E- learning course on a public health approach to addressing female genital mutilation

Module 4: Session 2

Ethical considerations in research on FGM

Learning objectives

- How to address ethical considerations in different types of research on FGM.
- List and explain the core principles for the ethical conduct of research involving human subjects.
- Know and understand key concepts in research ethics and their applications at each stage of research on FGM

Background

- Evidence-based decision-making requires strong evidence
- Research must have scientific and social value
- Research processes must respect the rights of participants
- FGM is a sensitive topic that requires careful consideration of ethical principles

Introduction

- Research on FGM involves inquiry on a highly sensitive and traumatic practice.
- Research on FGM has been conducted for many decades with no specific ethical guidance available as a resource for researchers.
- High quality ethical research on FGM is essential to the international, national and local efforts to end the practice.
- Investors, policy-makers and programmers need well conducted research on FGM to make evidence-based choices to maximize the impact of interventions, while ensuring that the rights of research participants are respected.

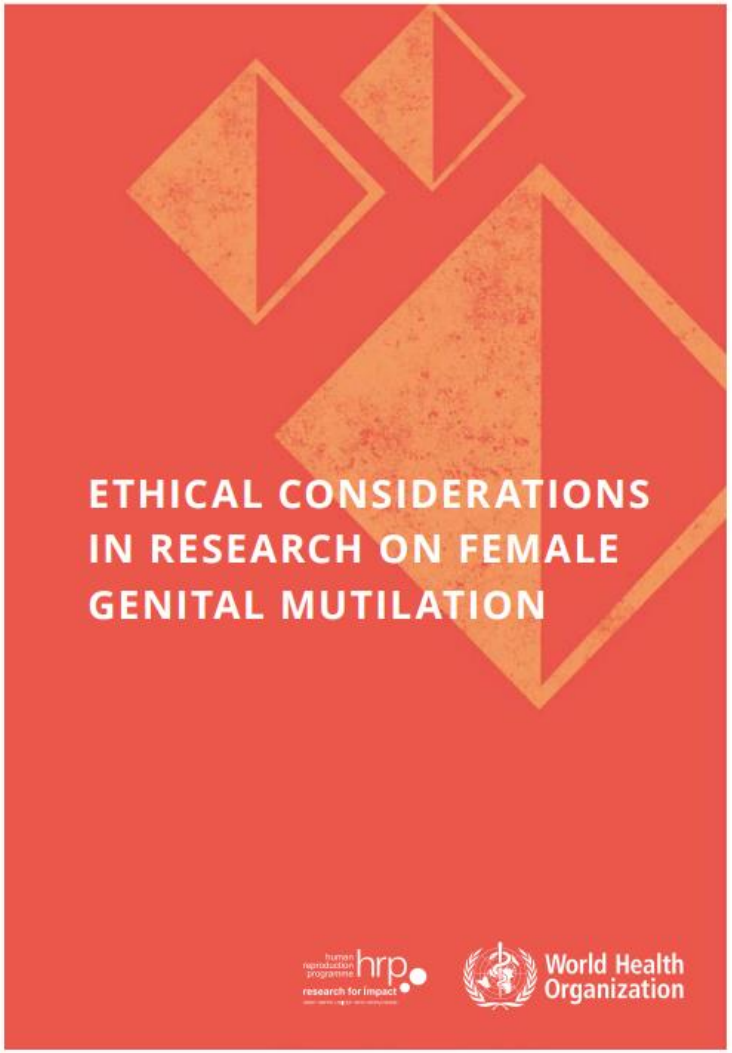
New resource

Content

- Stages of research process:
  - i. Study design
  - ii. Study implementation
  - iii. Data analysis and dissemination
- 6 hypothetical scenarios
- 3 checklists

Intended audience

- Researchers planning and conducting research
- Research ethics committees
- End users of research results



https://www.who.int/publications/i/item/9789240040731

Categories of research on FGM

Research on FGM:

- Takes place in a variety of settings – health facilities, community settings etc.
- Includes a range of study designs and methodologies, depending on the research question of interest
- Falls broadly into four categories:
  1. Descriptive studies
  2. Observational studies of associations/correlations
  3. Experimental and quasi-experimental intervention research
  4. Implementation research

Different study designs bring up different ethical challenges

Descriptive studies

- Contribute to the overall body of knowledge – FGM prevalence, FGM drivers.
- Increase the understanding of the characteristics, beliefs, power structures and practices of communities.
- Population-based data are critical for tracking the progress of indicators for global monitoring efforts, for example, the Sustainable Development Goals (SDGs).

