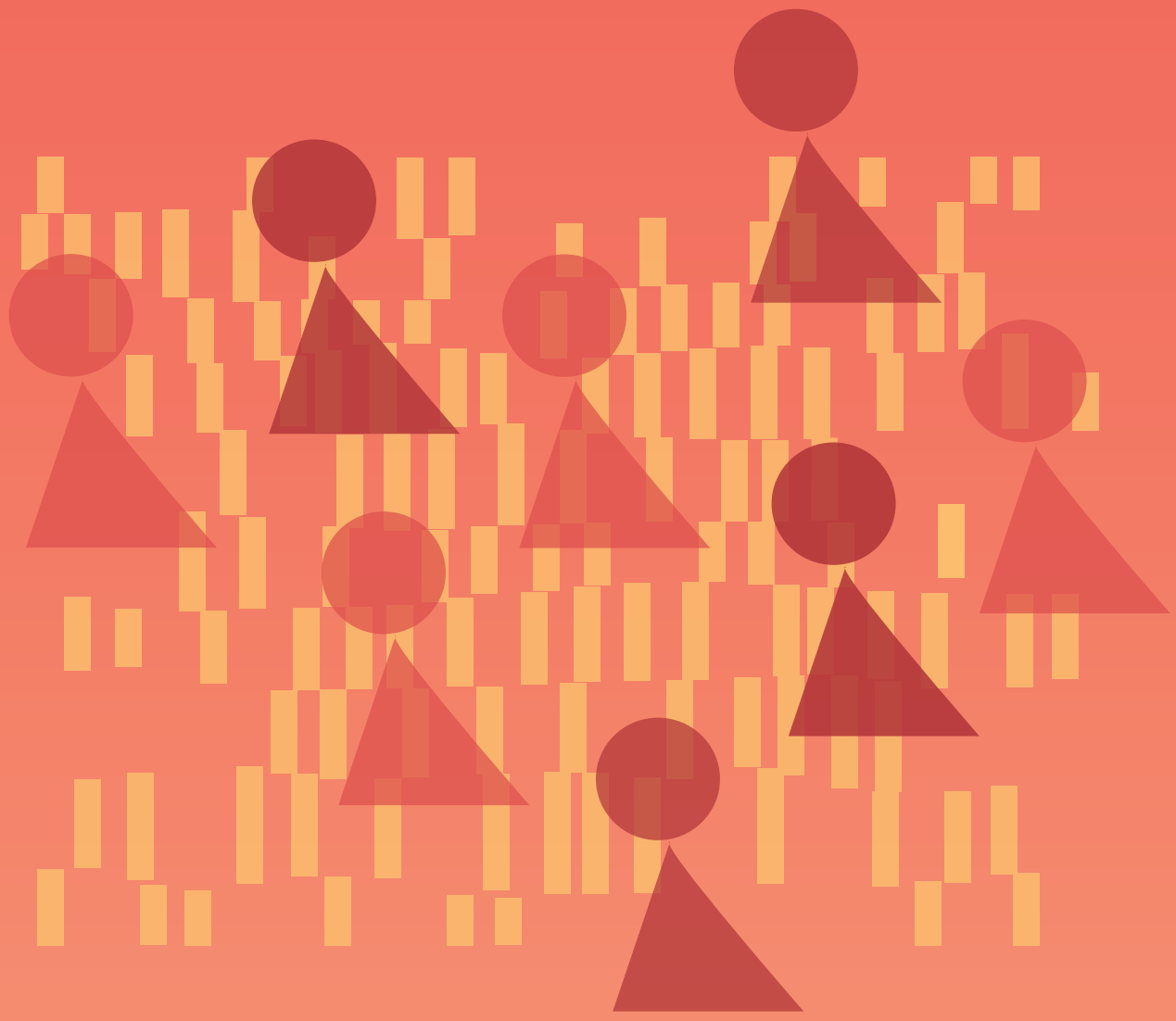
WHO guidelines on the management of health complications from female genital mutilation

World Health Organization



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Acronyms and abbreviations

CBT	cognitive behavioural therapy
CEDAW	Convention on the Elimination of All Forms of Discrimination against Women
CRC	Convention on the Rights of the Child
DOI	declaration of interest
ERG	External Review Group
FGM	female genital mutilation
GDG	Guideline Development Group
GRADE	Grading of Recommendations Assessment, Development and Evaluation
HRP	UNDP/UNFPA/UNICEF/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction
IEC	information, education and communication
NGO	nongovernmental organization
OHCHR	Office of the United Nations High Commissioner for Human Rights
PICO	population, intervention, comparator, outcome
PTSD	post-traumatic stress disorder
UN	United Nations
UNAIDS	Joint United Nations Programme on AIDS
UNDP	United Nations Development Programme
UNECA	United Nations Economic Commission for Africa
UNESCO	United Nations Educational, Scientific and Cultural Organization
UNFPA	United Nations Population Fund
UNHCR	United Nations High Commissioner for Refugees
UNICEF	United Nations Children's Fund
UNIFEM	United Nations Development Fund for Women (now UN Women)
UTI	urinary tract infection
WHO	World Health Organization

Glossary

Terms associated with female genital mutilation (FGM):

Infibulation (type III FGM)
Narrowing of the vaginal orifice with the creation of a covering seal by cutting and appositioning the labia minora and/or the labia majora, with or without excision of the clitoris.

Deinfibulation
The practice of cutting open the narrowed vaginal opening in a woman who has been infibulated, which is often necessary for improving health and well-being as well as to allow intercourse or to facilitate childbirth.

Re-infibulation
The procedure to narrow the vaginal opening in a woman after she has been deinfibulated (i.e. after childbirth); also known as re-suturing.

Medicalization of FGM
Situations in which the procedure (including re-infibulation) is practised by any category of health-care provider, whether in a public or a private clinic, at home or elsewhere, at any point in time in a woman's life.

Terms related to interventions:

Cognitive behavioural therapy (CBT)
A type of psychological therapy based on the idea that feelings are affected by thinking and beliefs. If unchecked, these thoughts and beliefs can lead to unhelpful behaviours. CBT typically has a cognitive component (i.e. helping the person develop the ability to identify and challenge unrealistic negative thoughts) and a behavioural component.

Digital health
The use of information and communication technologies in support of health and health-related fields.

Health education
The provision of accurate, truthful information so that a person can become knowledgeable about the subject and make an informed choice.

Information, education and communication (IEC)
A public health approach aiming at changing or reinforcing health-related behaviours in a target audience, concerning a specific problem and within a pre-defined period of time, through communication methods and principles.

Executive summary

Female genital mutilation (FGM) comprises all procedures that involve the partial or total removal of external genitalia or other injury to the female genital organs for non-medical reasons. The procedure has no known health benefits. Moreover, the removal of or damage to healthy genital tissue interferes with the natural functioning of the body and may cause several immediate and long-term health consequences. Girls and women who have undergone FGM are therefore at risk of suffering from its complications throughout their lives. In addition, FGM violates a series of well-established human rights principles, including the principles of equality and non-discrimination on the basis of sex, the right to life when the procedure results in death, and the right to freedom from torture or cruel, inhuman or degrading treatment or punishment, as well as the rights of the child.

The practice – prevalent in 30 countries in Africa and in a few countries in Asia and the Middle East – is now present across the globe due to international migration. Health-care providers in all countries may therefore face the need to provide health care to this population. Unfortunately, health workers are often unaware of the many negative health consequences of FGM and many remain inadequately trained to recognize and treat them properly.

Recognizing the persistence of FGM despite concerted efforts to eradicate or abandon the practice in some affected communities, and acknowledging the 200 million girls and women living with or at risk of suffering the associated negative health consequences, these guidelines aim to provide up-to-date, evidence-informed recommendations on the management of health complications from FGM. This document also intends to provide standards that may serve as the basis for developing local and national guidelines and health-care provider training programmes.

Target audience

These guidelines are intended primarily for health-care professionals involved in the care of girls and women who have been subjected to any form of FGM. This document also provides guidance for policy-makers, health-care managers and others in charge of planning, developing and implementing national and local health-care protocols and policies. The information contained in this document will also be useful for designing job aids and pre- and in-service professional training curricula in the areas of medicine, nursing, midwifery and public health for health-care providers caring for girls and women living with FGM.

Guideline development methods

This document was developed using standard operating procedures in accordance with the process described in the *WHO handbook for guideline development, second edition*.[1] In summary, the process involved: (i) identification of critical research questions and outcomes; (ii) commissioning of experts to conduct systematic reviews; (iii) retrieval of up-to-date evidence; (iv) quality assessment and synthesis of the evidence; (v) formulation of recommendations; and (vi) planning for the dissemination, implementation, impact evaluation and updating of the guidelines. The scientific evidence that informed the recommendations and best practice statements was synthesized using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) methods.[2] For each priority research question, evidence profiles were prepared from existing or commissioned systematic reviews. Values and preferences of clients and health-care providers were assessed using evidence from qualitative reviews on the context and conditions of interventions used to manage health complications of FGM.[3] The recommendations and best practice statements were developed using a consensus-based approach by the Guideline Development Group (GDG), an international group of experts in the field of FGM, during a meeting at the

1 WHO handbook for guideline development, 2nd ed. Geneva: World Health Organization; 2014.

2 Further information available at: http://www.gradeworkinggroup.org/

3 The GDG issued recommendations when the available evidence and ancillary criteria supported their development. When the available evidence is of low quality or weak but the contents of the recommended statement were based upon sound judgement and supported by human rights and equity principles, public or medical practices, and judged to have little to no risk of harm to health, best practice statements were issued.

World Health Organization (WHO) headquarters in Geneva on 1–2 September 2015.

Guidance: recommendations and best practice statements

The guideline development process led to the adoption of three statements of "guiding principles", five recommendations and eight best practice statements, covering the use of deinfibulation, mental health, female sexual health, and information and education (see *Guidance summary* tables). For each recommendation and best practice statement the quality of the evidence was graded as "very low", "low", "moderate" or "high", based on the GRADE methods. When no evidence was identified for a recommendation or best practice statement, or only indirect evidence was available, this was indicated in the summary of the evidence.

Recommendations were considered as "strong" (two recommendations) or "conditional" (three recommendations), based on the available evidence, as well as considerations of the balance between benefits and harms, women's and health-care providers' preferences, human and other resource implications, priority of the problem, equity and human rights issues, and acceptability and feasibility of the proposed intervention. Where there was a need for guidance, but no relevant research evidence was available, recommendations and best practice statements were agreed if they were supported by the public health or medical practice expertise of the members of the GDG. In order to ensure each recommendation and best practice statement could be understood and used as it was intended, the GDG offered further clarifications as needed, which are noted below the relevant recommendations and best practice statements where they are presented in full within the text of these guidelines.

Input from peer reviewers and a range of stakeholders, including colleagues working directly with girls and women living with FGM, was also sought and helped to further clarify the wording of the recommendations and best practice statements. Important knowledge gaps that need to be addressed through primary research were identified and included in the document.

The recommendations and best practice statements on the management of health complications from FGM are summarized in the table below. They will be reviewed and updated following identification of new evidence.

Guidance summary

Guiding principles
I Girls and women living with female genital mutilation (FGM) have experienced a harmful practice and should be provided quality health care.
II All stakeholders – at the community, national, regional and international level – should initiate or continue actions directed towards primary prevention of FGM.
III Medicalization of FGM (i.e. performance of FGM by health-care providers) is never acceptable because this violates medical ethics since (i) FGM is a harmful practice; (ii) medicalization perpetuates FGM; and (iii) the risks of the procedure outweigh any perceived benefit.

Summary of the recommendations (R) and best practice statements (BP)

DEINFIBULATION

R-1 Deinfibulation is recommended for preventing and treating obstetric complications in women living with type III FGM (strong recommendation; very low-quality evidence).

R-2 Either antepartum or intrapartum deinfibulation is recommended to facilitate childbirth in women living with type III FGM (conditional recommendation; very low-quality evidence).

R-3 Deinfibulation is recommended for preventing and treating urologic complications – specifically recurrent urinary tract infections and urinary retention – in girls and women living with type III FGM (strong recommendation; no direct evidence).

BP-1 Girls and women who are candidates for deinfibulation should receive adequate preoperative briefing (Best practice statement).

BP-2 Girls and women undergoing deinfibulation should be offered local anaesthesia (Best practice statement).

MENTAL HEALTH

R-4 Cognitive behavioural therapy (CBT) should be considered for girls and women living with FGM who are experiencing symptoms consistent with anxiety disorders, depression or post-traumatic stress disorder (PTSD) (conditional recommendation; no direct evidence).

BP-3 Psychological support should be available for girls and women who will receive or have received any surgical intervention to correct health complications of FGM (Best practice statement).

FEMALE SEXUAL HEALTH

R-5 Sexual counselling is recommended for preventing or treating female sexual dysfunction among women living with FGM (conditional recommendation; no direct evidence).

INFORMATION AND EDUCATION

BP-4 Information, education and communication (IEC)[4] interventions regarding FGM and women's health should be provided to girls and women living with any type of FGM (Best practice statement).

