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Scale up of female genital mutilation prevention and care in primary care settings in Guinea and Kenya

Submission date	**Recruitment status**	[_] Prospectively registered
28/08/2025	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
02/09/2025	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
19/11/2026	Other	[X] Record updated in last year

Plain English summary of protocol

Background and study aims

Female genital mutilation (FGM) is a harmful practice affecting more than 230 million women and girls globally. Despite the elevated risk of health complications among those who have been affected by this harmful practice, the health sector in some high FGM prevalence settings is neither actively engaged in FGM prevention nor able to provide standardized care for its complications. Yet health workers can be important opinion leaders in the communities they serve, particularly if they are supported to question their own beliefs and values around FGM.

Between 2020 – 2021, the World Health Organization (WHO), together with research partners in Guinea, Kenya and Somalia, tested a package to build the skills of nurses and midwives working in antenatal care (ANC) settings to provide FGM prevention and care services for women and girls at risk of FGM or already exposed to it. The study found that ANC providers in intervention clinics had significantly greater knowledge and skills and were more likely to communicate with their clients about FGM prevention than their counterparts at control sites. Similarly, ANC clients in the intervention clinics were significantly more likely than those in the control clinics to be strongly opposed to FGM after the clinic visit, to report that they did not intend to cut their daughters and to want to be actively engaged in FGM prevention efforts.

Based on those results, the same approach is being brought to scale in selected regions in Guinea and Kenya within public health clinics that were not reached through the original research because they were in the control group or were not randomly selected. Specifically, the study objectives are: 1) to determine if health workers exposed to the intervention package being scaled up will have improved FGM-related i) knowledge, ii) attitudes, iii) clinical management practices and, iv) prevention counselling skills; 2) among clients seeking services from health workers who have received the intervention package, to determine changes in their intention to have their daughters undergo FGM; 3) to assess the reach, fidelity, feasibility, and costs of implementing FGM prevention and care services at scale within ANC and immunization services; 4) to identify barriers and facilitators that affect scale up and sustainability of

implementing FGM prevention and care services in primary care setting. A secondary objective of this scale-up study is to test the validity of a tool for measuring health workers' FGM-related knowledge, attitudes, and practices (KAP).

Who can participate?
Adult health workers (aged 18+) providing routine ANC or immunization services at study facilities, and clients comprising pregnant women (aged 15–49) receiving ANC and mothers or family members bringing infants for immunization, all of whom must be seeking services from participating health workers.

What does the study involve?
The package includes two components- level one, which consists of dissemination of resources (e.g. clinical handbook and clinical guidelines on FGM prevention and care), a policy directive and posters, and level two which consists of a training of health workers working in ANC and immunization settings on person-centred communication for FGM prevention using a standardized package that encourages health workers to question their FGM-related values and beliefs and sensitizes them on local laws and regulations banning FGM and its medicalization. Health workers learn to apply a series of structured steps during routine clinical encounters in which they assess their client's views and attitudes on FGM, address their inherent beliefs, communicate for change and together with the client, discuss and decide on an appropriate course of action towards preventing FGM (the 'ABCD' approach). Using a cascade approach, a health worker from each facility participates in a three-day sensitization workshop and then offers the PCC training to other health workers providing ANC and immunization services in the facilities where they work.

Data collection will occur at baseline, three months and nine months. The level one package will be delivered to each facility following baseline data collection, and the PCC training will occur shortly after. Data collection at months three and nine will show immediate and longer-term impacts of the intervention.

What are the possible benefits and risks of participating?
Building the capacity of health workers to provide person-centred care, including improved communication skills, is expected to improve the quality of care in service provision beyond FGM prevention efforts. Potential risks and unintended harms include health workers receiving negative reactions from clients and family members who are supportive of FGM, and clients who might experience emotional distress in discussing the topic of FGM. Any unintended harms are to be promptly reported to the study team for the PIs to manage and report.

Research institutions in each of the study countries will be responsible for data collection and intervention implementation in collaboration with the Ministry of Health in each country. Ongoing data quality and safety will be monitored by the in-country principal investigator (PI) and data manager during collection, entry, and analysis. Periodic data audits at study initiation and thereafter, at regular intervals, will be conducted by the WHO/HRP team.

Where is the study run from?
Centre for Research in Reproductive Health in Guinea – Cellule de recherche en santé de la reproduction en Guinée (CERREGUI), and the Africa Coordinating Centre for the Abandonment of FGM/C (ACCAF), University of Nairobi, Kenya.

When is the study starting and how long is it expected to run for?
June 2023 to December 2026. Data collection in Guinea will be conducted between June 2024 and April 2025. Data collection in Kenya will be conducted between August 2025 and May 2026.