Data sources:

- Population-based household surveys –Demographic and Health Surveys (DHS) or the Multiple Indicator Cluster Surveys (MICS)
- Other surveys
- Ethnographic or anthropological investigations
- Rapid assessment processes- use a mix of quantitative and qualitative methods to gain an overview of FGM in a specific setting
- Case studies

Observational studies of associations/ correlations

- Observe differences between groups to identify risk factors or variables that may be associated with the likelihood of undergoing FGM
- May be cross-sectional or longitudinal, retrospective or prospective
- Data can be collected in households, health facilities, schools or other community settings
- Data collection tools – surveys, questionnaires etc.
- Data sources – existing medical records, population-based surveys

Experimental and quasi-experimental intervention research

Research on interventions can include those on:

- **Primary prevention interventions –** to prevent FGM from occurring in high-risk communities
- **Secondary prevention interventions –** to prevent it from reoccurring in the case of infibulated women who are de-infibulated
- **Tertiary prevention interventions –** involving treatment and care interventions to mitigate the health and psychosocial consequences of FGM and to actively encourage health-seeking behaviour and engagement with health systems regarding FGM-related morbidity

Implementation research (1)

- A scientific approach to understanding why and how the implementation of particular programmes, policies and interventions result in desired outcomes in real-world health settings.
- Study designs vary and depend on the research questions to be explored.
- Involves the scaling up of interventions previously shown to be effective in specific contexts, or seek to understand barriers and conditions under which specific strategies achieve results, thereby increasing the effectiveness and impact of subsequent intervention.
- When the studies are conducted appropriately and ethically, the findings of implementation research can ultimately improve how effective interventions are delivered and/or scaled up, and can ensure that particular groups are given equitable access.

Implementation research (2)

Specific ethical considerations

Who gives consent and who is affected by the research are important questions relating to implementation research:

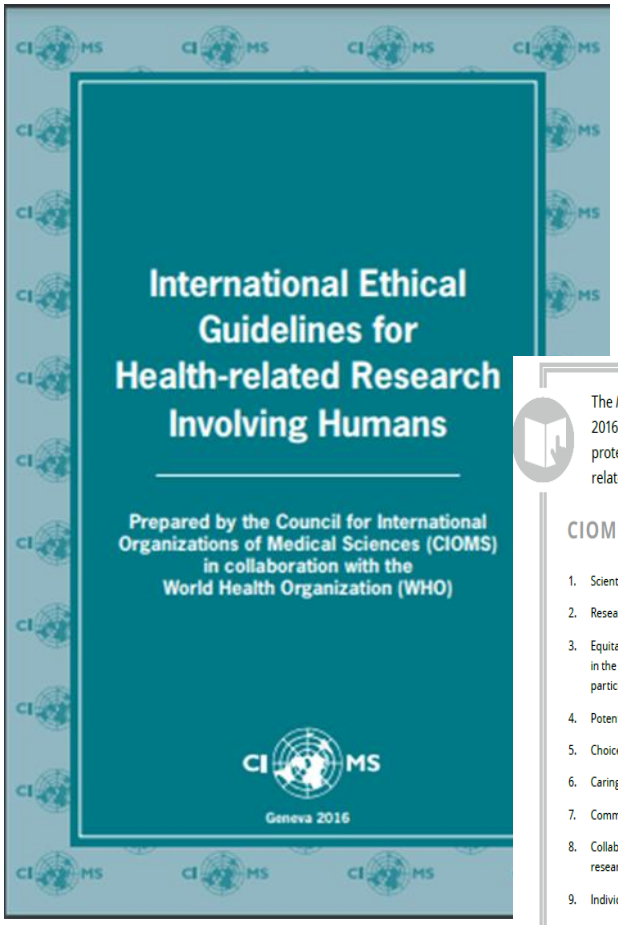
- Clients or patients may not be aware and may not have consented to the testing of new approaches in the place they are seeking services
- Participating health-care providers and other members of the health systems workforce may not have been fully informed of the research
- Community members might be unknowing research participants or recipients of an intervention in the community

Examples: studies investigating

- Scaling up the training of midwives to counsel mothers on the impact of FGM, based on positive outcomes in a pilot study
- Extending a successful school peer mentor programme on FGM prevention, from a girls' secondary school to a range of co-educational secondary schools in rural and urban settings

International ethical guidelines for health-related research involving humans

- The Council for International Organizations of Medical Sciences (CIOMS), founded in 1949 first developed research ethics guidelines in 1982
- Subsequent revisions in 1993, 2002, 2009 and 2016
- The 2016 CIOMS guidelines reflect importance of translational research, fair research in low-resource settings, community engagement, inclusion of potentially vulnerable groups
- The concepts outlined in the document relate to FGM research



The *International ethical guidelines for health-related research involving humans* (CIOMS, 2016) provide an authoritative ethical framework to inform decision-making for the protection and safeguarding of the rights and welfare of research participants in health-related research.

CIOMS GUIDELINES

1. Scientific and social value and respect for rights
2. Research conducted in low-resource settings
3. Equitable distribution of benefits and burdens in the selection of individuals and groups of participants in research
4. Potential individual benefits and risks of research
5. Choice of control in clinical trials
6. Caring for participants' health needs
7. Community engagement
8. Collaborative partnership and capacity-building for research and research review
9. Individuals capable of giving informed consent
10. Modifications and waivers of informed consent
11. Collection, storage and use of biological materials and related data
12. Collection, storage and use of data in health-related research
13. Reimbursement and compensation for research participants
14. Treatment and compensation for research-related harms
15. Research involving vulnerable persons and groups
16. Research involving adults incapable of giving informed consent
17. Research involving children and adolescents
18. Women as research participants
19. Pregnant and breastfeeding women as research participants
20. Research in disasters and disease outbreaks
21. Cluster randomized trials
22. Use of data from the online environment and digital tools in health-related research
23. Requirements for establishing research ethics committees and for their review of protocols
24. Public accountability for health-related research
25. Conflicts of interest

Ethical principles in research (1)

- How a research is conducted has implications for the rights and welfare of the participants, for the quality and validity of the results and how the findings subsequently inform programmes and policies.