BP-5 Health education[5] information on deinfibulation should be provided to girls and women living with type III FGM (Best practice statement).

BP-6 Health-care providers have the responsibility to convey accurate and clear information, using language and methods that can be readily understood by clients (Best practice statement).

BP-7 Information regarding different types of FGM and the associated respective immediate and long-term health risks should be provided to health-care providers who care for girls and women living with FGM (Best practice statement).

BP-8 Information about FGM delivered to health workers should clearly convey the message that medicalization is unacceptable (Best practice statement).

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4 WHO defines information, education and communication (IEC) interventions as "a public health approach aiming at changing or reinforcing health-related behaviours in a target audience, concerning a specific problem and within a pre-defined period of time, through communication methods and principles". Source: Information, education and communication – lessons from the past; perspectives for the future. Geneva: World Health Organization; 2001.

5 Health education is the provision of accurate, truthful information so that a person can become knowledgeable about the subject and make an informed choice. Source: Training modules for the syndromic management of sexually transmitted infections: educating and counselling the patient. Geneva: World Health Organization; 2007.

1. Background

Female genital mutilation (FGM) comprises all procedures that involve the partial or total removal of external genitalia or other injury to the female genital organs for non-medical reasons *(1)*. Although it is internationally recognized as a violation of human rights and legislation to prohibit the procedure has been put in place in many countries, to date the practice is still being reported in 30 countries in Africa and in a few countries in Asia and the Middle East *(1, 2)*. Some forms of FGM have also been reported in other countries, including among certain ethnic groups in Central and South America *(1)*. The rise in international migration has also increased the number of girls and women living in the various diaspora populations, including in Europe and North America, who have undergone or may undergo the practice *(3, 4)*.

It is estimated that over 200 million girls and women worldwide are living with the effects of FGM *(2)*, and despite efforts to eradicate the practice, every year some 3 million girls and women are at risk of FGM and are therefore exposed to the potential negative health consequences of this harmful practice *(4)*.

The World Health Organization (WHO), as part of its core mandate to provide assistance to Member States in achieving the goal of the highest attainable standard of health for all, issued in 2008 an interagency statement on eliminating FGM. The statement describes, among other things, the negative implications of the practice for the health and, very importantly, for the human rights of girls and women, and declared vigorous support for its abandonment *(1)*. The aspiration to alleviate the associated adverse health conditions and to restore violated human rights constitutes the cornerstone of these guidelines.

1.1 Types of FGM

WHO classifies FGM into four types *(1)*, as shown in Box 1.1. The first image shows unaltered female genitalia for comparison.

1.2 Reasons why FGM is performed

FGM is practised for a variety of sociocultural reasons, varying from one region and ethnic group to another. The primary reason is that it is part of the history and cultural tradition of the community. In many cultures, it constitutes a rite of passage to adulthood and is also performed in order to confer a sense of ethnic and gender identity within the community. In many contexts, social acceptance is a primary reason for continuing the practice. Other reasons include safeguarding virginity before marriage, promoting marriageability (i.e. increasing a girl's chances of finding a husband), ensuring fidelity after marriage, preventing rape, providing a source of income for circumcisers, as well as aesthetic reasons (cleanliness and beauty) *(5)*. Some communities believe that FGM is a religious requirement, although it is not mentioned in major religious texts such as the Koran or the Bible. In fact, FGM predates Islam and is not practised in many Muslim countries, while it is performed in some Christian communities *(5)*.

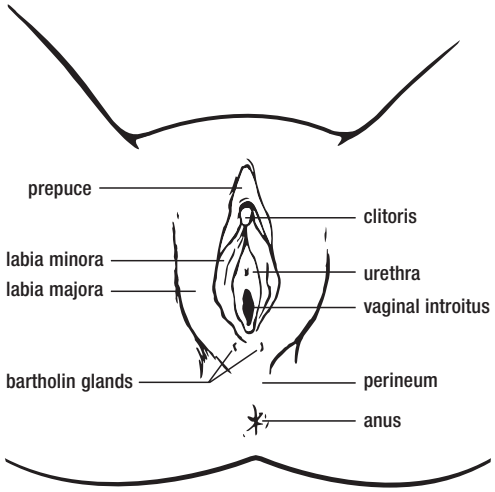
Whatever the reason provided, FGM reflects deep-rooted inequality between the sexes. This aspect, and the fact that FGM is an embedded sociocultural practice, has made its complete elimination extremely challenging. As such, efforts to prevent and thus eventually eradicate FGM worldwide must continue, in addition to acknowledging and assisting the existing population of girls and women already living with its consequences whose health needs are currently not fully met.

1.3 Health risks from FGM

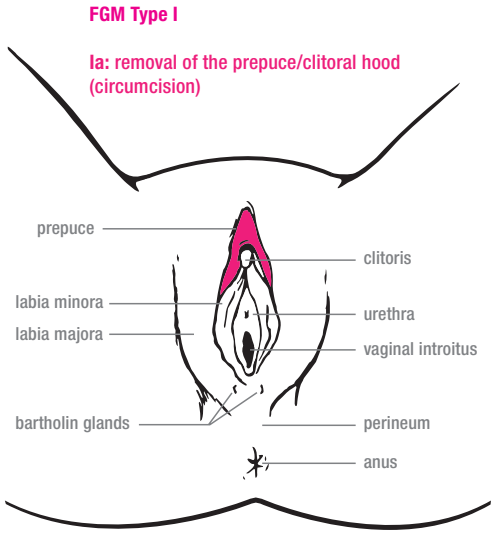
FGM has no known health benefits, and those girls and women who have undergone the procedure are at great risk of suffering from its complications throughout their lives. The procedure is painful and traumatic *(1)*, and is often performed under unsterile conditions by a traditional practitioner who has little knowledge of female anatomy or how to manage possible adverse events *(6)*. Moreover, the removal of or damage to healthy genital tissue interferes with the natural

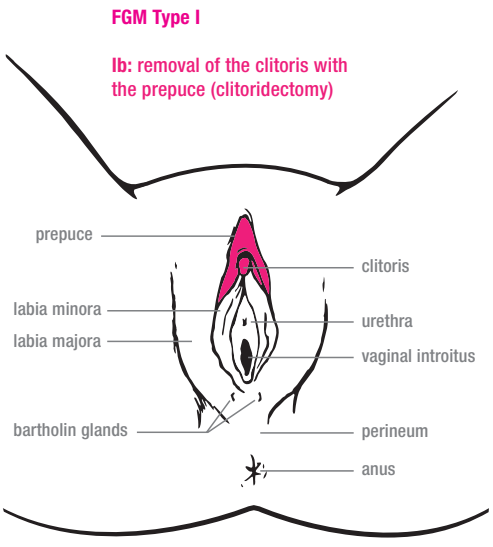
Box 1.1: Types of FGM*

Unaltered genitalia



Type I Partial or total removal of the clitoris (clitoridectomy) and/or the prepuce



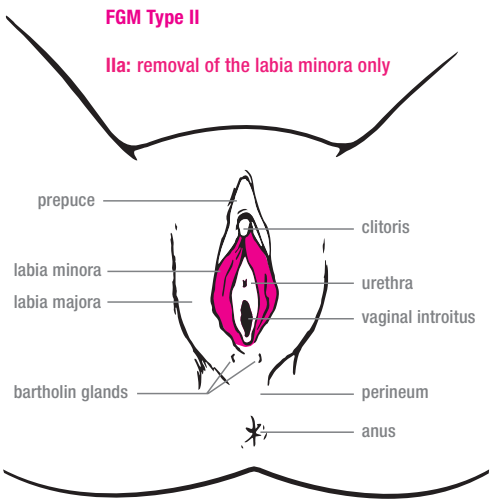


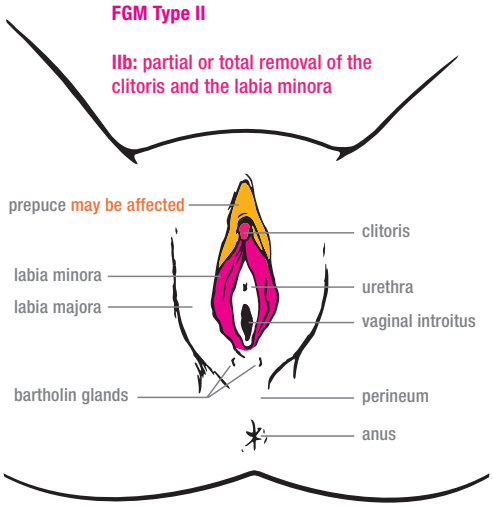
* Abdulcadir J, Catania L, Hindin MJ, Say L, Petignat P, Abdulcadir O. Female Genital Mutilation: A visual reference and learning tool for healthcare professionals. 2016 (under review).

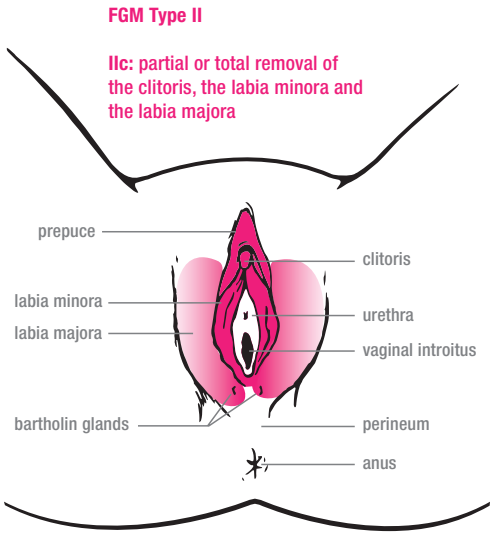
(box continues on next page)

Box 1.1: Types of FGM

Type II Partial or total removal of the clitoris and the labia minora, with or without excision of the labia majora (excision)







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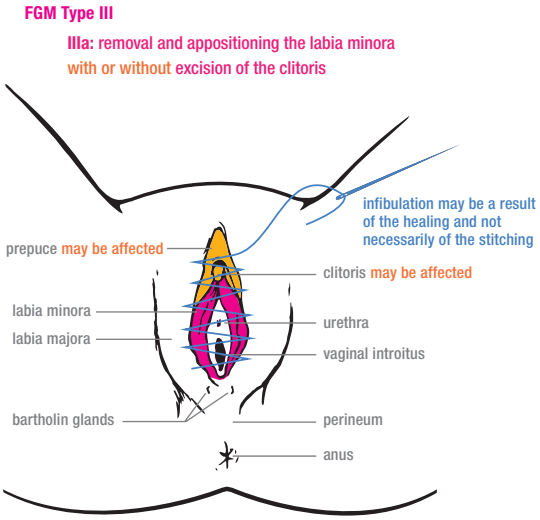
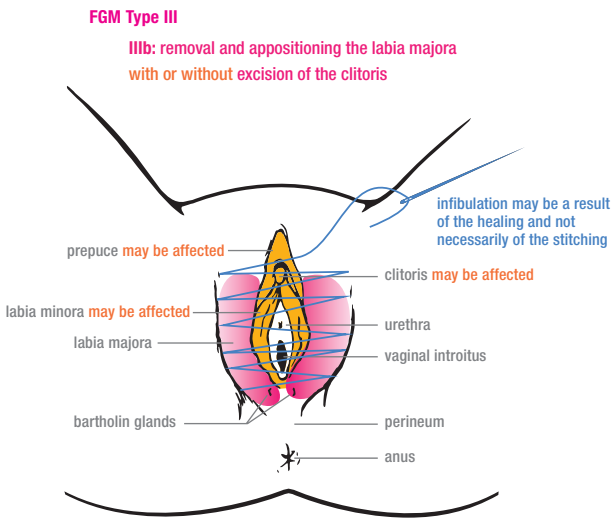
Box 1.1: Types of FGM

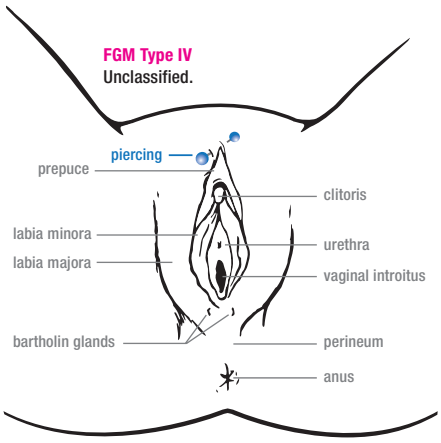
Type III Narrowing of the vaginal orifice with the creation of a covering seal by cutting and appositioning the labia minora and/or the labia majora, with or without excision of the clitoris (infibulation)





Re-infibulation The procedure to narrow the vaginal opening in a woman after she has been deinfibulated (i.e. after childbirth); also known as re-suturing

Type IV All other harmful procedures to the female genitalia for non-medical purposes, for example: pricking, pulling, piercing, incising, scraping and cauterization



functioning of the body and may cause several immediate and long-term genitourinary health consequences *(6–8)* (see Box 1.2). The evidence indicates that there might be a greater risk of immediate harms with type III FGM, relative to types I and II, and that these events tend to be considerably under-reported *(6)*.