Who is funding the study?
The Human Reproduction Programme (HRP) (UNDP/UNFPA/UNICEF/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction), housed at WHO in Geneva, Switzerland.

Who is the main contact?
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Additional identifiers

Protocol serial number
A66053

Study information

Scientific Title
Scale up of female genital mutilation prevention and care services in primary care in Guinea and Kenya: A quasi-experimental, pre- versus post-test study

Study objectives
The primary objective of the study is to assess the effectiveness of an evidence-based intervention package related to female genital mutilation (FGM) prevention and care within the health system in Guinea and Kenya when brought to scale. Specifically, the study objectives are: 1) to determine if health workers exposed to the intervention package being scaled up will have improved FGM-related i) knowledge, ii) attitudes, iii) clinical management practices and, iv) prevention counselling skills; 2) to determine if clients seeking services have reduced intention to have their daughters undergo FGM; 3) to assess the reach, fidelity, feasibility, and costs of implementing FGM prevention and care services at scale when delivering routine antenatal care and immunization services; 4) to identify barriers and facilitators that affect scale up and sustainability of implementing FGM prevention and care services in primary care setting. A secondary objective of this scale up study is to test the validity of a tool for measuring health workers' FGM-related knowledge, attitudes, and practices.

Ethics approval required
Ethics approval required

Ethics approval(s)

1. Approved 04/12/2023, Research Ethics Review Committee (WHO ERC) (Avenue Appia 20, Geneva, 1211, Switzerland; +41 22 791 21 11; ercsec@who.int), ref: A66053/007095

2. Approved 06/12/2023, University of Nairobi/Kenyatta National Hospital ERC (PO Box 20723, Nairobi, 00202, Kenya; +254 020 726300; uonknh_erc@uonbi.ac.ke), ref: P795/10/2023

3. Approved 04/11/2023, Comité National d'Ethique pour la Recherche en Santé (CNERS) (Ministère de la Santé et de l'Hygiène Publique, Conakry, CKRY 001, Guinea; +224 622 25 31 27; oumou45@yahoo.fr), ref: 191/CNERS/23

Primary study design
Interventional

Study design
Multi-country implementation research study using a pre- and post-test assessment

Study type(s)
Prevention, Screening, Treatment

Health condition(s) or problem(s) studied
Prevention of female genital mutilation and management of its complications: XXI Factors influencing health status and contact with health services

Interventions
The intervention package that will be scaled up will consist of two levels, as implemented and tested in a previous phase. The level one component will involve provision of the following resource materials at each study clinic: local ministry of health (MoH) policies/directives on the role of healthcare workers in providing FGM prevention and care services displayed at participating health facilities; WHO clinical guidelines on management of health complications of FGM; WHO clinical handbook, which includes chapters on how to detect and manage FGM-related complications, how to communicate sensitively and how to provide care for specific populations; posters opposing FGM medicalization and promoting comprehensive care for women and girls affected by FGM; and job aids to guide provision of care. In-country research partners will distribute these materials to all study sites after baseline data collection and sensitize staff on how to utilize them.

The level two component will involve training health workers working in antenatal care and immunization settings on the person-centred communication (PCC) for FGM prevention counselling approach and on the provision of treatment and care for FGM complications using the WHO clinical handbook. The training will also encourage health workers to question their FGM-related values and beliefs and sensitize them on local laws and regulations banning FGM and its medicalization. Health workers will learn to apply a series of structured steps during routine clinical encounters in which they assess their client’s views and attitudes on FGM, address their inherent beliefs, communicate for change and together with the client, discuss and decide on an appropriate course of action towards preventing FGM (the ‘ABCD’ approach). Master PCC trainers will be selected in both countries, drawing from trainers and participants in the previous phase of research. They will participate in a three-day sensitization workshop using a cascade approach and will offer the PCC training to other health workers providing ANC and immunization services in the facilities where they work.

Clients will be recruited in equal numbers between ANC and immunization services when a facility offers both services. Unique clients will be selected and interviewed at each time point at each participating site. 10 in-depth interviews will be conducted in each country with clients at month 9 using an in-depth interview guide. Five in-depth interviews will be conducted in each country with district health managers at month 9 using an in-depth interview guide.