- **Core principles for the ethical conduct of research involving human subjects are:**
  - **Respect for persons**
  - **Beneficence**
  - **Justice**

- These principles place ethical obligations on researchers and research ethics committees

(see next slide for explanations)

Ethical principles in research (2)

Core principles for the ethical conduct of research involving human subjects	
Respect for persons	• Highlights the importance of three components of informed consent (information, comprehension and voluntariness) • Distinguishes between people with and without autonomy to protect their own interests • Places a strong focus on how those with diminished autonomy should be treated (e.g. children, and people without the mental capacity to protect their own interests)
Beneficence	• To do no harm and to maximize possible benefits while minimizing possible harms • Beneficence in the process of assessment of risks and benefits need to consider the context of the research initiative
Justice	• Fairness in the selection of participants and in how the research findings are applied • Research subjects are not selected solely because of ease of accessing them or because of their vulnerability • Learning from the research should not benefit some groups more than other groups because of their status

Existing guidance for researching violence against women, and other sensitive topics

- WHO (2001) Putting women first: ethical and safety recommendations for research on domestic violence
  - It has been subsequently adapted for specific populations, including trafficked women (WHO, 2003), women in emergencies (WHO, 2007), and for supporting research and testing interventions to address violence against women (WHO, 2016).

- Contreras-Urbina and others (2019)
  - It applied the WHO ethical and safety recommendations for researching, documenting and monitoring sexual violence in emergencies and explored ethical and methodological considerations under four headings: (1) risk-benefit assessment, (2) methodological and conceptual approaches, (3) safety considerations, and (4) analysis and research uptake.

- WHO (2018) The WHO guidance for research on sexual and reproductive health topics among adolescent populations
  - It explores four themes that are relevant to research on FGM, namely: (1) defining adolescents as a study population, (2) determining an adolescent's capacity and maturity in the research context, (3) conflict between ethical and legal obligations in relation to adolescent research participants, and (4) information sharing.

Ethical principles and frameworks to research on FGM: **Privacy**

- It is a fundamental element of ethical research to ensure the rights of research participants to privacy.

- Researchers must ensure that participants are in control of the type and level of information they choose to divulge about themselves throughout the research process, and that personal information is collected and stored in a way to ensure privacy.

- In communities where FGM is practised, questions of identity, power and voice are intimately linked to the FGM status of a girl or woman, and the nature of the information that might be shared during research on FGM or other sensitive topics is often highly personal and linked to personhood.

- Throughout the data-collection process, it should be ensured that research participants have trust in the people interviewing them and do not feel coerced to disclose a greater depth of information than they are comfortable with.

Ethical principles and frameworks to research on FGM: **Vulnerability (1)**

- Women and girls participating in research on FGM are potentially vulnerable to a range of psychosocial and physical harms.
- These may have immediate and long-term implications for them and their families.
- These harms may be:
  - unintended harms or secondary trauma from the retelling of traumatic events, and
  - sanctions for not conforming to social norms associated with the practice where the prevalence of FGM is high.
- Contextual factors play a significant role in determining the different forms of vulnerability of individuals and groups.
- The appropriate protection of vulnerable persons is central to undertaking ethical research, and researchers should ensure that they have access to participation and have adequate protection from harms.

Ethical principles and frameworks to research on FGM: **Vulnerability (2)**

- The "layers" of vulnerability, with each additional layer adding to the degree of an individual's overall vulnerability should be acknowledged and addressed throughout a research on FGM.
- Procedures in place to protect privacy and to maintain confidentiality can help to mitigate vulnerabilities to some extent but, may not eliminate them completely.
- Therefore, appropriate support services and referrals should be put in place during – and preferably continue after – the research which should be accessible to all research participants, including individuals or communities in control groups.
- Vulnerable groups and individuals should not be excluded from research on FGM since their perspectives can better inform findings.

Ethical principles and frameworks to research on FGM: **Confidentiality (1)**

- The purpose of managing confidentiality throughout the research process is to reduce the risk of harm through the disclosure of sensitive data that could be attributed to specific research participants.

- Sensitive data on FGM research include:
  - **personal information**
  - **experiences**
  - **beliefs**
  - **behaviours**

Ethical principles and frameworks to research on FGM: **Confidentiality (2)**

- It is the responsibility of members of the research team to establish the overall framework within which confidentiality is managed by ensuring that:
  - appropriate procedures and protocols are in place to ensure data are anonymized and stored securely to avoid individual identification;
  - research team members are trained and provided with the resources required to adhere to the protocols on confidentiality;
  - community leaders, community mobilizers and other key members of host communities are aware of the protocols on privacy and confidentiality;
  - research participants, particularly in focus group discussions, are made aware of their responsibility to maintain confidentiality of information shared by other research participants; and
  - confidentiality is maintained in the dissemination phase, including not disclosing any identifying information that can link to individuals in the presentation of results.