Regarding the obstetric risks associated with FGM, a WHO study group that conducted an analysis on FGM in 2006 concluded that women living with FGM are significantly more likely than those who have not had FGM to have adverse obstetric outcomes, and that this risk seems to be greater with more extensive forms of the procedure *(9)*. These adverse outcomes may also affect the health of the newborn *(10)* (see Box 1.2).

For many girls and women, undergoing FGM can be a traumatic experience that may leave a lasting psychological mark and cause a number of mental health problems *(11, 12)* (see Box 1.2).

Given that some types of FGM involve the removal of sexually sensitive structures, including the clitoral glans and part of the labia minora, some women report reduction of sexual response and diminished sexual satisfaction. In addition, scarring of the vulvar area may result in pain, including during sexual intercourse *(6, 11)* (see Box 1.2).

In addition to these health risks, a number of procedures and day-to-day activities may be hindered due to anatomical distortions, including gynaecological examinations, cytology testing, post-abortion evacuation of the uterus, intrauterine device (IUD) placement and tampon usage, especially in the case of type III FGM.

Providing exact data regarding the direct health impacts of FGM has been a challenging task due to the small sample sizes and methodological limitations of the available studies. Despite these limitations, over the past decade or so, evidence of the direct health impacts of FGM has accrued, enabling recent systematic reviews and meta-analyses to provide summaries of these health impacts. Box 1.2 contains a summary of all health risks related to FGM.

Although there is evidence showing that these adverse health outcomes are associated with FGM, and that many communities have started to acknowledge this association, in reality health-care providers are still often unaware of the many negative health consequences and remain inadequately trained to recognize and treat them properly.

1.4 FGM and human rights

Recognizing the persistence of FGM despite concerted efforts to eradicate or abandon the practice in some affected communities, and recognizing the increased need for clear guidance on the treatment and care of women who have undergone FGM, WHO has developed these guidelines to include a focus on human rights and gender inequality *(13)*.

In December 2012, the Member States of the United Nations (UN) agreed in UN General Assembly resolution 67/146 to intensify efforts to eliminate FGM, as a practice that is "an irreparable, irreversible abuse that impacts negatively on the human rights of women and girls" *(14)*.

For the past several decades, a diverse group of scholars, advocates, legislators and health-care practitioners have offered differing views and ideas about how to best respond to this UN resolution. One consistent and powerful theme in these conversations is a call for common recognition of FGM as a denial of girls' and women's ability to fully exercise their human rights and to be free from discrimination, violence and inequality.

FGM violates a series of well-established human rights principles, norms and standards, including the principles of equality and non-discrimination on the basis of sex, the right to life when the procedure results in death, and the right to freedom from torture or cruel, inhuman or degrading treatment or punishment, as well as the rights of the child (see Box 1.3). As it interferes with healthy genital tissue in the absence of medical necessity and can lead to severe consequences for a woman's physical and mental health, FGM is also a violation of a person's right to the highest attainable standard of health *(1)*.

A variety of human rights treaties and agreements have also pronounced FGM to be a manifestation of violence against girls and women, and a practice that sustains unequal gender norms and stereotypes that contravene human rights. Human rights treaty monitoring bodies have consistently made clear that harmful practices like FGM

Box 1.2: Health risks of FGM

Risk	Remarks
IMMEDIATE RISKS *(6, 8)*	
Haemorrhage	
Pain	
Shock	Haemorrhagic, neurogenic or septic
Genital tissue swelling	Due to inflammatory response or local infection
Infections	Acute local infections; abscess formation; septicaemia; genital and reproductive tract infections; urinary tract infections The direct association between FGM and HIV remains unclear, although the disruption of genital tissues may increase the risk of HIV transmission.
Urination problems	Acute urine retention; pain passing urine; injury to the urethra
Wound healing problems	
Death	Due to severe bleeding or septicaemia
OBSTETRIC RISKS *(9, 10)*	
Caesarean section	
Postpartum haemorrhage	Postpartum blood loss of 500 ml or more
Episiotomy	
Prolonged labour	
Obstetric tears/lacerations	
Instrumental delivery	
Difficult labour/dystocia	
Extended maternal hospital stay	
Stillbirth and early neonatal death	
Infant resuscitation at delivery	
SEXUAL FUNCTIONING RISKS *(6, 11)*	
Dyspareunia (pain during sexual intercourse)	There is a higher risk of dyspareunia with type III FGM relative to types I and II *(6)*.
Decreased sexual satisfaction	
Reduced sexual desire and arousal	
Decreased lubrication during sexual intercourse	
Reduced frequency of orgasm or anorgasmia	

Box 1.2: Health risks of FGM

Risk	Remarks
PSYCHOLOGICAL RISKS *(12)*	
Post-traumatic stress disorder (PTSD)	
Anxiety disorders	
Depression	
LONG-TERM-RISKS *(6, 8)*	
Genital tissue damage	With consequent chronic vulvar and clitoral pain
Vaginal discharge	Due to chronic genital tract infections
Vaginal itching	
Menstrual problems	Dysmenorrhea, irregular menses and difficulty in passing menstrual blood
Reproductive tract infections	Can cause chronic pelvic pain
Chronic genital infections	Including increased risk of bacterial vaginosis
Urinary tract infections	Often recurrent
Painful urination	Due to obstruction and recurrent urinary tract infections

constitute a form of discrimination based on sex, gender, age and other grounds *(19)*. Several regional human rights agreements also take up the issue, especially the Protocol on the Rights of Women in Africa ("the Maputo Protocol"), which mandates legal prohibition of harmful practices such as FGM *(20)*. For a comprehensive list of international and regional human rights treaties and consensus documents providing protection and containing safeguards against FGM, please see Annex 1.

The UN Convention on the Elimination of All Forms of Discrimination against Women (CEDAW) and the UN Convention on the Rights of the Child (CRC) further called for an end to the practice, as have a variety of other UN human rights treaty bodies *(19)*. They have clarified that states' "obligations to respect, fulfil and protect" the rights of girls and women require that they take action to ensure that girls and women can live free from harmful practices, such as FGM.

The obligation to **respect** requires states to refrain from interfering directly or indirectly with the enjoyment of rights. In the case of FGM, it may require states to ensure that the health system is not used to perform this practice, as is the case with medicalization of FGM. The obligation to **fulfil** requires states to take appropriate legislative, administrative, budgetary, judicial and other actions to prevent and eliminate FGM. Finally, the obligation to **protect** requires states to ensure that third parties do not violate the rights of girls and women and that protective measures are in place, such as health, legal and social services. This means that states must set in place systems and structures to support "women and children who are victims of harmful practices" by ensuring access to "immediate support services, including medical, psychological and legal services", as well as emergency medical services *(19)*.

The right to health means that states must generate conditions in which everyone can be as healthy as possible. Despite some progress, governments face persistent challenges in meeting their international obligations within their national laws and policies related to FGM. These range from failing to fully implement and enforce existing laws, failing to foresee and address unintended consequences of laws and policies, and taking misguided actions that may increase the practice,

such as the medicalization of FGM (see section 1.5), which is often instituted as a harm-reduction measure *(13)*. Health interventions targeted at women suffering from FGM-related complications can contribute, from within the health system, to the safeguarding and restoration of a number of health-related human rights. In order to achieve this, appropriate evidence-based clinical guidance accompanied by adequate training of health-care providers is a key requirement. While the promotion and protection of human rights is ultimately the responsibility of governments, it is clear that health-care providers have a critical role to play in ensuring that efforts to eradicate FGM and provide care for women living with FGM are accomplished with the utmost attention and consideration of girls' and women's human rights *(13)*.

1.5 Medicalization of FGM

The medicalization of FGM refers to situations in which the procedure (including re-infibulation) is practised by any category of health-care provider, whether in a public or a private clinic, at home or elsewhere, at any point in time in a woman's life. This definition was first adopted by WHO in 1997 *(21)*, and reaffirmed in 2008 by 10 UN agencies in the interagency statement, *Eliminating female genital mutilation (1)*. The interagency statement strongly emphasizes that regardless of whether FGM is carried out by traditional or medical personnel, it represents a harmful and unethical practice, with no benefits whatsoever, which should not be performed under any circumstances.

Communities may be increasingly turning to health-care providers to perform the procedure for a combination of reasons. An important contributing factor is the fact that FGM has been addressed for years as a health issue, using what is known as the "health risk approach". This approach has involved locally respected health experts expressing concern about the health risks of FGM, in the form of a didactic and factual delivery of messages *(22)*. In several high-prevalence countries, this approach unfortunately did not result in individuals, families or communities abandoning the practice, but began to shift it from traditional circumcisers to modern health-care practitioners in the hope that this would reduce the risk of various complications *(21, 22)*. This brought to light the problem that although providing information about the associated health risks of FGM is an important part of its elimination, it is not sufficient to eradicate a practice strongly based on cultural beliefs and deeply embedded in societal traditions.

As an additional side-effect of the "health risk approach" to FGM, some professional organizations and governments have increasingly supported less radical forms of cutting (e.g. the pricking of the clitoris), performed under hygienic and medically controlled conditions; such harm-reduction strategies are an attempt to reduce the risk of severe complications arising from the procedure when carried out in precarious conditions.

These circumstances – paired with the fact that a number of health-care providers still consider certain forms of FGM not to be harmful and a large proportion of them are unable or unwilling to state a clear position when confronted with crucial issues like requests for performing FGM or re-infibulation *(5)* – have contributed to increasing the popularity of medicalized FGM across Africa and in the Middle East. In addition, the involvement of health-care providers in performing FGM is likely to confer a sense of legitimacy on the practice and could give the impression that the procedure is good for women's health, or at least that it is harmless *(21)*.

Efforts to stop this unintended consequence were initiated by WHO in 1979 at the first international conference on FGM, held in Khartoum, Sudan, where WHO established that it is unacceptable to suggest that performing less invasive forms of FGM within medical facilities will reduce health complications. Since then, this position has been endorsed by numerous other medical professional associations, international agencies, nongovernmental organizations (NGOs) and governments. The condemnation of medicalization of FGM was further highlighted and reiterated in the 2008 interagency statement on the elimination of FGM *(1)*. It has been recognized that stopping the medicalization of FGM is an essential component of the holistic, human-rights-based approach towards the elimination of the practice: when communities see that health-care providers have taken a stand in favour of the abandonment of the procedure and have refrained from performing it, this will foster local debate and questioning of the practice.

Box 1.3: Human rights violated by the practice of FGM

HUMAN RIGHT	RATIONALE
Right to the highest attainable standard of health	Because FGM can result in severe physical and mental harm and because it constitutes an invasive procedure on otherwise healthy tissue without any medical necessity, it is seen as a violation of the right to health. The International Covenant on Economic, Social and Cultural Rights recognizes the right of all human beings to the "highest attainable standard of physical and mental health"*(15)*.
Right to life and physical integrity, including freedom from violence **Right to freedom from torture or cruel, inhuman or degrading treatment**	FGM can cause severe physical and mental damage, sometimes resulting in death. As such, it interferes with a woman's right to life and physical integrity and freedom from violence. The right to physical integrity includes the right to freedom from torture, inherent dignity of the person, the right to liberty and security of the person, and the right to privacy. This category of rights is protected by various human rights instruments including: the Universal Declaration of Human Rights, Articles 1 and 3; the International Covenant on Economic, Social and Cultural Rights, Preamble; the International Covenant on Civil and Political Rights (ICCPR), Preamble and Article 9; and the Convention on the Rights of the Child (CRC), Article 19 *(15–18)*.
Right to equality and non-discrimination on the basis of sex	FGM perpetuates the fundamental discriminatory belief of the subordinate role of girls and women, which fits within the definition of discrimination against women. This refers to "any distinction, exclusion or restriction made on the basis of sex which has the effect or purpose of impairing or nullifying the recognition, enjoyment or exercise by women, irrespective of their marital status, on a basis of equality of men and women, of human rights and fundamental freedoms in the political, economic, social, cultural, civil or any other field" *(19)*.
Rights of the Child	Because FGM is predominantly performed on girls under the age of 18, the issue becomes fundamentally the protection of the rights of children. The Convention on the Rights of the Child (CRC) acknowledges the role of parents and families in making decisions for children, but places the ultimate responsibility for protecting the rights of a child in the hands of the government (Article 5). The CRC also established the "best interests of the child" standard in addressing the rights of children (Article 3). FGM is recognized as a violation of that best interest standard and a violation of children's rights. In addition, the CRC mandates governments to abolish "traditional practices prejudicial to the health of children" (Article 24) *(18)*.

