanton, USAID Ms. Mary Nell Wegner, MHTF
10:00am	Overview of Fistula Care *Plus* (FC+) project	Ms. Bethany Cole, FC+
10:15am	Review of research conducted during Fistula Care (FC) project Q&A	Dr. Vandana Tripathi, FC+ FC+ staff, partners, and advisors
12:00pm	Lunch	
1:00pm	Overview of research topics/questions proposed for FC+ and priority-setting criteria	Ms. Karen Beattie, FC+ Dr. Vandana Tripathi, FC+
2:30pm	Break	
2:45pm	Small group discussions of research ideas	
4:00pm	Re-convene, Q&A	Ms. Mary Nell Wegner, MHTF
4:30pm	Discuss "homework" & Day 2 agenda (break by 5:00pm)	Dr. Vandana Tripathi, FC+
5:00pm	Reception	

WEDNESDAY, 9 JULY 2014

Time	Session	Speaker
8:30am	Breakfast	
9:00 am	Review of Day 1	Dr. Joseph Ruminjo, FC+
9:30am	Small group discussion to select research priorities	
10:30am	Break	
10:45am	Report back on small group research priorities Discussion of results	Small group rapporteurs
12:00pm	Lunch	
1:00pm	Presentation of individual research topic ratings Q&A/discussion of rating results	Dr. Vandana Tripathi, FC+
1:30pm	Discussion of emerging priority research topics and questions	Ms. Mary Nell Wegner, MHTF
2:30pm	Discussion of next steps and research at FC+/EH	Ms. Karen Beattie, FC+ Dr. Vandana Tripathi, FC+
3:00pm	Thanks & closing remarks (break by 4:00pm)	Ms. Ana Langer, MHTF Ms. Mary Ellen Stanton, USAID Ms. Karen Beattie, FC+

Appendix C: List of Potential Research Topics

Each topic was assigned a primary category; however, some are relevant to multiple categories.

I. Clinical/biomedical research related to fistula prevention and treatment:

A. PREVENTION
- Pathophysiology of obstructed labor
- Normal urination patterns during labor, including association of urination difficulties with postpartum consequences
- Evidence-based modifications to partograph form or guidance (e.g., what should action/alert lines and related response look like in rural settings without CEmOC capacity?)
- Acceptability, safety, and effectiveness of symphisiotomy as a prevention mechanism in settings with inadequate C-section capacity
- Clinical evidence regarding the efficacy, safety, and cost-effectiveness of catheterization for fistula prevention (after obstructed/prolonged labor) or conservative treatment

B. TREATMENT
- Optimal pre-operative waiting period between occurrence of fistula and fistula surgery
- Factors associated with repeat fistula, whether new fistula following successful repair or breakdown of repair during subsequent pregnancy/delivery
- Necessity of C-section for delivery after fistula repair
- Criteria to define women deemed incurable (WDI)
- Incidence of WDI and strategies for management
- Fistula classification, including: a) Criteria to identify and grade complexity through pre- and/or intra-operative evaluation; and b) Identification of the best options for an effective and feasible (simple, standardized, internationally acceptable and predictive) fistula classification/staging system
- Need for and optimal use of prophylactic antibiotics before, during, and/or after fistula repair surgery
- An optimal post-operative management package for simple fistula surgery, evaluating separate interventions in addition to catheterization and antibiotics (e.g., bladder training, drinking regimen, pelvic floor exercises) or multiple components concurrently
- Residual incontinence after fistula repair, including incidence, causes and predictors, and effective prevention and treatment
- Testing of emerging repair and incontinence technologies that are feasible for scalable use in low-resource settings, such as urethral and fistula plugs
- Relative efficacy of different fistula repair techniques (adjusting for case mix, operator expertise, and quality of pre- and post-operative care)
- Techniques to achieve higher closure rates for complex fistula
- Determinants of iatrogenic fistula (e.g., following C-sections)
- Traumatic fistula from sexual violence, including range of cases and differences from obstetric fistula in repair and outcomes
- Prevalence of anal sphincter/3rd-4th degree perineal damage concurrent with obstetric fistula
- Safety and cost-effectiveness of different types of anesthesia for fistula repair
- Diversions in the management of urogenital fistula, including clinical and quality of life outcomes