Ethical principles at all stages of research: **Study design**

The following should be considered when designing FGM related studies:

1. **Justification of research** see Hypothetical scenario A in the next slide
2. **The Legal status of FGM**
3. **The ambiguity of language in relation to FGM -** see Hypothetical scenario B in the next slide
4. **Community engagement**
5. **Research capacity-building**
6. **Obtaining informed consent**

Hypothetical scenarios on ethical principles during study design (adapted from: WHO, 2021)

HYPOTHETICAL SCENARIO A

Research relevance

BACKGROUND:

A research team that has extensive experience conducting research on child health is encouraged by colleagues to conduct research on the drivers of FGM, since the institution will be eligible for funds specifically related to research on this topic. The research team is based in a country that has high levels of FGM and many members of the team have an interest in this topic; they therefore decide to take up this recommendation so they can learn more about this important public health issue. The team writes a proposal for a descriptive study using mixed methods, including interviewing a range of stakeholders.

ETHICAL CHALLENGE:

Since the research team is not well acquainted with the topic of FGM, they are not aware that there are several existing studies, some from the country where they are based, exploring the drivers of FGM. The research they are seeking to carry out will not fill relevant research gaps and will likely duplicate existing studies.

PROPOSED SOLUTION:

Before developing the proposal, the research team should carry out a literature review to determine the relevance of their research questions and to ensure that their study fills a research gap and does not duplicate existing efforts. They should also meet community leaders, health providers and opinion formers, including those representing women and girls, to ensure that their research is relevant and feasible in the specific context, with a preference for research that will inform the development of a programmatic initiative or test the effectiveness of an existing programmatic intervention.

HYPOTHETICAL SCENARIO B

Use of standardized language

BACKGROUND:

A research team is conducting a population-based study in an emergency setting with displaced persons to understand the health and psychosocial needs of the population being served in this setting. The researchers suspect that many of the women have experienced multiple forms of trauma and they would like to assess the constellation of their experiences, including FGM, to ensure that programmes and services are appropriately responding to their needs. Since FGM is one of many topics of interest, the research team is exploring how to ask about FGM status.

ETHICAL CHALLENGE:

The phrasing of questions to assess FGM status can have implications for the validity of the data. Researchers who are not familiar with the topic or who may be inquiring about FGM status as a secondary topic in a survey might opt for a more general question, such as, "Have you ever undergone female genital mutilation or cutting?" This question can lead to underreporting if women do not consider the procedure they underwent to be FGM. Carrying out research that underestimates prevalence rates of FGM because of inadequate measurement is unethical because it will adversely affect resource allocation due to biased results.

How can questions about a woman's FGM status be asked sensitively while also providing accurate and comparable information?

PROPOSED SOLUTION:

The DHS and the MICS, two population-based surveys, include modules on FGM that are administered in countries where FGM is practised. These modules are considered valid and reliable measures of self-reported FGM status. The questions ask women about the extent of their FGM experience, including a question on whether their genitals have been cut, whether flesh has been removed and whether they have been stitched closed. The advantage of these standardized questions is that responses can be compared across settings and they are considered valid measures of reporting.

The use of local terminology familiar to the study population can be a sensitive way for interviewers to introduce the topic of FGM. Wherever possible, researchers should then use standardized terminology to clarify the responses to increase the accuracy and comparability of the data.

Ethical principles during study design checklist (adapted from: WHO, 2021)

CHECKLIST

STUDY DESIGN

Research teams and research ethics committees have responsibility for the following aspects of ethically conceptualizing, designing and justifying research on FGM.

Positioning the study in the wider research context:

- ○ The research builds on existing knowledge and previous research on FGM and addresses specific knowledge gaps.
- ○ The research is grounded in a theory of change model.
- ○ The research is expected to result in new knowledge and/or understanding about FGM.
- ○ National stakeholders on FGM have been appropriately involved in the conceptualization of the study.
- ○ The local, national and international benefits of undertaking this research are articulated in measurable terms.

Engagement with the community – understanding the local context and engaging local stakeholders:

- ○ Local stakeholders and opinion formers on FGM have been involved in the conceptualization of the research.
- ○ Local stakeholders have been actively involved in the assessment of potential benefits and risks of undertaking this research and have agreed that the potential benefits outweigh the risks of harm.
- ○ The capacity-building of local organizations has been incorporated into the research process.

Ethical principles during study design checklist cont'd (adapted from: WHO, 2021)

Minimizing risks to research participants:

- ○ The range of potential risks to research participants (physical, psychological and psychosocial) of participating in the research are identified, including the potential sanctions to which community members opposing social norms might be subjected.
- ○ Active measures have been incorporated in the study design to minimize the risks of harm for all research participants.
- ○ Appropriate support and referral services are available and/or individuals have been identified and adequately trained to provide support and protection.
- ○ Accurate information on FGM, and related protection and support services are provided, and any participant requiring additional support as a result of study participation will have access to these services, including participants in control arms.
- ○ Systems are incorporated into the study design to monitor risks to participants throughout the research process.