On this basis, WHO has issued within these guidelines a guiding principle statement against the medicalization of FGM, aiming to stop this practice (see section 3.1). One fundamental measure needed to tackle this situation is the creation of protocols, manuals and guidelines to guide health-care providers in dealing with issues related to FGM, including what to do when faced with requests from parents or family members to perform FGM on girls, or requests from women to perform re-infibulation after delivery. Technical knowledge about how to recognize and manage complications of FGM, including suitable obstetric care and how to counsel women on FGM-related issues, must be provided in order to emphasize the health-care provider's role as a caregiver

rather than a perpetrator *(21)*. Therefore, adequate training becomes not only a preventive measure, but also an urgently needed tool for coping with the reality that millions of women have already undergone FGM and must live with its consequences.

In the course of developing these guidelines (see Methods, section 2.1), the Guideline Development Group (GDG) noted that an increasingly relevant issue related to FGM is female genital cosmetic surgery (FGCS). Although parallels may exist between FGM and FGCS procedures (which include labial reduction or vaginal tightening because of social, cultural and community norms that promote a particular aesthetic of female beauty and appropriate female bodies), critical differences are evident. FGM as described by the WHO classification *(1)* and referred to within this document is the result of a procedure that is performed on individuals without full informed consent, and who may face profound direct or indirect coercion to take part in these procedures, which are done in the absence of any potential medical benefit. The underlying reasons for performing FGM in the context discussed within these guidelines perpetuate deep-rooted inequality between the sexes and constitute human rights violations, as described above and noted in the 2009 UN report to the General Assembly on the Girl Child: FGM is "perpetrated without a primary intention of violence but is de facto violent in nature" *(23)*.

Thus, although outside of the immediate scope of these guidelines, the GDG thereby differentiated FGM from FGCS. In the event that FGCS is requested by an individual who is fully autonomous and able to give consent, the individual should be given complete preoperative counselling, including a discussion of normal variation and physiological changes over the lifespan, as well as the possibility of unintended consequences of cosmetic surgery to the genital area. The lack of evidence regarding outcomes and the lack of data on the impact of subsequent changes during pregnancy or menopause should also be discussed and considered part of the informed consent process *(24)*.

1.6 Objectives of the guidelines

1.6.1 Why these guidelines were developed

Following the publication of the 2008 interagency statement on elimination of FGM co-signed by WHO and nine UN partner agencies *(1)*, the UN General Assembly resolution 67/146 of December 2012, *Intensifying global efforts for the elimination of female genital mutilations*, called on Member States to:

> . . . protect and support women and girls who have been subjected to female genital mutilations and those at risk, including by developing social and psychological support services and care, and to take measures to improve their health, including sexual and reproductive health, in order to assist women and girls who are subjected to the practice;

and to:

> . . . develop, support and implement comprehensive and integrated strategies for the prevention of female genital mutilations, including the training of social workers, medical personnel, community and religious leaders and relevant professionals, and to ensure that they provide competent, supportive services and care to women and girls who are at risk of or who have undergone female genital mutilations, and encourage them to report to the appropriate authorities cases in which they believe women or girls are at risk *(14)*.

Since the release of the interagency statement and the resolution, significant efforts have been made to counteract FGM, through (i) research to generate further evidence to inform both policy and health interventions; (ii) working with communities on prevention strategies; (iii) advocacy; and (iv) passing of laws. The last involves enabling legislation against FGM and focuses primarily on punitive measures against practitioners and community members who perform FGM, as well as parents who support or condone it. Laws against FGM exist in more than half of the countries where FGM is a traditional practice, as well as in many of the countries with communities of immigrants from countries where FGM is practised. While legal prohibitions create an important enabling environment for abandonment efforts, and

criminal prosecutions can send a strong message against the practice, if these are not combined with education and community mobilization, they risk placing health-care practitioners in the position of enforcers of punitive policies, potentially damaging their relationships with their clients and limiting their capacity to engage in rights-based and gender-equality-promoting health practices *(13)*. A framework that includes preventive measures to promote abandonment, as well as punitive measures for those who engage in the practice, has been shown to have a positive effect when coupled with community-based work *(21)*.

In spite of the positive signs resulting from these efforts, prevalence of the practice in many areas remains high and millions of women live today with the negative health consequences of FGM *(1)*. In this regard, the development of pertinent, evidence-based clinical guidelines for health workers is of key importance. First and foremost, guidelines help guide clinical decision-making and ensure the delivery of standardized, quality health services to girls and women currently suffering complications of FGM.

Secondly, guidelines serve as an important basis for both pre- and in-service medical training programmes, which are urgently needed not only in countries with a high prevalence of FGM, but also in high-income countries that are home to growing diaspora communities of people who have migrated from regions where FGM is widespread. As a result, health-care providers across the globe, many of whom have received little or no formal education on the issue of FGM, may find themselves ill-prepared to make sensitive enquiries about FGM and to treat and care for girls and women with FGM-related complications *(25)*.

Further, the development of guidelines offers a unique opportunity to systematically review the available evidence in specific areas of interest, and in this way to identify and target critical research gaps that are crucial to expanding our knowledge in any given scientific field.

Lastly, the technical knowledge conveyed within these guidelines on how to recognize and manage complications of FGM makes it clear that the procedure is inherently harmful to the health of girls and women and, what is more, that it is a violation of several human rights, including the human right to the highest attainable standard of health. This is especially relevant with regard to the efforts to stop medicalization, placing the emphasis on the role of health workers as caregivers who must not also become perpetuators of a harmful practice.

1.6.2 Purpose of these guidelines

The main purpose of these guidelines is to provide evidence-informed recommendations on the management of health complications associated with or caused by FGM.

The guidance provided covers selected topics related to FGM that were considered critically important by an international, multidisciplinary group of health-care providers, patient advocates and other stakeholders. These guidelines, therefore, do not include all reported FGM-related health conditions, but this should on no account be taken to indicate that those conditions are not also real or important.

Additionally, these guidelines, and in particular the knowledge gaps it identifies, may be used as a blueprint for the design of research protocols that could further enrich the scarce evidence currently available on the management of health conditions that may arise from FGM.

1.6.3 Target audience

These guidelines are intended primarily for health-care professionals involved in the care of girls and women who have been subjected to any form of FGM. These health-care professionals may include, among others, obstetricians and gynaecologists, surgeons, general medical practitioners, midwives, nurses and other country-specific health cadres. Health-care professionals involved in the provision of mental health care and educational interventions, such as psychiatrists, psychologists and social workers, are also part of the target audience. This document also provides guidance for policy-makers, health managers and others in charge of planning, funding and implementing pre- and in-service professional training, and for those responsible for developing training curricula in the areas of medicine, nursing, midwifery and public health.

2. Methods

This document was developed according to the standards and requirements specified in the *WHO handbook for guideline development, second edition (26)*. In summary, the process included: (i) identification of critical research questions and outcomes; (ii) commission of systematic reviews to experts; (iii) retrieval of evidence; (iv) quality assessment and synthesis of the evidence; (v) presentation of the evidence using a structured approach; and (vi) formulation of recommendations.

2.1 Guideline contributors

The guideline development process was guided by three main groups (a detailed description of their roles is available in Annex 2). The WHO Steering Group, comprising a core group of WHO staff members and consultants from the Adolescents and at-Risk Populations team within the Department of Reproductive Health and Research, led the guideline development process. The Guideline Development Group (GDG), formed of 15 external (non-WHO) international stakeholders, including health-care providers, researchers, health programme managers, human rights lawyers and women's health advocates, advised on the content of the guidelines and formulated the evidence-based recommendations. Finally, an External Review Group (ERG) of relevant international stakeholders reviewed the final guideline document to identify any factual errors and commented on the clarity of the language, contextual issues and implications for implementation.

2.2 Declaration of interests by external contributors

All GDG members and other external contributors were required to complete a standard WHO Declaration of Interest (DOI) form before engaging in the guideline development process and taking part in any of the guideline meetings. Before finalizing experts' invitations to participate in the development of the guidelines, the WHO Steering Group reviewed all the DOI forms using the criteria for assessing the severity of a conflict of interest in the *WHO handbook for guideline development (26)*. None of the meeting participants declared a conflict of interest that was considered significant enough to pose any risk to the guideline development process or to reduce its credibility. A summary of the DOI statements and how conflicts of interest were managed is included in Annex 3.

2.3 Identification of priority research questions and outcomes – scoping exercise

After an initial scoping review of the available literature, the WHO Steering Group identified and drafted a list of potential priority questions and outcomes related to health complications from FGM using the population, intervention, comparator, outcome (PICO) format. This preliminary list was then presented to the GDG during the first guideline development meeting held in Geneva, Switzerland, in February 2015. Based on the outputs of this meeting, an online scoping survey containing the updated list of potential research questions was prepared in order to obtain input. Survey participants were asked to rate the importance of the questions on a scale from 1 to 9 and to provide input on the selection and rating of the outcomes. In this context, questions that scored between 7 and 9 were ranked as "critical", while those with a score between 4 and 6 were considered as "important, but not critical". The questions that scored lower than 4 were not considered to be important for the purposes of these guidelines. A web annex containing the scoping survey and the complete list of questions is available upon request.

The survey was sent out electronically to international experts in the field of FGM nominated by members of the GDG. In an effort to include as many respondents as possible, a public link to the survey, was included on the Department of Reproductive Health and Research website. Provided that all 33 potential questions were ranked either as "critical" or "important, but not critical" by survey respondents, and given that the number of systematic reviews that could be commissioned was limited due to resources, the WHO Steering

Group agreed to include the 11 most highly rated questions in the scope of the guidelines.

Given that the initial search for articles performed by the systematic review team revealed a paucity of robust studies pertaining to almost all relevant research topics, the WHO Steering Group, in conjunction with the systematic review lead investigator and the guideline methodologist (see Annex 2), revised the list of questions in an effort to broaden their scope. Thus, complying with the priority topics selected by survey participants, a number of questions that shared the same intervention were identified and merged into a broader research question that included the common intervention and an expanded list of outcomes. Both the original and prioritized lists of research questions are available upon request.

2.4 Evidence retrieval

A systematic and comprehensive retrieval of evidence was conducted to identify published studies concerning the FGM-related health complications prioritized during the scoping exercise. None of the priority questions could be answered using an existing, recent systematic review (published less than two years prior) of currently available publications. Therefore, to inform the development of the recommendations, 10 new reviews were commissioned from an external team of systematic reviewers from the Nigerian Branch of the South African Cochrane Centre.

A standard protocol was prepared for each systematic review, containing the PICO question and the criteria for identification of studies, including search strategies, methods for assessing risk of bias and the plan for data analysis. The WHO Steering Group and the guideline methodologist reviewed and endorsed the protocols before the team of reviewers carried out each review. To identify relevant studies, systematic searches of several electronic databases were conducted, including MEDLINE, CENTRAL via CSRO, CINHAL Plus (EBSCOhost), Web of Science, SCOPUS, PILOT, African Index Medicus, LILACS, PsycINFO (EBSCOhost), POPLINE, WHOLIS via LILACS, ERIC (EBSCO host), NYAM Library, ClinicalTrials.gov, African Journals Online (AOL) and Pan African Clinical Trials Registry. The search strategies employed to identify the studies and the specific criteria for inclusion and exclusion of studies were reported using the PRISMA Guidelines and flow diagram, and are described in the individual systematic reviews. There were no restrictions on language or publication dates.

2.5 Quality assessment, synthesis and grading of the evidence

The external team of systematic reviewers performed a quality assessment of the body of evidence using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology.[6] Following this approach, the quality of evidence for each outcome was rated as "high", "moderate", "low" or "very low", based on the following set of pre-established criteria: (i) limitations in the study design and execution; (ii) inconsistency of the results; (iii) indirectness; (iv) imprecision; and (v) publication bias *(26)*.

In the final step of the assessment process, GRADE profiler software was used to construct GRADE evidence profiles (or "summary of findings" tables) for each priority research question for which evidence was available; these tables include the assessments and judgements relating to the elements described above and the illustrative comparative risks for each outcome and are available in the Web Annex: GRADE tables.[7]

2.6 Qualitative research and human rights evidence

To obtain evidence on the values and preferences of girls and women living with FGM and health workers who provide health care to this population, four additional systematic reviews of qualitative research were carried out by an external consultant in collaboration with the WHO Steering Group. These reviews focused on the contexts and conditions surrounding:

- medical/surgical interventions
- psychological interventions
- counselling interventions and
- health information interventions.

6 Further information available at: http://www.gradeworkinggroup.org/

7 Available at: http://www.who.int/reproductivehealth/topics/fgm/management-health-complications-fgm/en/

Each of these four qualitative systematic reviews aimed to: (i) understand stakeholder experiences and perceptions of the interventions; (ii) identify and summarize contextual barriers and facilitators to implementation of the interventions; and (iii) explore how the context and conditions of implementation relate to the outcomes reported in the effectiveness reviews.

Given that the provision of health services to women living with FGM should be accomplished with the utmost care and consideration of girls' and women's human rights, two literature reviews were commissioned from an external group of human rights experts to better understand the public health and human rights/gender equality linkages that pertain to FGM. These two reviews sought to identify evidence on: (i) interventions to address and/or promote gender equality and human rights in the context of FGM programmes and policies; and (ii) how specific manifestations of gender inequality and neglect/violations of human rights affect and are affected by FGM.