II. Epidemiological research – determinants and distribution

- Prospective community-based studies to measure fistula incidence and describe proportion of different forms of obstetric fistula and risk factors associated with each
- Improved approaches for population- and health facility-based collection of data on fistula incidence and prevalence, including to link data from both settings
- Improved estimation models to calculate incidence and prevalence of obstetric fistula, e.g., applying known risk factors and information regarding population characteristics and health services access
- Development of an evidence-based causal pathway for fistula incidence, including proximate determinants of fistula (demographic, obstetrical, socio-economic) and associations of these with fistula occurrence
- Association of fistula treatment outcomes with socio-cultural factors, such as family planning use, poverty, education, and gender equity
- Association of fistula incidence and treatment outcomes with other clinical conditions, such as HIV, other infections, female genital mutilation, and malnutrition
- Development and validation of a symptoms-based diagnostic interview tool
- Measurement of the burden of disease (e.g., expressed as DALYs) related to obstructed/prolonged labor (including prolapse, stress incontinence, obstetric fistula, etc.)
- Community mapping of women living with fistula to support planning of outreach and referral interventions and services

III. Service delivery research

- Relative effectiveness of different models for functionally integrated (e.g., co-located, vs. referral to other facilities/providers) access to family planning services post-repair
- Barriers and enablers of family planning use following repair
- Effective models of screening and referral for fistula and related morbidities during postpartum care (both maternal and newborn), including how to link community and facility data.
- Effectiveness of the Fistula Care (FC) Levels of Care framework regarding prevention and treatment
- Effective program models to ensure access to C-sections after fistula repair
- Effectiveness of different approaches for post-repair services (e.g., physiotherapy and counseling)
- Optimal counseling approaches in fistula surgery, including related to informed consent
- Relative effectiveness of training and post-training support models to ensure competence in fistula repair
- Barriers and enablers to clinician/facility provision of fistula services after fistula training
- Models for effective supervision after fistula training (including mHealth)
- Clinical/operational guidelines to support safe use of catheterization for fistula prevention, conservative treatment, and management following surgical repair
- Models for quality assessment and assurance at fistula repair sites, particularly lower volume sites
- Effective approaches to improving obstetric care to prevent fistula, e.g., addressing delays in the recognition, referral or care-seeking for, and management of obstructed labor.
- Effective mechanisms to increase access to timely preventive interventions, e.g., emergency communication and transportation

- Strategies, including behavioral interventions, to improve labor monitoring to strengthen the early recognition and management of obstructed/prolonged labor (including but not restricted to strengthening partograph use)
- Improving labor monitoring for 'late arriving' facility births, i.e., how to incorporate community/family information
- Effective interventions to address barriers to accessing fistula repair services
- Importance of 3- or 6- month post-repair follow-ups in terms of clinical outcomes, quality of life, and socio-behavioral outcomes
- Adequacy/non-inferiority of mobile-phone follow-ups relative to facility-based post-repair follow-up
- Approaches for integrating other "serious birth injuries" with fistula in training and service delivery.
- Field testing of standardized record-keeping tools for fistula services
- Evaluation of clinical quality and outcomes of different models of treatment, e.g., stand-alone fistula centers vs. general with wholly or partially integrated services or ongoing/fixed sites vs. outreach/camps
- Strategies to improve bladder care during labor & delivery (including intra-partum fluid intake, encouragement of urination at appropriate intervals, catheterization when necessary)