Intervention Type
Behavioural

Primary outcome(s)
1. Health workers' knowledge, attitudes, clinical management practices, and provision of FGM prevention counselling among health workers will be measured using a standardized instrument measuring these concepts adapted from a previous study, at baseline, month 3 and month 9. Knowledge is assessed in Q1 – Q3 of the HCP questionnaire, attitudes are assessed in Q6 – Q21 of the HCP questionnaire, clinical management practices are assessed in Q22 – Q29 of the HCP questionnaire, and FGM prevention counselling will be assessed in Q6 - Q12 in the client EXT questionnaire.
2. Reduced intentions to have FGM performed on their daughters among clients will be measured among health service users based on responses to a question inquiring about respondents' intentions if they (hypothetically) had a daughter who was the age at which girls are traditionally subjected to FGM (Q17 in the client EXT questionnaire) at three time points (baseline, month 3 and month 9)

Key secondary outcome(s)
1. The validity of health care providers' knowledge, attitudes, and practices (KAP) measurement tool measured using the KAP measurement component of the questionnaire in the health workers standardized questionnaire (Q1 – Q3, Q6 – Q21, Q22 – Q29 in the HCP questionnaire), correlation analysis will be conducted to check for problematic variables (e.g., those that correlate too highly). Principal factor estimation and oblimin rotation techniques will be used to investigate latent variables. Item response techniques will be used to test the items in the latent KAP domains and items intended to measure those domains.
2. The assessment of the reach, fidelity, feasibility, and costs of implementing FGM prevention and care services at scale within ANC and immunization services will be undertaken using the following methods:
2.1. The reach of FGM prevention and care services will be measured during the in-depth interviews with health facility clients and district health managers at month 9 using an in-depth interview guide.
2.2. Fidelity of implementation will be measured as the proportion of clients reporting correct responses on Q5 – Q12 in the EXT questionnaire at baseline, month 3 and month 9, as well as responses on IDIs with clients and district managers.
2.3. Feasibility of implementation will be measured in Q30 – Q31 in the HCP questionnaire at baseline, month 3 and month 9; Q6 – Q10 in the facility checklist (CHK) at baseline, month 3 and month 9; In-depth interviews with clients and district health managers at month 9.
3. Costs of implementation will be measured in HCP Q31 at month 9, which inquires about the time to implement the intervention, combined with budgetary information.
4. Barriers and facilitators to scale-up and sustainability will be measured at month 9 during in-depth interviews with clients and district health managers; responses on the facility checklist Q3 – 17 at month 9, and patient satisfaction as measured in Q13 of the EXT at baseline, month 3 and month 9 and patient change in attitude about FGM as measured in Q14 of the EXT at baseline, month 3 and month 9

Completion date
31/12/2026

Eligibility

Key inclusion criteria
Health workers:
Adult health workers aged 18 years and over at study facilities who provide routine antenatal care (ANC) or immunization services

Clients:
1. For ANC clients, participants will include pregnant women aged 15 -49 years receiving routine ANC services.
2. For immunization clients, participants will include mothers or family members bringing infants for routine immunization services. 3. The clients should be seeking services from one of the health workers who is participating in the study.

Participant type(s)
Carer, Health professional, Service user

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
15 Years

Upper age limit
80 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
Health workers:
1. Not based at a particular study site, but are present on a substitute basis for a short time period
2. Who will retire in the subsequent nine months

Clients:
1. Women whose primary clinic visit is not related to ANC or childhood immunization or who are less than 15 years old
2. Clients seeking immunization services for someone other than an infant or young child

Date of first enrolment

06/06/2024

Date of final enrolment
15/06/2026

Locations

Countries of recruitment
Guinea

Kenya

Study participating centre
Africa Coordinating Centre for the Abandonment of FGM/C (ACCAF)
University of Nairobi, Department of Obstetrics & Gynecology, College of Health Sciences
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Study participating centre
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Sponsor information

Organisation
World Health Organization

ROR
https://ror.org/01f80g185

Funder(s)

Funder type
Not defined

Funder Name
Human Reproduction Programme (HRP) (the UNDP/UNFPA/UNICEF/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction)

Results and Publications

Individual participant data (IPD) sharing plan
Data are available upon reasonable request. The de-identified data set will be retained in the WHO HRP electronic archival system. Any use of the de-identified analytic data set for secondary research purposes will be governed by the WHO data use regulation. Requests for the data dictionary and dataset can be sent to pallittoc@who.int.

IPD sharing plan summary
Available on request, Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		25/07/2026	19/11/2026	Yes	No
Other files	Client exit interview (unique clients at baseline, M3 and M9)		29/08/2025	No	No
Other files	Facility checklist (baseline M3, M9)		29/08/2025	No	No
Other files	Health worker questionnaire (baseline M3 and M9)		29/08/2025	No	No
Other files	Health worker socio-demographic information (baseline)		29/08/2025	No	No