The evidence obtained from the above-mentioned reviews helped inform the GDG about the values and preferences and human rights and equity issues, which constituted important considerations in deciding on the direction and strength of the issued recommendations.

2.7 Formulation of recommendations

Prior to the second guideline development meeting, which took place in September 2015, the guideline methodologist in conjunction with members of the WHO Steering Group formulated an initial draft statement for each priority question, which served as a blueprint for each of the finalized recommendations and some of the best practice statements. During the September meeting, all draft statements, evidence summaries and corresponding GRADE tables (where evidence was available) were presented to the GDG members. Before issuing a final recommendation or best practice statement, participants discussed the presented evidence and systematically reviewed each proposed draft statement considering a set of established criteria (see Box 2.1).

Box 2.1. Factors considered while formulating each recommendation and best practice statement

Quality of the available evidence
Balance between benefits and harms
Values and preferences of girls and women living with FGM, and of health-care providers
Resource implications
Priority of the addressed health problem
Equity and human rights issues
Acceptability of the proposed intervention
Feasibility of the proposed intervention

Using each draft statement as a starting point, participants could decide to recommend, recommend against, or not make a final recommendation or best practice statement. Additionally, before issuing a final recommendation, the strength of each issued statement was agreed upon. The GDG's use of the different categories for the strength of a recommendation is explained in Annex 4.

Best practice statements were issued when the available direct evidence was of low quality or absent, and the contents of the recommended statement were based on sound practical judgement, in addition to being supported by human rights and equity principles, public health or medical practice, and when they were judged to carry little to no risk of harm to health.

The final adoption of each best practice statement and recommendation – and its strength – was decided by consensus, which was defined as the agreement of all the participants. Unanimous agreement was reached for all but one recommendation. This recommendation was put to vote and stood by simple majority. This situation was recorded as such in the text accompanying the recommendation. WHO staff at the meeting, external technical experts involved in the collection and grading of the evidence, and observers were not eligible to vote.

2.8 Document preparation and peer review

Following the GDG meeting, members of the WHO Steering Group prepared a draft of the full guideline document containing all the recommendations and best practice statements formulated by the GDG as well as the key points of the deliberations and decisions of the meeting participants. The draft guidelines were then sent electronically to all GDG members for further comments before being sent to the External Review Group (ERG) for peer review (for a full list of the ERG members, please see Annex 2). The WHO Steering Group carefully evaluated all the input from the ERG members, which was limited to correction of factual errors and language clarity, and provided responses to each of their comments and then sent these responses back to each external reviewer. No major disagreements arose during this process and no modifications were made to the direction, strength or content of the recommendations.

3. Guidance

During the guideline development meeting in September 2015, the participants adopted three guiding principle statements, five recommendations and eight best practice statements covering health interventions for preventing and treating health risks of FGM.

3.1 Guiding principles

Decades of prevention work undertaken by local communities, governments, and national and international organizations have contributed to a reduction in the prevalence of FGM in some areas *(1)*. However, the overall rate of decline in prevalence of FGM has been slow. Therefore, all recommendations and best practice statements issued in these guidelines are framed by the following three guiding principles that reflect the stance of WHO and a wider group of UN agencies[8] and the Guideline Development Group (GDG) with regard to FGM and the need to end this harmful practice.

I Girls and women living with FGM have experienced a harmful practice and should be provided quality health care.

II All stakeholders – at the community, national, regional and international level – should initiate or continue actions directed towards primary prevention of FGM.

III Medicalization of FGM (i.e. performance of FGM by health-care providers) is never acceptable because this violates medical ethics since (i) FGM is a harmful practice; (ii) medicalization perpetuates FGM; and (iii) the risks of the procedure outweigh any perceived benefit.

3.2 Recommendations and best practice statements

The recommendations contained in these guidelines were issued after consideration of the existing evidence (when available) and its quality, in addition to a series of factors as mentioned in section 2: Methods (see Box 2.1).

In general, the quality of evidence was low across most recommendations and best practice statements, and for a number of topic areas no evidence was available. Despite the low quality or non-existence of the evidence, some interventions were endorsed and labelled as "best practice statements" if they were supported by the GDG's sound practical judgement. These statements were also required to carry little to no risk of harm to health, and be supported by internationally recognized human rights standards and principles.

The justification for each of these decisions was recorded, along with key issues that need to be considered for implementation. The corresponding research gaps identified in each topic area were also included. Where clinical recommendations were based on indirect evidence (i.e. evidence that was not directly from the population of women living with FGM), this was labelled accordingly.

3.2.1 Deinfibulation (recommendations 1–3 and best practice statements 1–2)

Deinfibulation is a minor surgical procedure carried out to re-open the vaginal introitus in women living with type III FGM. In order to achieve this, a trained health professional performs an incision of the midline scar tissue that covers the vaginal introitus until the external urethral meatus, and eventually the clitoris, are visible. The cut edges are then sutured, which allows the introitus to remain open. This procedure is performed to improve health and well-being, as well as to allow intercourse and/or to facilitate childbirth.

8 OHCHR, UNAIDS, UNDP, UNECA, UNESCO, UNFPA, UNHCR, UNICEF, UN Women (formerly UNIFEM). See list of acronyms for full agency names.

Recommendation 1: Deinfibulation is recommended for preventing and treating obstetric complications in women living with type III FGM

Strength of recommendation: Strong (very low-quality evidence)

SUMMARY OF EVIDENCE (SEE WEB ANNEX: GRADE TABLES)

The evidence was extracted from a systematic review investigating the effects of deinfibulation for preventing and treating obstetric complications in women with type III FGM *(27)*. The review included four case–control studies: two conducted in the United Kingdom *(28, 29)* and two in Saudi Arabia *(30, 31)*.

Two studies compared women with type III FGM. One group had deinfibulation during labour and the other laboured and delivered without deinfibulation *(28, 29)*. The studies found better obstetric outcomes among women who underwent deinfibulation during labour, compared with women who remained infibulated. Caesarean section and postpartum haemorrhage rates were statistically significantly lower in women with deinfibulation (very low-quality evidence).

Two studies compared women with type III FGM who underwent deinfibulation during labour to women who had never undergone FGM (therefore, non-infibulated) *(30, 31)*. Both groups had similar rates of episiotomy and duration of second stage of labour. Rouzi et al. (2001) further showed, when comparing women with deinfibulation to women who had not undergone FGM, that their mean amount of blood loss, length of maternal hospital stay (in days), and rates of caesarean section, vaginal lacerations, and newborns' Apgar scores at 1 and 5 minutes were not statistically different (very low-quality evidence).

Additional evidence from a WHO collaborative prospective study carried out in six African countries shows a potentially causal, dose-response risk between increasingly extensive types of FGM and adverse obstetric and neonatal outcomes, with greater risk for adverse reproductive health outcomes with FGM types II and III *(9)*. The evidence further suggests that FGM does not impact fetal development (no association between FGM and birth weight), but has an impact on delivery, with higher rates of fresh stillbirths among women living with FGM *(9)*.

RATIONALE

Considering the potential dose–response relationship described between the types of FGM and the risk of obstetric complications, and based on the clinical benefits described within the evidence reviews, which in addition show that when using women who were never infibulated as controls, performing deinfibulation during vaginal delivery is a management option that does not increase the likelihood of superimposed obstetric complications, the GDG recommended reversing type III FGM through deinfibulation for preventing and treating obstetric complications.

In addition the GDG noted:

Based on the causal relationship between type III FGM (infibulation) and a number of health complications identified by the WHO collaborative prospective study carried out in six African countries *(9)*, deinfibulation can be considered as a surgical procedure that can re-open the narrowed introitus, restoring the anatomy of the pelvic outlet (to the extent possible). This may contribute to a reduction of overall health-care costs by encouraging a trial of labour (rather than using history of FGM alone as the indication for caesarean section), or avoiding severe perineal injury due to spontaneous lacerations or episiotomy performed at the time of delivery. Both caesarean section and repair of third- and fourth-degree lacerations require significantly higher levels of surgical skill and

may themselves have longer-term adverse outcomes resulting in higher health-care costs (e.g. care and management of urinary incontinence due to pelvic floor instability, conditions that may arise as a result of perineal lacerations).

In addition to being medically unnecessary, FGM interferes with healthy genital tissue and can lead to severe consequences for a woman's physical and mental health. Its practice has therefore been considered by international and regional human rights bodies as a violation of a person's right to the highest attainable standard of health. When performed with informed consent, restoring the anatomy and physiology (to the extent possible) through deinfibulation may therefore be seen as a necessary part of upholding a woman's right to health and ensuring access to health-care goods and services needed by women to enjoy the full extent of this right.

IMPLEMENTATION REMARKS

Providers conducting deinfibulation must be adequately trained on how to carry out this surgical procedure. Nonetheless, the relatively simple nature of this surgical procedure would allow for the training of mid-level health workers to perform deinfibulation, with the consequent reduction of the required human and financial resources.

Available qualitative evidence shows that the lack of knowledge among health workers regarding deinfibulation is not only an important reason why providers may avoid performing deinfibulation, even in contexts in which it has been requested, but it also affects women who describe the providers' inexperience as a significant source of fear *(32)*. The GDG therefore noted that adequate health-care provider training is a crucial and urgently needed step in the implementation of this recommendation.

Recommendation 2: Either antepartum or intrapartum deinfibulation is recommended to facilitate childbirth in women living with type III FGM, depending on the context

Strength of recommendation: Conditional (very low-quality evidence)

Given that both antepartum and intrapartum deinfibulation appear to be comparable in terms of obstetric outcomes, the decision about the timing of the procedure should be based on the following contextual factors:

- preference of the woman
- access to health-care facilities
- place of delivery
- health-care provider's skill level.

SUMMARY OF EVIDENCE (SEE WEB ANNEX: GRADE TABLES)

Evidence on the timing of deinfibulation for childbirth in women with type III FGM was extracted from a systematic review investigating the effects of antepartum or intrapartum deinfibulation on the outcomes of childbirth *(33)*. The review included five retrospective, observational studies: two conducted in the United Kingdom *(29, 35)*, two in Saudi Arabia *(30, 31)*, and one in Sweden *(34)*.

The analysis was limited to the two case–control studies *(29, 35)* that directly compared the timing of deinfibulation – antepartum and intrapartum. The findings show that duration of labour, perineal lacerations, postpartum haemorrhage, and rates of episiotomy were not significantly different based on the timing of deinfibulation (very low-quality evidence).

RATIONALE

According to the available evidence, obstetric outcomes appear comparable irrespective of the timing of deinfibulation – antepartum or intrapartum – between women living with type III FGM who are deinfibulated and women who present in labour with no infibulation (low certainty).

Given the above, and due to the paucity of direct evidence on women's preferences regarding the timing of deinfibulation, members of the GDG considered that the decision should be founded on the following contextual factors.

1. Preference of the woman: Women should be consulted on their preferences. For example, if a client places high importance on the postoperative aesthetic results, antepartum deinfibulation should be preferred in order to allow adequate healing time and optimal aesthetic results.
2. Access to health-care facilities: In settings where women may encounter unintended delays while reaching health-care facilities due to difficult access, antepartum deinfibulation should be preferred.
3. Place of delivery: Given that deinfibulation should be carried out by a trained health-care provider, in contexts where home deliveries are common, antepartum deinfibulation should be prioritized. The same applies to settings where the health-care facility has a high patient load.
4. Health-care provider's skill level: Anatomical conditions like tissue oedema and distortion during labour may pose difficulties for less-experienced health-care professionals performing intrapartum deinfibulation. In this case, antepartum deinfibulation should be preferred.

In settings with experienced, well-trained providers, intrapartum deinfibulation is an acceptable procedure.

IMPLEMENTATION REMARKS

The available qualitative evidence suggests a lack of clarity on the responsibility for various tasks along the care continuum among health-care providers caring for women living with FGM *(32)*, which may represent a barrier to identifying women who are in need of deinfibulation to prevent FGM-related obstetric risks. In this regard, the GDG emphasized the importance of establishing a clear referral pathway, in particular for pregnant women living with type III FGM, and encouraged efforts to define the roles and responsibilities of health-care personnel within the client continuum of care from antenatal care to the postpartum period.

Recommendation 3: Deinfibulation is recommended for preventing and treating urologic complications – specifically recurrent urinary tract infections and urinary retention – in girls and women living with type III FGM

The GDG could not reach consensus regarding the strength of this recommendation. Therefore, it was put to the vote: among 12 of the 14 attending GDG members who were eligible and opted to vote on this topic, 11 voted for "strong" while 1 voted for "conditional".[9]

Strength of recommendation: Strong (no direct evidence)

SUMMARY OF EVIDENCE

A systematic review investigating the effects of deinfibulation on the prevention or treatment of recurrent urinary tract infections (UTIs) and urinary retention among women who have undergone type III FGM (infibulation) was carried out to help inform this recommendation *(36)*. The authors found no studies that met the inclusion criteria; therefore direct evidence on the effects of deinfibulation on restoring normal function is at present not available.