<u>IV. Community-based and other programmatic research</u>

- Improved tools for measurement of clients' quality of life and socio-economic impact pre and post repair, addressing topics such as: Are women able to achieve fertility desires? What is rate of fistula re-occurrence? What is the impact of fistula treatment on women and their families?
- Social and economic costs to patients related to fistula repair
- Community/home birthing practices that may increase the risk of fistula
- Effectiveness of village safe motherhood communities and resources required to sustain these
- "Community"/pictorial partograph –piloting/evidence regarding role in improving referral
- Community/client surveys on stigma and ostracism, and reintegration, of women with fistula, including for WDI and following successful repair
- Components, effectiveness, and cost of different models of social reintegration
- Women's decision-making re: seeking repair services
- Experiences of pregnancy and childbirth for women living with fistula

Appendix D: Individual Ratings of Research Topics

The ratings presented in the following tables are based on 17 completed surveys (out of 28 total participants). Topics were rated on a 1 to 5 Likert scale for each of five criteria: overall priority, feasibility, technical importance, non-saturation, and potential program impact.

Table D.1: Top 5 Research Topics – Overall Priority (descending order)

Priority rank	Clinical/biomedical research	Epidemiological research	Service delivery improvement research	Community-based/other programmatic research
1st	Evidence re: catheterization for fistula prevention/conservative treatment	Community mapping of women living with fistula to support planning services	Barriers/enablers to provision of fistula services after training	Women's motivation for care-seeking for routine maternity care and for complications
2nd	Residual incontinence after fistula repair	Development/validation symptoms-based diagnostic interview tool	Training and post-training support models to ensure competence in repair	Effectiveness and cost of different models of social reintegration
3rd	Determinants of iatrogenic fistula (e.g., following C-sections)	Improved approaches for population- & facility-based collection of data on fistula incidence & prevalence	Models for effective supervision after fistula training (e.g., mHealth)	Effectiveness of village safe motherhood communities and resources
4th	Testing repair/incontinence technologies (e.g., plugs)	Improved estimation models to calculate incidence and prevalence of OF	Testing the effectiveness of different outreach strategies	Improved tools for measurement of clients' quality of life and socio-economic impact
5th	Fistula classification criteria and systems	Prospective community-based studies to describe fistula incidence, types, risk factors	Effective interventions to address barriers to accessing fistula repair	Women's decision-making re: seeking repair services

Table D.2: Top 5 Research Topics – Feasibility (descending order)

Priority rank	Clinical/biomedical research	Epidemiological research	Service delivery improvement research	Community-based/other programmatic research
1st	Residual incontinence after fistula repair	Development/validation symptoms-based diagnostic interview tool	Field testing of standardized record-keeping tools for fistula services	Women's motivation for care-seeking for routine maternity care and for complications
2nd	Evidence re: catheterization for fistula prevention/conservative treatment	Association of fistula treatment outcomes with socio-cultural factors	Barriers/enablers to provision of fistula services after training	Improved tools for measurement of clients' quality of life and socio-economic impact
3rd	Testing repair/incontinence	Evidence-based causal pathway for fistula	Barriers and enablers of family	Effectiveness of village safe motherhood

	technologies (e.g. plugs)	incidence and determinants	planning use following repair*	communities and resources
4th	Safety/cost-effectiveness of different types of anesthesia for fistula repair	Association of fistula incidence and treatment outcomes with other clinical conditions (e.g., HIV)	Training and post-training support models to ensure competence in repair	"Community"/pictorial partograph – piloting/evidence regarding role in improving referral
5th	Criteria to define women deemed incurable (WDI)	Community mapping of women living with fistula to support planning of services	Effective models for integrated access to family planning post-repair*	Social and economic costs to patients related to fistula repair

Table D.3: Top 5 Research Topics – Technical Importance (descending order)