Ethical principles during study design checklist cont'd (adapted from: WHO, 2021)

Methodology:

- ○ The methodology takes into account cultural sensitivities in relation to FGM in the research settings.
- ○ The study design places justice at its core, ensuring the balance of benefits and risks at the level of the individual and the group as well as the overall study.
- ○ The sampling strategy is appropriate for the research question(s).
- ○ Any information given or questions asked are explicit, unambiguous and use appropriate local language.
- ○ Sensitive and standardized processes are in place to protect privacy and to obtain informed consent, including for participants under 18 years of age.
- ○ Systems and protocols are in place to manage confidentiality throughout the research process.
- ○ Research tools and techniques are developed collaboratively with appropriate local stakeholders and are adequately piloted.
- ○ Dissemination processes at local and national levels are included in the research design.
- ○ Regardless of whether FGM is the primary or secondary aspect of the research, appropriate systems and processes are in place to ensure adequate training and support on FGM for the research team members.

Ethical principles during study design checklist cont'd (adapted from: WHO, 2021)

Selection, training and support for research team members:

Research team members are principal investigators, data managers, statisticians, research assistants and research coordinators. Data collectors are generally not considered part of research teams, although in small-scale studies, research team members might do some or all of the data collection.

- ○ Appropriate procedures are developed for the selection of research team members and data collectors, and ensure the appropriate skill mix while also reflecting the participating communities and stakeholder groups.
- ○ Any potential conflicts of interest of the research team are declared and resolved.
- ○ Adequate training and ongoing support for all the members of the research team and the data collectors are incorporated into the planning process, with particular emphasis on the sensitive nature of research on FGM.
- ○ Data collection among women and girls on FGM-related topics, such as personal beliefs and experiences related to FGM, should be conducted by female data collectors, unless the participant is selected because of their professional role (e.g. health-care provider, policy-maker), in which case the sex of the data collector does not need to be restricted.
- ○ The range of potential risks to data collectors and research team members (physical, psychological and psychosocial) of participating in the research have been identified, including any potential sanctions or adverse consequences for community members involved in data collection.
- ○ Active measures have been incorporated in the study design/protocol, to minimize the risks of harm for all involved in the research.
- ○ Appropriate debriefing will be available to all research team members and data collectors, and support will be available to any individuals adversely affected by their engagement in the research study.

Ethical principles at all stages of research: Study implementation

Considerations include:

- **Sample selection:** selection of sites, selection of individual research participants
- **Risks to research participants and research team members:** physical, psychological, psychosocial (see next slide hypothetical scenario C).
- **Linkages to referral services:** an important element of beneficence – provision of information on FGM types, legal status, health complications; referral resources to support individuals at risk of undergoing FGM or who have undergone FGM
- **Selection, support and training of research team and data collectors:** consider sex, ethnic and linguistic characteristics of data collectors and research participants, social desirability bias and concerns regarding confidentiality (see next slide hypothetical scenario D)

Hypothetical scenarios on ethical principles during study implementation (adapted from: WHO, 2021)

HYPOTHETICAL SCENARIO C

Protecting confidentiality in group settings

BACKGROUND:

A research team is undertaking an observational study to measure the impact of an alternative rites-of-passage (ARP) programme. The ARP programme replaces the traditional FGM ceremony with an activity that celebrates girls' passage from girlhood to womanhood through dance, song and learning about local cultural practices, without the girls undergoing FGM.

In addition to carrying out a survey to measure changes in attitudes and practice in relation to FGM among families participating in this programme, the research team intends to conduct focus group discussions with some of the mothers whose daughters participated in the ARP programme.

ETHICAL CHALLENGE:

Focus group discussions can be an excellent way to understand the perceptions and views of participants when the groups are well structured and moderated. However, personal and confidential information might be shared in the focus groups. This information could result in the stigmatization of individuals and their families if shared beyond the focus group discussion.

How might the research team minimize the risk of confidential information being shared outside the focus group discussion?

PROPOSED SOLUTION:

1. Consider key informant interviews instead of, or as well as, focus group discussions. Focus group discussions provide opportunities to explore attitudes, reactions, social norms and community dynamics, whereas key informant interviews provide a more confidential space within which to explore personal experiences and behaviours.

2. If focus group discussions are used:

   - the composition of focus groups should bring together people who would feel comfortable in dialogue with each other, and the composition of the groups should be as homogenous as possible;

   - the moderator should ask focus group members to keep information disclosed to the group confidential and remind them that the research team cannot ensure the confidentiality of information that they choose to disclose in the presence of others.

HYPOTHETICAL SCENARIO D

Privacy and safe spaces

BACKGROUND:

A research team wishes to interview women seeking routine health-care services about FGM to assess the quality of care received by women and how effective the health-care providers are in providing services related to FGM prevention and care. Some of the questions that women are asked are related to their FGM status and their opinions about the practice. The research team needs to protect the privacy of the participants by providing a safe space to conduct the interview in a busy clinic setting.

ETHICAL CHALLENGE:

Conducting research on sensitive topics requires a private and safe space to ensure that respondents feel sufficiently comfortable to respond truthfully and accurately and are assured that their responses will be kept confidential. Data confidentiality is a standard aspect of data collection, but privacy during data collection can also affect confidentiality, and researchers must ensure that responses cannot be overheard or observed in writing.

How can researchers ensure this level of privacy in a busy clinic setting and how should they proceed if they cannot guarantee privacy?

PROPOSED SOLUTION:

The research team must make arrangements to ensure the availability of a private space for data collection at the health facility, whether this is an empty office, an extra consultation room or a dedicated space allocated for the study.