RATIONALE

Additional evidence from a systematic review that explored the effects of FGM on physical health outcomes confirms that reduced urinary flow beneath the infibulation scar can result in symptoms of urinary obstruction, which may lead to recurrent UTIs due to stasis of urine, conditions which commonly appear in this population *(6)*.

Based on the above evidence and the clinical experience of medical practitioners within the GDG, the group further emphasized that several urological conditions normally treated with low-complexity medical procedures among women with no FGM (i.e. catheterization for acute urinary retention or prior to elective and/or emergency caesarean section) cannot easily be treated with these same procedures in the presence of type III FGM (infibulation). This may turn health conditions of low complexity into serious, potentially fatal situations that could be averted if deinfibulation was performed in a timely manner. Thus, despite the lack of direct evidence on the effects of deinfibulation on restoring normal function, the GDG relied on expert opinion and recommended deinfibulation for treating urinary conditions among girls and women living with type III FGM. With this recommendation, the GDG aimed to prevent severe negative health outcomes due to complications related to urological conditions in the context of infibulation.

The GDG further endorsed this intervention, based on the fact that FGM violates a series of well-established human rights principles, norms and standards, including the principles of equality and non-discrimination on the basis of sex, the right to life and bodily integrity, the right to the highest attainable standard of health and the right to freedom from torture or cruel, inhuman or degrading treatment or punishment. Therefore, based on the human rights argument addressed in recommendation No. 1, the GDG also highlighted that the restoration of the anatomy and physiology (to the extent possible) through deinfibulation should be seen not only as a treatment for urological health complications, but also as an attempt to reinstate a violated human right, in particular the right to the highest attainable standard of health.

IMPLEMENTATION REMARKS

Providers conducting deinfibulation must be adequately trained on how to carry out this surgical procedure. The training of mid-level health workers to perform deinfibulation represents an acceptable approach that can lower the costs of the intervention and increase access to the procedure.

9 The GDG member who voted for a conditional recommendation did so given the urgent need for robust studies that directly examine deinfibulation for the treatment of urologic conditions in this population.

Best practice statement 1: Girls and women who are candidates for deinfibulation should receive adequate preoperative briefing

Evidence on values and preferences of women who underwent deinfibulation suggests that some women may report initial discomfort with the postoperative appearance of deinfibulated labia *(32)*. Therefore, in addition to obtaining preoperative consent, when counselling women with a history of FGM, health-care personnel should always provide balanced, unbiased counselling on expected benefits and potential risks associated with a procedure in a clear preoperative briefing. In the context of deinfibulation, this briefing should include information regarding the anatomical and physiological changes that can be expected after deinfibulation (i.e. faster micturition, increased vaginal discharge).

Best practice statement 2: Girls and women undergoing deinfibulation should be offered local anaesthesia

As with any other surgical procedure, the GDG noted that irrespective of the timing, deinfibulation should be carried out under local anaesthesia. However, given that local anaesthesia may not be readily available in some low-resource settings, in situations in which deinfibulation may be critical for the progression of labour or in the event of a life-threatening condition, deinfibulation should be carried out regardless of the unavailability of local anaesthesia. For example, this may be done to relieve obstructed second stage of labour to deliver the fetal head, similar to performing an episiotomy.

Research implications

Recognizing the importance of deinfibulation in preventing complications and improving birth outcomes for women with type III FGM, research is needed on how to ameliorate the practice around deinfibulation among different cadres of providers in a range of clinical settings and cultural contexts. Many providers are not well informed about how and when to deinfibulate women, and there are many gaps in evidence on how to improve practice in this regard.

Some specific research gaps identified include the following:

- Research to understand the factors that promote uptake of or act as barriers to deinfibulation is urgently needed, in particular regarding:
  - women's knowledge and acceptance of the deinfibulation procedure
  - male partners' views and knowledge on the surgical procedure
  - content and quality of existing deinfibulation training programmes for health-care providers.
- Additional research is needed regarding urological consequences, not only to understand the risk of urological complications among women with type III FGM, but also to understand the effects of deinfibulation on urologic outcomes, particularly on recurrent UTIs and urinary retention. Establishing whether women with type III FGM are at an increased risk of urological complications can be done through retrospective studies and will be an important step in justifying the need for deinfibulation to reduce urological complications. In addition, evaluating long-term clinical outcomes of women who have undergone deinfibulation will provide much needed evidence on the role of deinfibulation in improving health and reducing urological complications of women with type III FGM.
- There is a need for additional research to determine how to best inform women on deinfibulation options during pregnancy or childbirth, which will inform how to improve uptake of deinfibulation. In particular, research is needed to compare deinfibulation outcomes not only between the ante- and intrapartum periods, but also among different time points within the antepartum phase.

3.2.2 Mental health (recommendation 4 and best practice statement 3)

Girls and women living with FGM are more likely to have a psychiatric diagnosis than women without FGM *(11)*. This has been further detailed in several studies that have documented depression and anxiety disorders including post-traumatic stress disorder (PTSD) among this population, following the FGM procedure *(12, 37–41)*. These data suggest that FGM and its associated health risks are psychological stressors that can lead to a variety of negative psychiatric outcomes, including the above-mentioned conditions.

Recommendation 4: Cognitive behavioural therapy (CBT) should be considered for girls and women living with FGM who are experiencing symptoms consistent with anxiety disorders, depression or post-traumatic stress disorder (PTSD)

Strength of recommendation: Conditional (no direct evidence)

CBT may be considered provided that:

- a psychiatric diagnosis of anxiety disorder, depression or PTSD has been established, and
- it is offered in contexts where individuals are competent (i.e. trained and supervised) to provide the therapies.

In resource-constrained settings, stress management may be the most feasible treatment option *(42)*. Further information available at: http://www.who.int/mental_health/emergencies/mhgap_module_management_stress/en/

SUMMARY OF EVIDENCE

A systematic review investigating the effects of CBT for PTSD, depression or anxiety disorders in girls and women living with FGM was conducted to help inform this recommendation *(43)*. The authors found no studies that met the inclusion criteria and therefore direct evidence could not be used for this recommendation.

RATIONALE

CBT represents an evidence-based treatment that can effectively reduce or resolve symptoms of PTSD, depression and anxiety disorders associated with other conditions, including survivors of torture and war and victims of sexual violence *(44–46)*. Given existing evidence on the beneficial effects of psychological treatment with CBT for these disorders in other populations, the GDG agreed it would be reasonable to assume that this intervention can also benefit girls and women living with FGM. As the indirect evidence refers only to these three psychiatric conditions, the GDG felt a conditional recommendation was warranted and noted that it should apply exclusively to girls and women living with FGM with a confirmed psychiatric diagnosis and be delivered by adequately trained individuals.

From a human rights point of view, the right to the highest attainable standard of health, as recognized under international and regional standards, includes the right to a state of complete physical, mental and social well-being. The right has been interpreted to include:

> [T]he creation of conditions which would assure to all medical service and medical attention in the event of sickness, both physical and mental, including the provision of equal, timely access to basic preventive, curative, rehabilitative health services . . . which would also include appropriate mental health treatment and care *(47)*.

IMPLEMENTATION REMARKS

Regarding the feasibility of this intervention, and in particular the shortage of health-care personnel adequately trained to deliver CBT in most low- and middle-income countries, the GDG recommended consulting the *Assessment and management of conditions specifically related to stress: mhGAP intervention guide module,* which contains a number of interventions for clients presenting with PTSD that can be safely delivered by community health workers, including psycho-education and alternative stress management techniques (e.g. breathing exercises, progressive muscle relaxation) *(42)*. Further information available at: http://www.who.int/mental_health/emergencies/mhgap_module_management_stress/en/

Additionally, the GDG discussed evidence from supplementary studies that support the use of Internet-based CBT (i.e. psychological self-help programmes mediated via the Internet) as an efficacious treatment for individuals with a confirmed primary diagnosis of PTSD *(48)*. Because web-based programmes can be accessed anonymously and anywhere a computer is available, these services have the potential to surmount stigma, as well as geographical and financial barriers to accessing mental health treatment *(49)*, making them a plausible therapeutic option for this population.

Best practice statement 3: Psychological support should be available for girls and women who will receive or have received any surgical intervention to correct health complications of FGM

Available qualitative evidence on values and preferences of girls and women living with FGM from two studies conducted in Gambia and among migrant populations in Norway and the Netherlands shows that women may experience several negative psychological outcomes secondary to the performance of FGM, including anxiety, fear, sense of betrayal, pain and anger *(50)*. This is additionally supported by evidence from a meta-analysis which shows that women living with FGM have a higher risk of having a psychiatric diagnosis compared to women with no FGM *(11)*. The former explains why psychological support interventions may be especially needed among this population, particularly in the context of stressful life events that may remind the client of the initial trauma caused by the FGM procedure, such as surgical procedures to correct FGM-related complications.

There is no direct evidence on the effect of psychological interventions on post-operative outcomes for girls/women undergoing a procedure to manage health complications associated with FGM. As a result, the GDG considered indirect evidence on the effects of psychological interventions on recovery from surgery in other populations, including abdominal and hernia surgeries *(51–52)*. The GDG noted the benefits of psychological support in terms of postoperative pain, recovery and psychological well-being, when offered as an adjunct to surgical procedures.

Supported by the indirect evidence and the fact that psychological support includes activities that range from special programmes to quite simple, inexpensive modifications of – or additions to – required medical procedures, including the provision of procedural information or emotional support, the GDG considered that the intervention should be available to women undergoing surgical procedures to correct complications from FGM.

From a human rights perspective, the GDG strongly emphasized that the right to the highest attainable standard of health includes the right to a state of both complete physical and mental health, together with social well-being *(47)*. This recommendation would therefore stand in accordance with the realization of the right to health of girls and women living with FGM.

POLICY AND PROGRAMMATIC REMARKS

Regarding the human resources needed to provide psychological support in the context of surgical procedures to correct health complications from FGM, the GDG acknowledged that delivering mental health interventions can rely heavily on health personnel rather than on technology or equipment, and that most low- and middle-income countries have insufficient trained and available human resources. In this regard, based on guidance on task shifting from the Mental Health Gap Programme (mhGAP) *(53)*, the GDG suggested that some of the priority interventions can be delivered by community health workers, after specific training and with the necessary supervision. Further information available at: http://www.who.int/mental_health/emergencies/mhgap_module_management_stress/en/ *(42)*.

Research implications

The increased risk of adverse mental health effects from FGM suggests that women with FGM may need additional psychological support in general and when seeking surgical intervention related to complications from FGM. However, there is a need for additional epidemiological research to demonstrate the influence of FGM on specific mental health effects. In addition, there is a need for evidence regarding what type of psychological intervention would be the most helpful to girls and women living with FGM.

Development and testing of the content of psychological support and health education as well as modes of delivery of such interventions are important steps in developing evidence-based best practice. Whether psychological support is provided by lay providers, psychologists or other providers, the content and delivery will vary. Some outcomes that can be assessed through interventions research using experimental or quasi-experimental designs include reduced emotional distress, improved coping mechanisms, improved understanding of anatomy and health risks associated with FGM, as well as understanding the risks and benefits of a surgical procedure to address the health complications of FGM.

In particular, further research is needed to examine the effectiveness of CBT for treating PTSD and depression symptoms among girls and women living with FGM. Specific outcomes that can be measured include reduced PTSD symptomatology, improved functioning, reduced emotional distress and depression.

In addition, more evidence is needed on modes of delivering CBT (i.e. through trained health-care providers or community-health workers or through self-help programmes via the Internet, where appropriate) in order to determine the effectiveness and acceptability of different delivery methods.

3.2.3 Female sexual health (recommendation 5)

The achievement of the highest attainable standard of health also comprises the right to sexual health. Sexual health is widely understood as a state of physical, emotional, mental and social well-being in relation to sexuality and it encompasses not only certain aspects of reproductive health – such as being able to control one's fertility through access to contraception and abortion, and being free from sexually transmitted infections (STIs), sexual dysfunction and sequelae related to sexual violence or FGM – but also the possibility of having pleasurable, safe sexual experiences, free of coercion, discrimination and violence *(54)*.

Recommendation 5: Sexual counselling is recommended for preventing or treating female sexual dysfunction among women living with FGM

Strength of recommendation: Conditional (no direct evidence)

This is conditional because there is a general lack of direct evidence regarding the use of sexual counselling specifically among women living with FGM, and it is anticipated that this topic will be highly sensitive.

SUMMARY OF EVIDENCE

A systematic review investigating the effects of sexual counselling for treating or preventing sexual dysfunction in women living with FGM was conducted to help inform this recommendation *(55)*. The authors found no studies that met the inclusion criteria and therefore direct evidence could not be used.