Priority rank	Clinical/biomedical research	Epidemiological research	Service delivery improvement research	Community-based/other programmatic research
1st	Evidence re: catheterization for fistula prevention/conservative treatment	Community mapping of women living with fistula to support planning of services	Clinical/operational guidelines to support catheterization	Women's motivation for care-seeking for routine maternity care and for complications
2nd	Residual incontinence after fistula repair	Development/validation symptoms-based diagnostic interview tool	Effective interventions to address barriers to accessing fistula repair	Women's decision-making re: seeking repair services
3rd	Determinants of iatrogenic fistula (e.g., following C-sections)	Improved estimation models to calculate incidence and prevalence of OF	Effective models of screening and referral for fistula and related morbidities during postpartum care	Effectiveness of village safe motherhood communities and resources
4th	Testing repair/incontinence technologies (e.g., plugs)	Prospective community-based studies to describe fistula incidence, types, risk factors	Testing the effectiveness of different outreach strategies	Improved tools for measurement of clients' quality of life and socio-economic impact
5th	Criteria to define women deemed incurable (WDI)	Improved approaches for population- & facility-based collection of data on fistula incidence & prevalence	Training and post-training support models to ensure competence in repair	Social and economic costs to patients related to fistula repair

Table D.4: Top 5 Research Topics – Unsaturated Topic (descending order)

Priority rank	Clinical/biomedical research	Epidemiological research	Service delivery improvement research	Community-based/other programmatic research
1st	Evidence re: catheterization for fistula prevention/conservative	Community mapping of women living with fistula to support planning of	Testing the effectiveness of different outreach	Effectiveness and cost of different models of social reintegration

	treatment	services	strategies	
2nd	Residual incontinence after fistula repair	Development/validation symptoms-based diagnostic interview tool	Effective models of screening and referral for fistula and related morbidities during postpartum care	"Community"/pictorial partograph – piloting/evidence regarding role in improving referral
3rd	Determinants of iatrogenic fistula (e.g., following C-sections)	Improved estimation models to calculate incidence and prevalence of OF	Clinical/operational guidelines to support catheterization	Women's decision-making re: seeking repair services
4th	Criteria to define women deemed incurable (WDI)	Prospective community-based studies to describe fistula incidence, types, risk factors	Models for effective supervision after fistula training (e.g., mHealth)	Community/client surveys on stigma and ostracism, and reintegration
5th	Incidence of WDI and strategies for management	Improved approaches for population- & facility-based collection of data on fistula incidence & prevalence	Optimal counseling in fistula surgery (e.g., informed consent)	Community/home birthing practices that may increase the risk of fistula

Table D.5: Top 5 Research Topics – Potential program impact (descending order)

Priority rank	**Clinical/biomedical research**	**Epidemiological research**	**Service delivery improvement research**	**Community-based/other programmatic research**
1st	Evidence re: catheterization for fistula prevention/conservative treatment	Community mapping of women living with fistula to support planning services	Testing the effectiveness of different outreach strategies	Effectiveness of village safe motherhood communities and resources required
2nd	Residual incontinence after fistula repair	Development/validation symptoms-based diagnostic interview tool	Clinical/operational guidelines to support catheterization	Women's decision-making re: seeking repair services
3rd	Evidence-based modifications to partograph form or guidance	Improved estimation models to calculate incidence and prevalence of OF	Effective models of screening and referral for fistula and related morbidities during postpartum care	Effectiveness and cost of different models of social reintegration
4th	Determinants of iatrogenic fistula (e.g., following C-sections)	Improved approaches for population- & facility-based collection of data on fistula incidence & prevalence	Effective interventions to address barriers to accessing fistula repair	Social and economic costs to patients related to fistula repair
5th	Acceptability, safety, and effectiveness of symphisiotomy and other alternatives to C-section	Prospective community-based studies to describe fistula incidence, types, risk factors	Approaches for integrating other "serious birth injuries" with fistula in training and service delivery.	Community/client surveys on stigma and ostracism, and reintegration

The spread of mean ratings for each topic varied across research categories, as shown in Table D.6.

Table D.6: Responses and Mean Ratings across Research Categories

Category	Number of responses	Mean rating of highest-rated topic	Mean rating of lowest-rated topic
Clinical/biomedical research	10	4.40	1.80
Epidemiological research	14	2.02	2.82
Service delivery improvement research	15	4.68	3.11
Community-based/other programmatic research	14	3.59	2.82