If a safe and confidential space cannot be guaranteed for the data collection then the research team should not proceed. Privacy and confidentiality are essential elements of research and the research team cannot compromise on these conditions. Without privacy and confidentiality guaranteed, the validity of the findings would be compromised as respondents might not respond accurately if they fear their responses could be overheard or observed.

Ethical principles during study implementation checklist (adapted from: WHO, 2021)

CHECKLIST

STUDY IMPLEMENTATION

Research teams and research ethics committees have responsibility for the following aspects of the ethical implementation of research on FGM.

Research team members:

- ○ The research team members are fully aware of and comfortable in their respective roles and in talking about FGM.
- ○ The data collectors have received appropriate training in participant selection and using the research tools.
- ○ Measures are in place to minimize any risks to the safety of data collectors and other research team members.
- ○ Debriefing and ongoing support are available to all research team members, both in carrying out the research and in managing any vicarious trauma they might experience.

Community mobilization and participant selection:

- ○ The appropriate authorities and/or community leaders are aware of the research and, where appropriate, have approved the involvement of their organization/community, and are fully aware of the data-collection process and its requirements.
- ○ The concept of confidentiality is fully understood by the authorities and/or community leaders.
- ○ Robust and clear procedures are in place for the selection of research participants.

Ethical principles during study implementation checklist cont'd (adapted from: WHO, 2021)

Conduct of individual interviews and/or focus group discussions:

- ○ The purpose of the research and how the findings will be used and disseminated are explained in clear and straightforward language, and participants have opportunities to ask questions.
- ○ Strategies are in place to protect the privacy, safety and confidentiality of all research participants:
  - ○ The informed-consent process is ongoing throughout their participation;
  - ○ Protocols are in place to support research team members to manage signs of anxiety or distress;
  - ○ Research team members are equipped to refer research participants for further support or information on FGM.

Ensuring data security and confidentiality throughout the research process:

- ○ Protocols are in place to ensure data are kept secure at the time of data collection, data transfer, data management and analysis.
- ○ Anonymization of data takes place at the earliest opportunity.
- ○ Protocols are in place for data storage at the appropriate points in the research process.

Ethical principles during study implementation checklist cont'd (adapted from: WHO, 2021)

Minimizing risks to participants:

- ○ Measures to reduce the risks to the participants are included in both research protocols and in training/ preparation for research team members.
- ○ Community leaders are aware of the risks to participants and willing to take steps to minimize these.
- ○ Referral services are identified and all research team members are made aware of the referral resources for appropriate support.
- ○ Systems are in place to provide information on FGM and to provide referrals, as appropriate.

Minimizing risks to the research team members:

- ○ Standard operating procedures are established to record and review any adverse events and unintended consequences on participants.
- ○ Measures to reduce the potential risks to data collectors and research team members are included in standard operating procedures and during training.
- ○ Support for the data collectors and research team is available as needed.
- ○ Debriefing sessions are conducted to provide opportunities for all research team members to talk about the impact of their involvement in the research process.
- ○ Support structures and mental health referrals are available to research team members who may be adversely affected by the research, including through vicarious trauma.

Ethical principles at all stages of research: Analysis and dissemination

- Researchers and donors have an ethical obligation to help ensure that their findings are properly interpreted and used to advance policy and intervention development.

- CIOMS (2016) calls for research to be translational and recommends that community engagement continues through all stages of the research, including during dissemination.

Ethical principles at all stages of research: Analysis and interpretation

- Disclosure of study limitations when presenting findings - sample size, lack of generalizability of findings, measurement limitations, lack of controlling for confounding, or other risk of bias
- Avoiding stigmatization: especially when these might reinforce negative stereotypes of specific ethnic or religious groups (see hypothetical scenario E)

HYPOTHETICAL SCENARIO E

Avoiding stigmatization through dissemination

BACKGROUND:

A research team is conducting a secondary analysis of a population-based survey. The team is particularly interested in understanding the factors that are associated with FGM by analysing how different sociodemographic characteristics are associated with FGM. They plan to disseminate these findings in the national media.

ETHICAL CHALLENGE:

During the analysis, the research team finds that one minority ethnic group in the country, which is regularly the focus of negative media coverage, has higher rates of FGM and higher rates of gender-based violence. Releasing the findings has the potential to cause further alienation of children from this ethnic group who already face discrimination and bullying at school.