RATIONALE

Current evidence from a systematic review that looked at the effects of FGM on the sexual functioning of women substantiates the proposition that a woman whose genital tissues have been partly removed is more likely to experience increased pain and reduction in sexual satisfaction and desire *(56)*. In this regard, the GDG underlined that surgery alone – in particular clitoral reconstruction – does not treat all aspects of sexual dysfunction that may occur among women living with FGM *(57)*, and other medical interventions such as the use of genital lubricants have not been extensively studied. What is more, studies show that the use of gels may not be acceptable among women and their partners, depending on personal sexual practices and the degree to which men exercise influence in determining whether and how these products are used *(58)*. Given the above, and in recognition that women's sexuality is multifactorial and depends, among other things, on the interaction of anatomic, cognitive and relational factors, the GDG noted that offering treatment alternatives for sexual dysfunction – in this case sexual counselling – to this population should be seen as a priority.

Based on clinical experience and indirect evidence that supports sexual counselling as an effective treatment for sexual dysfunction in other populations, including patients with breast cancer and cardiovascular disease *(59–62)*, the GDG considered the intervention to be beneficial, provided it is adequately adapted to different countries and cultural contexts. The GDG agreed that in order to avoid unintended adverse effects, like intimate partner violence or social stigma, characteristics such as client's age, marital status and potential inclusion of the male partner must be taken into consideration when offering sexual counselling to women living with FGM.

Additionally, according to General Recommendation No. 24 on Article 12 of the Convention on the Elimination of All Forms of Discrimination against Women (CEDAW), parties should ensure, without prejudice or discrimination, the right to sexual health information, education and services for all girls and women *(63, 64)*. In this regard, offering sexual counselling helps promote the fulfilment of the right of girls and women living with FGM to a healthy sexual life.

Research implications

Establishing whether FGM increases risks of pain during intercourse and other forms of sexual dysfunction is an important step in developing interventions. In addition, more research is needed to investigate the efficacy of sexual counselling interventions in treating sexual dysfunction among women living with FGM.

Studies are needed on the efficacy of available surgical and non-surgical treatment options for girls and women with FGM experiencing both acute and chronic vulvar and clitoral pain (see also section 3.3.1).

In addition, there is a need for research to assess the efficacy of sexual therapy independent of and in conjunction with clitoral reconstruction in improving sexual health among women living with FGM.

3.2.4 Information and education (best practice statements 4–8)

Best practice statement 4: Information, education and communication (IEC) interventions regarding FGM and women's health should be provided to girls and women living with any type of FGM

WHO defines IEC interventions as "a public health approach aiming at changing or reinforcing health-related behaviours in a target audience, concerning a specific problem and within a pre-defined period of time, through communication methods and principles" *(65)*.

In this regard, a recent systematic review that included five studies conducted in African countries *(66)* investigated the effects of providing information and education interventions involving FGM and health-related topics to girls and women living with any type of FGM (see Web Annex: GRADE tables). The review concluded that IEC interventions appear to have positive effects on girls and women living with FGM and other community members by reducing:

- the willingness of women to recommend FGM for their daughters;
- the shyness among women to discuss FGM; and
- new cases of FGM among girls aged 5–10 years, two years after women and men attended educational sessions.

This systematic review identified a number of IEC interventions that were carried out within communities with high prevalence of FGM such as:

- participatory educational modules on women's health, basic hygiene, problem-solving and human rights issues *(67–70)*;
- targeted advocacy against FGM *(67, 71)*;
- mass media campaigns to stimulate and publicize dialogue around FGM and its associated harmful effects *(67, 71)*; and
- community-based initiatives to mobilize groups to create public declarations against FGM *(68)*.

It was noted, however, that programmes that empower women, particularly adolescent girls and young women, by encouraging them to learn about their bodies and to exercise their rights, remain extremely rare *(72)*. According to UN estimates, the vast majority of adolescents and young people lack access to information and education about their bodies and about the negative consequences associated with FGM *(73)*.

Therefore, supported by the evidence and the fact that the provision of education and information to girls and women is in line with international human rights, norms and standards and constitutes an

important measure for reducing inequalities, the GDG agreed that this type of educational intervention should be encouraged and further developed in countries where FGM is either practised or present. The GDG noted that although specific IEC interventions cannot be recommended at present, due to the paucity of evidence, this should constitute an important research priority.

However, the GDG emphasized the importance of ensuring adequate content of the IEC interventions in order to avoid unintended adverse effects, such as recreating trauma, particularly among girls and women diagnosed with PTSD.

Therefore, educational interventions should be:

- evidence-informed and scientifically accurate
- non-prejudicial
- non-judgemental
- sensitive and respectful
- non-stereotypical
- based on adolescents' evolving capacities (when provided to this group).

POLICY AND PROGRAMMATIC REMARKS

The GDG noted that well-designed, effective IEC programmes can be resource-intensive, mainly due to the human resources required to implement them and the time required for effective knowledge shifting to occur. Although these associated costs will vary depending on the nature of the intervention, ways of lowering expenditures should be sought during the design of such programmes. This may include adapting existing programmes to local contexts and using innovations, including digital health strategies, for example.

Best practice statement 5: Health education and information on deinfibulation should be provided to girls and women living with type III FGM

Health education is the provision of accurate and truthful information so that a person can become knowledgeable about a subject and make an informed decision *(74)*. In the case of deinfibulation for girls and women living with type III FGM, health education aims to provide scientific, non-coercive information to help clients understand the surgical procedure, its benefits and also its potential associated complications.

Health education on deinfibulation should contain the following:

- a description of the surgical procedure;
- health benefits of deinfibulation;
- potential immediate and long-term adverse surgical outcomes;
- anatomical and physiological changes clients may experience after the procedure;
- information on adequate postoperative care; and
- information about the health consequences of re-infibulation and the benefits of not re-infibulating.

The GDG emphasized that providing health education and information on deinfibulation to women

living with FGM may serve two purposes. Firstly, to guarantee the client's principle of autonomy, expressed through free, full and informed decision-making, which is a central theme in medical ethics, and is embodied in human rights law. Respecting autonomy in decision-making requires that any counselling, advice or information provided by health workers or other support staff be non-directive, enabling individuals to make decisions that are best for themselves *(63)*.

Secondly, informing girls and women about the health effects of deinfibulation and also the implications of re-infibulation may contribute to reducing the requests for re-infibulation, a procedure that has been increasingly banned in several countries. This was supported by available evidence extracted from a systematic review investigating the impact of counselling before deinfibulation on client satisfaction and the rate of requests for re-infibulation among women with type III FGM *(75)* (see Web Annex: GRADE tables). The only study meeting the inclusion criteria was an abstract from a prospective case–control study *(76)*. This study reported reduced rates of requests for re-infibulation among women with type III FGM post-delivery after receiving antenatal counselling prior to deinfibulation, although these results did not reach statistical significance (very low-quality evidence).

POLICY AND PROGRAMMATIC REMARKS

Available qualitative evidence indicates that the fact that women may delay seeking care and may be ashamed to publicly discuss problems related to FGM represents a potentially important barrier to the intervention *(77)*. Consequently, the GDG emphasized the importance of developing strategies for reaching out to this population, in addition to designing health education programmes that are easily accessible and provide a welcoming environment.

Best practice statement 6: Health-care providers have the responsibility to convey accurate and clear information, using language and methods that can be readily understood by clients

Individuals have the right to be fully informed by appropriately trained personnel *(63)*. This signifies that health-care providers have the responsibility to convey accurate, clear information, using language and methods that can be readily understood by the client (e.g. with the assistance of an interpreter if necessary) together with proper, non-coercive counselling, in order to facilitate full, free and informed decision-making *(78)*.

Best practice statement 7: Information regarding different types of FGM and the associated respective immediate and long-term health risks should be provided to health-care providers who care for girls and women living with FGM

Caring for girls and women living with FGM requires knowledgeable health-care providers, adequately trained to identify, treat or refer clients who may present with a range of health complications due to different types of FGM. Although evident, this requirement is in many cases not fulfilled, as expressed by the available qualitative evidence discussed by the GDG.

Evidence from a knowledge, attitudes and practices (KAP) study on FGM carried out among Flemish midwives *(79)* and a systematic review on context and conditions surrounding health information interventions on FGM highlighted the emotional distress experienced by health-care professionals caring for women with FGM, mainly due to lack of provider training and skills to manage the care of these clients *(80)*. Providers also mentioned a feeling of low competence in handling discussions about

FGM with women, and openly indicated their need for more information on the subject. Consequently, women report experiences of poor communications with health workers, which are exacerbated by their own feelings of shyness while discussing FGM. These studies therefore indicate that both providers and clients need informational interventions and that the provision of knowledge may offer mutual benefits for both client and provider.

In addition, the GDG discussed available evidence extracted from a systematic review investigating the effects of providing information about the consequences of FGM to health-care providers caring for girls and women living with FGM *(81)* (see Web Annex: GRADE tables). The only study that could be included was a controlled before-and-after study conducted in Mali that reported statistically significant improvement of providers' ability to name any type of FGM after attending training sessions that involved the provision of information on female anatomy, FGM and the prevalence of FGM in Mali and other regions *(82)*. A positive trend was observed with regard to the effects of the training on health-care providers' knowledge about immediate and long-term risks of FGM, although these results did not reach statistical significance (very low-quality evidence).

The GDG concluded that improving health-care providers' abilities to correctly identify and record the different types of FGM, in addition to adequately recognizing the associated health complications, constitutes a fundamental step towards improving the quality of health care, with the additional benefit of strengthening the capacity of monitoring FGM.

POLICY AND PROGRAMMATIC REMARKS

The GDG stressed that regular, ongoing capacity-building programmes on FGM should be seen as a priority for health personnel, both in high-FGM-prevalence countries and countries that are home to diaspora communities affected by FGM. Unfortunately, despite a few encouraging examples in some African countries *(83, 84)*, FGM is rarely covered in detail in the training curricula of nurses, midwives, doctors and other health-care professionals. The GDG suggested this best practice statement could serve as a cornerstone for the development of core curricula for both academic and in-service training in an effort to fill gaps in professional education.

Finally, in order to lower the possible costs associated with the intervention, as for best practice statement No. 4, the GDG encouraged considering the adaptation of existing programmes to local contexts and the use of emerging innovations, including digital health strategies, for example.

Best practice statement 8: Information about FGM delivered to health workers should clearly convey the message that medicalization is unacceptable

The GDG expressed concern about increased medicalization being a potential unintended effect of providing information about FGM to health workers. To avoid this, all provided information should:

- specifically address medicalization and its risks;
- contain scientifically accurate and evidence-based content;
- also target non-medical staff, who in certain settings perform some health-care tasks; and
- be delivered in local languages (i.e. proper translations) in order to ensure adequate comprehension.

Research implications

There is a need for more rigorous evaluation of training and education interventions aimed at clients and providers.

For example, while there are several promising community-based IEC interventions aimed at improving knowledge, changing norms and reducing FGM, the lack of rigorous evaluations of the effectiveness, acceptability and sustainability of these interventions has resulted in a knowledge gap. Evidence is needed on whether a particular programme or approach has achieved its intended outcomes before it can be recommended or scaled up. Incorporating an evaluation component into existing programmes and/or testing community-based interventions through experimental or quasi-experimental research designs is an important step in designing evidence-based IEC programmes to reduce FGM in communities with a high prevalence of FGM.

In addition, training and education aimed at providers should assess how to improve providers' knowledge about types of FGM and health consequences, their attitudes regarding FGM, and their manner of interacting with clients.

Further, more rigorous evaluations are needed on how education interventions aimed at health-care providers impact clients' experiences and their interactions with providers. This can be done by assessing client satisfaction during an evaluation or through more experimental research designs in which client outcomes are compared among those treated by providers who received specialized training and those who did not.

Health education surrounding surgical intervention is a necessary component in informed care, but evidence on outcomes of these health education sessions is crucial for improving the content and delivery of these health education interventions for clients. In particular, two key outcomes were identified as research priorities by the GDG – client satisfaction and the rate of requests for re-infibulation. Additional outcome measures that can be explored include impact of health education interventions on women's knowledge about anatomy, health effects of FGM, and health benefits of deinfibulation. There is also a need for evidence on how male partner involvement in the health education process can impact women's satisfaction with services, and their rate of requests for re-infibulation.

3.3 Interventions for which no recommendations were issued

In addition to the topics covered by the recommendations and best practice statements issued and included in these guidelines, the GDG discussed the results of two additional systematic reviews during the guideline development meeting. These reviews investigated the effects of surgical and non-surgical interventions for the treatment of vulvar pain (vulvodynia) and clitoral pain, and the safety and efficacy of clitoral reconstruction in girls and women girls living with FGM.

Due to lack of evidence (in the case of interventions for treating vulvodynia and clitoral pain) and safety concerns (in the case of clitoral reconstruction), the GDG decided not to issue any recommendations regarding these interventions at present and strongly encouraged further research in these areas.

Nonetheless, in recognition of the clinical importance of vulvodynia and clitoral pain and the increasing interest and advertisement for clitoral reconstruction as a strategy to restore sexual pleasure and female identity, the GDG considered it relevant to include a brief discussion of both topics within these guidelines, as provided in this section.