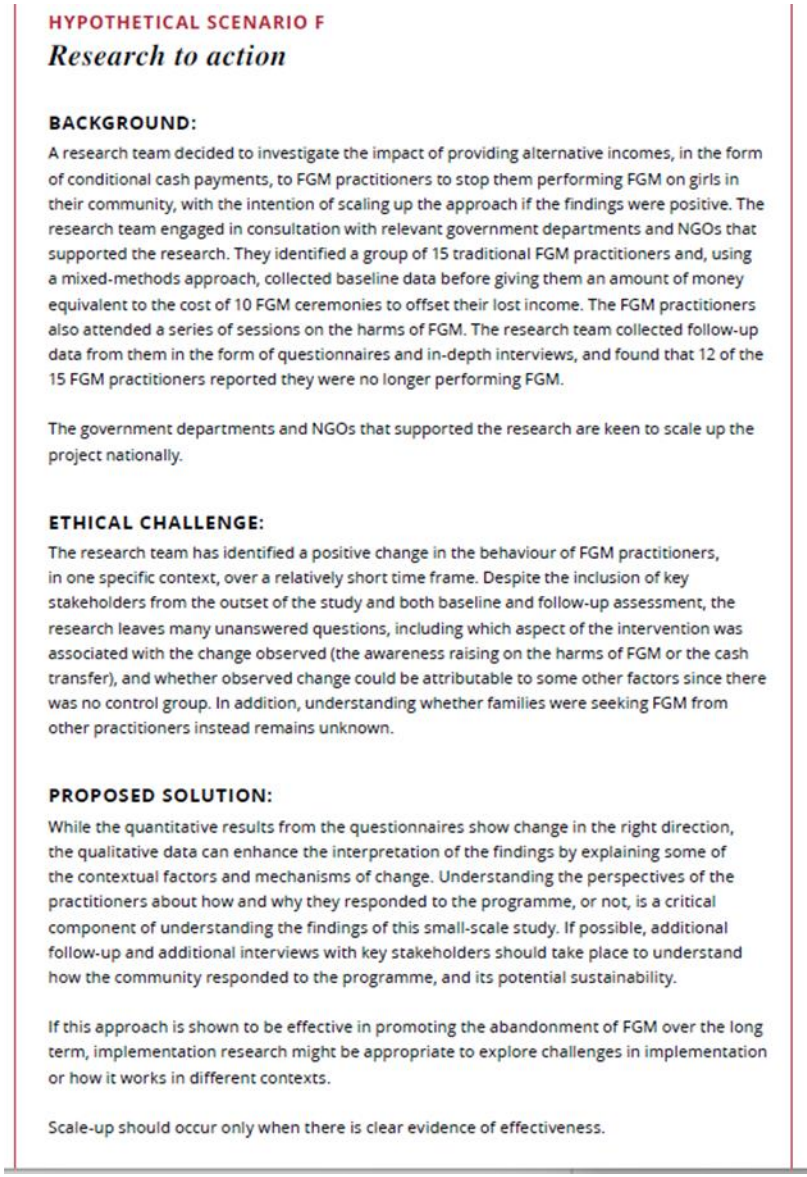
PROPOSED SOLUTION:

The research team should consider convening relevant national stakeholders, including representatives from the affected community, to discuss the range of findings, including other explanatory factors, and to decide jointly how to ensure that the research findings are used to improve programming without further stigmatizing members of this group.

Hypothetical scenarios (adapted from: WHO, 2021)

Ethical principles at all stages of research: Dissemination of research findings

- Contributes to the policy-making discourse - engagement of policy-makers in dialogue about the findings of research
- Contributes to ongoing advocacy and programmatic activities
- Enables stakeholders across different sectors to come together for cross-sectoral dialogue to explore potential interventions and increase collaboration (see hypothetical scenario E)



HYPOTHETICAL SCENARIO F

Research to action

BACKGROUND:

A research team decided to investigate the impact of providing alternative incomes, in the form of conditional cash payments, to FGM practitioners to stop them performing FGM on girls in their community, with the intention of scaling up the approach if the findings were positive. The research team engaged in consultation with relevant government departments and NGOs that supported the research. They identified a group of 15 traditional FGM practitioners and, using a mixed-methods approach, collected baseline data before giving them an amount of money equivalent to the cost of 10 FGM ceremonies to offset their lost income. The FGM practitioners also attended a series of sessions on the harms of FGM. The research team collected follow-up data from them in the form of questionnaires and in-depth interviews, and found that 12 of the 15 FGM practitioners reported they were no longer performing FGM.

The government departments and NGOs that supported the research are keen to scale up the project nationally.

ETHICAL CHALLENGE:

The research team has identified a positive change in the behaviour of FGM practitioners, in one specific context, over a relatively short time frame. Despite the inclusion of key stakeholders from the outset of the study and both baseline and follow-up assessment, the research leaves many unanswered questions, including which aspect of the intervention was associated with the change observed (the awareness raising on the harms of FGM or the cash transfer), and whether observed change could be attributable to some other factors since there was no control group. In addition, understanding whether families were seeking FGM from other practitioners instead remains unknown.

PROPOSED SOLUTION:

While the quantitative results from the questionnaires show change in the right direction, the qualitative data can enhance the interpretation of the findings by explaining some of the contextual factors and mechanisms of change. Understanding the perspectives of the practitioners about how and why they responded to the programme, or not, is a critical component of understanding the findings of this small-scale study. If possible, additional follow-up and additional interviews with key stakeholders should take place to understand how the community responded to the programme, and its potential sustainability.

If this approach is shown to be effective in promoting the abandonment of FGM over the long term, implementation research might be appropriate to explore challenges in implementation or how it works in different contexts.

Scale-up should occur only when there is clear evidence of effectiveness.

Hypothetical scenarios (adapted from: WHO, 2021)

Ethical principles during data analysis and dissemination checklist cont'd (adapted from: WHO, 2021)

CHECKLIST

DATA ANALYSIS AND DISSEMINATION

Research teams and research ethics committees have responsibility for the following aspects of data analysis, interpretation and dissemination of findings of research on FGM.

Minimizing risks to participants:

- ○ The confidentiality and safety of all research participants is maintained in the analysis and presentation of data through anonymity, especially when presenting disaggregated results.

Authenticity:

- ○ Limitations of the methodology and sampling processes and the risk of bias are fully recognized in the interpretation of the findings.
- ○ Descriptive accounts related to individuals or communities are accurately and sensitively portrayed.
- ○ Quotations are used in the context in which they were provided.

Local ownership and dissemination of findings and capacity-building:

- ○ When research is a collaboration between local researchers and external partners, local research teams should be responsible for engaging in dialogue about the findings in the local context.
- ○ Research participants and communities are given an opportunity to learn about the research results before they are disseminated more widely.
- ○ Stakeholders (e.g. health facility leaders, NGO/CBO members) have opportunities to engage in dialogue about the findings and can consider data-to-action workshops to identify how to feed results into policy and programmatic processes.

Ethical principles during data analysis and dissemination checklist cont'd (adapted from: WHO, 2021)

Publication in a range of formats and styles:

- ○ The findings are available in relevant languages in a range of formats appropriate to different audiences, including peer-reviewed publications, research reports, policy briefs, infographics, radio programmes and in other accessible formats.
- ○ Any conflicts of interest of researchers are declared and resolved.

Dissemination locally, nationally and internationally:

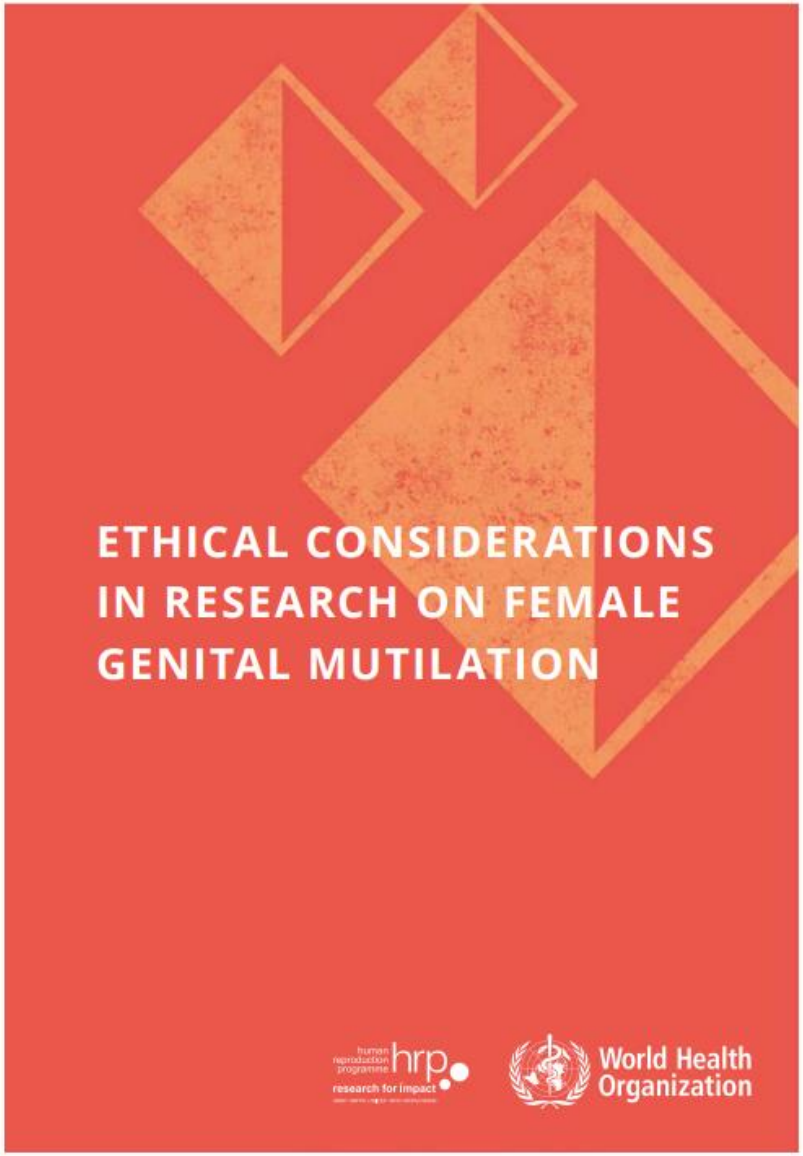
- ○ Findings are disseminated locally to actively encourage dialogue and discussion around policy and programming.
- ○ Findings are disseminated through national and international forums.

Key messages

- High quality ethical research on FGM are needed to guide efforts at the international, national and local levels to end the practice.
- How a research on FGM is conducted affects the rights and welfare of the participants, the quality and validity of the results and the use of the research findings to inform programmes and policies.
- Researchers and ethics committees have ethical responsibilities to maintain the core principles of respect for persons, beneficence and justice.
- The sensitive nature of FGM demands that special considerations are taken when applying these principles during the planning and conduct of a research on FGM as well as in the interpretation and dissemination of research results.
- The concepts of privacy, vulnerability and confidentiality, as well as voluntariness must underpin all stages of the research process.

Reference

- Ethical considerations in research on female genital mutilation. Geneva: World Health Organization; 2021. Licence: CC BY-NC-SA 3.0 IGO. Available from: https://www.who.int/publications/i/item/9789240040731



Thank you!