3.3.1 What are the treatment alternatives for vulvodynia and clitoral pain in girls and women with any type of FGM?

A systematic review investigating the effects of surgical and non-surgical interventions for the treatment of vulvodynia and clitoral pain in girls and women living with FGM was presented to help inform this discussion. The authors found no studies that met the inclusion criteria therefore direct evidence was not available.

Given the current lack of direct evidence in this topic, the GDG agreed that vulvodynia and clitoral pain should be alleviated based on clinical judgement and client preferences. Some available treatment alternatives include:

- use of water-soluble lubricants during sexual intercourse
- easing pressure on the vulvar area (i.e. avoid activities like bicycling)
- local anaesthetics (i.e. lidocaine gel).

In addition, the GDG emphasized that several potential adverse events are associated with surgical interventions (i.e. pain, additional scarring and bleeding) and stated that unless a clear direct cause for pain (e.g. scar tissue, clitoral neuroma, abscess, cyst) is identifiable, surgical procedures should be avoided.

In the case of asymptomatic women living with FGM who request surgery, the GDG expressed strong reservations about performing any kind of surgical intervention and agreed that in situations where interventions are performed on the basis of clinical judgement, the management of these cases should always start with the least invasive procedure available.

3.3.2 What is the role of clitoral reconstruction?

The GDG discussed available evidence from a systematic review that examined the safety and efficacy of clitoral reconstruction in women who had undergone FGM *(57)*.

The evidence for all measured outcomes was rated as being of very low quality; all studies presented serious risk of bias due to participant selection, high loss to follow-up and the use of non-validated scales for assessing clitoral function (see Web Annex: GRADE tables).

One case–control study carried out in Egypt reported improved sexual function at six months after surgery *(85)*, and three additional prospective cohort studies carried out in France and Burkina Faso described slight or real improvement in clitoral pleasure postoperatively *(86–88)*. None of the above-mentioned studies used validated scales for measuring the described outcomes. One study showed at least slight improvement in chronic vulvar pain symptoms and dyspareunia among women at one year of follow-up *(87)*.

Three studies reported complication rates that fluctuated between 5.3% and 23.6% *(86–88)*. These complications included postoperative readmission rates up to 5.3% and reoperation rates between 3.7% and 4.2%. One study reported reduced clitoral response in 12 out of 53 women who had experienced regular orgasms preoperatively *(87)*.

The available evidence shows that reconstructive clitoral surgery may improve chronic clitoral pain as well as dyspareunia symptoms among women who have had clitoral tissue excised or damaged due to FGM. While these results may appear promising, the GDG expressed considerable apprehension regarding the methodological limitations of the included studies, in particular the large or unknown loss to follow-up and the use of non-validated scales for measuring clitoral function, in addition to the unacceptably high rates of reported complications. The GDG also stated concern regarding the possibility of further damage to neighbouring structures such as the urethra and the clitoral neurovascular bundle, with the consequent deterioration of clitoral function as reported in two of the included studies.

The GDG further cautioned that endorsing clitoral reconstruction in the absence of conclusive evidence of benefit could lead to the exploitation of expectations that cannot be met for many women living with the consequences of this harmful practice, who in recent years have increasingly taken interest in the procedure as a potential means of improving their sexual well-being. It was also noted that a recommendation in favour of this procedure could not be implemented equitably because the procedure is not yet available in the majority of countries with a high prevalence of FGM.

4. Dissemination and implementation

The dissemination and implementation of these guidelines are crucial steps for improving the quality of health care and health outcomes for girls and women living with FGM. The WHO Department of Reproductive Health and Research has adopted a formal "Knowledge-to-Action" (KTA) framework for the dissemination, adaptation and implementation of guidelines.[10] In addition to this KTA framework, the actions described in this section will further facilitate these processes.

4.1 Dissemination of the guidelines

The recommendations and best practice statements contained in these guidelines will be translated into Arabic and French and disseminated with the cooperation of a broad network of international partners, including: WHO country and regional offices; ministries of health; WHO collaborating centres; professional associations; other UN agencies, particularly the United Nations Population Fund (UNFPA) and the United Nations Children's Fund (UNICEF); and NGOs. They will also be available on the WHO website[11] and in the WHO Reproductive Health Library (RHL).[12] In addition, an executive summary aimed at clinicians and a wide range of policy-makers and programme managers will be developed and disseminated through WHO country offices and their respective partners, focusing particularly on countries with high prevalence of FGM.

A series of systematic reviews, which were the result of the scoping exercise carried out in preparation for the development of these guidelines, will be published in a peer-reviewed journal. Lastly, a package of practical tools – including a clinical handbook, job aids and training curricula for health-care providers, and health policy and health systems strengthening tools – will be developed based on the recommendations and best practice statements contained in these guidelines.

4.2 Implementation of the guidelines

The successful introduction into national programmes and health-care services of evidence-based policies related to interventions to improve health outcomes among girls and women living with FGM relies on well-planned and participatory, consensus-driven processes of adaptation and implementation. These may include the development of new national guidelines or adaptation of existing national guidelines or protocols using these WHO guidelines as a reference.

The recommendations and best practice statements contained in these guidelines should be adapted into locally appropriate documents that can meet the needs of each country and its health services, while taking the availability of human and financial resources into account; this should include national policy as well as local clinical guidance. In this context, modifications may be limited to conditional recommendations, and justification for any changes should be made in an explicit and transparent manner.

An important requisite for the implementation of the recommendations and best practice statements contained in this document is the creation of an enabling environment for their use (i.e. availability of medical supplies and a private area for talking with clients while providing psychological support), paired with adequate training of health-care practitioners and managers to enable the use of evidence-based practices. In this process, the role of local professional societies is also important, and an inclusive and participatory process should be encouraged.

10 Further information on the KTA Framework is available at: http://www.who.int/reproductivehealth/topics/best_practices/greatproject_KTAframework/en/

11 These guidelines, including all language versions and web annexes, will be available at: http://www.who.int/reproductivehealth/topics/fgm/management-health-complications-fgm/en/

12 RHL is available at: http://apps.who.int/rhl/en/

4.3 Monitoring and evaluating the impact of the guidelines

Ideally, implementation of the recommendations and best practice statements contained in these guidelines should be monitored at a health-care facility level. Interrupted time-series of clinical audits or criterion-based clinical audits could be used to obtain data related to changes in the care that is given to girls and women who experience health complications from FGM. Clearly defined review criteria and monitoring and evaluation indicators are needed and could be associated with locally agreed targets. Final selection of indicators in each country context should consider measurability and feasibility. The following list includes several suggested indicators:

- the number of countries establishing primary care guidelines on management of health complications from FGM, and changes in national and health-care guidelines in accordance with WHO guidelines;
- the proportion of health-care providers trained:
  - to identify the different types of FGM
  - to know the prevalence and health risks of the procedure
  - to prevent and manage complications of FGM;
- the proportion of health-care facilities that have carried out an institution-wide assessment of all policies, protocols and practices that impact girls and women living with FGM, including adequate referral pathways, human resources, training provided to health workers, and available written policies and protocols distributed to decrease medicalization of the practice and to prevent and manage complications among girls and women who have undergone FGM;
- the proportion of women living with type III FGM who received deinfibulation before or during childbirth;
- the proportion of women living with type III FGM who requested re-infibulation after being deinfibulated to facilitate childbirth;
- the proportion of health-care providers who perform any form of FGM, including re-infibulation;
- the proportion of women living with FGM who were provided with information about the health risks associated with the practice; and
- the number of medical and allied health faculties that implemented undergraduate and postgraduate training on FGM, including identification of types of FGM, health risks associated with it, prevention and management of health complications from FGM, and the risks associated with the medicalization of the practice.

4.4 Updating the guidelines

These guidelines will be updated following the identification of new evidence that indicates a need to change one or more of the recommendations. Given that the evidence for all recommendations was either of low quality or non-existent, new recommendations or a change in the published recommendations may be warranted before the end of the usual five-year period. The WHO Steering Group will continue to follow the research developments in the field of FGM, particularly in the areas that were identified as research priorities during the retrieval and examination of evidence for these guidelines.

WHO welcomes suggestions regarding additional topics for inclusion in the updated guidelines. Please send your suggestions by email to: rhr_monitoring_eval@who.int

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Annex 1: International and regional human rights treaties and consensus documents providing protection and containing safeguards against female genital mutilation

International treaties

Universal Declaration of Human Rights, adopted 10 December 1948. General Assembly Resolution 217. UN Doc. A/810. http://www.un.org/en/universal-declaration-human-rights/

Convention relating to the Status of Refugees, adopted 28 July 1951 (entry into force, 22 April 1954). http://www.unhcr.org/pages/49da0e466.html

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International Covenant on Economic, Social and Cultural Rights, adopted 16 December 1966 (entry into force, 3 January 1976). http://www.ohchr.org/EN/ProfessionalInterest/Pages/CESCR.aspx

Convention on the Elimination of all Forms of Discrimination against Women, adopted 18 December 1979 (entry into force, 3 September 1981). http://www.un.org/womenwatch/daw/cedaw/text/econvention.htm

Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment, adopted and opened for signature, ratification and accession by General Assembly resolution 39/46 of 10 December 1984 (entry into force, 26 June 1987). http://www.ohchr.org/EN/ProfessionalInterest/Pages/CAT.aspx

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Annex 2: Guideline contributors

The guideline development process was guided by three main groups:

WHO Steering Group

The WHO Steering Group, comprising a core group of WHO staff members and consultants from the Adolescents and at-Risk Populations team of the Department of Reproductive Health and Research, led the guideline development process. The group was in charge of the scoping review for the guidelines, drafting the PICO questions (population, intervention, comparator, outcome), and overseeing the evidence retrieval and writing of the guidelines. The Steering Group was also in charge of selecting the members of the collaborating groups, and organizing the guideline development meetings. The members of the Steering Group are presented on the next pages of this annex.

Guideline Development Group (GDG)

The WHO Steering Group invited 15 external international stakeholders to form the GDG, including health-care providers, researchers, health-care programme managers, human rights lawyers and women's health advocates. This was a diverse and gender-balanced group, who advised on the contents of the guidelines, helped define the research questions and outcomes that guided the evidence synthesis, collaborated on the interpretation of the evidence, and formulated the evidence-based recommendations. The members of the GDG are presented on the following pages of this annex.

External Review Group (ERG)

This group included three technical experts and other stakeholders with an interest in the health of girls and women living with FGM. The ERG was geographically balanced and gender representative, and no member declared a conflict of interest. The group reviewed the final guidelines document to identify any factual errors and commented on the clarity of the language, contextual issues and implications for implementation. The group also ensured that the guideline decision-making processes had incorporated contextual values and the preferences of potential users of the recommendations, health-care professionals and policy-makers. It was not within the group's remit to change the recommendations formulated by the GDG. The members of the ERG are presented on the next pages of this annex.

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Annex 3: Summary of declared interests from Guideline Development Group (GDG) members and how they were managed

Name and expertise contributed to guideline development	Declared interest(s)	Management of conflict(s) of interest
Dr Jasmine Abdulcadir Role: Content expert and end-user	None declared	Not applicable
Ms Joya Banerjee Role: Gender expert	None declared	Not applicable
Dr Owolabi Bjalkander Role: Content expert and end-user	None declared	Not applicable
Dr Susana Fried Role: Human rights expert	None declared	Not applicable
Professor Adriana Kaplan Marcusán Role: Content expert and end-user	None declared	Not applicable
Professor Joseph Karanja Role: Content expert and end-user	None declared	Not applicable
Professor Caitlin Kennedy Role: Methodologist	None declared	Not applicable
Dr Morissanda Kouyaté Role: Consumer representative	None declared	Not applicable
Professor Els Leye Role: Content expert and end-user	i. Her institution has received grants for research. ii. She was a member of the FGM risk estimations in the European Union (EU).	The conflict was not considered serious enough to affect GDG membership
Professor Martin M. Meremikwu Role: Content expert and end-user	None declared	Not applicable
Dr Nawal Nour Role: Content expert and end-user	None declared	Not applicable
Professor Olayinka Olusola Omigbodun Role: Content expert and end-user	None declared	Not applicable
Professor Gamal Serour Role: Content expert and end-user	None declared	Not applicable
Professor Moustapha Toure Role: Content expert and end-user	None declared	Not applicable
Dr Ingela Wiklund Role: Content expert and end-user	None declared	Not applicable

Annex 4: Factors considered while rating the quality of the evidence

Each recommendation contained in these guidelines encompasses a direction (in favour or against) and, as discussed in this annex, the degree of strength: strong or conditional.

The Guideline Development Group (GDG) used the following different categories for the strength of a recommendation:[15]

Strong recommendations mean the GDG is confident that the desirable effects of adherence to a recommendation outweigh the undesirable effects.

Conditional recommendations mean the GDG concludes that the desirable effects of adherence to a recommendation probably outweigh the undesirable effects, but is not confident of that conclusion.

Implications of a strong recommendation:

For clients – Most people in this situation would want the recommended course of action and only a small proportion would not.

For clinicians – Most clients should receive the recommended course of action.

For policy-makers – The recommendation can be adopted as a policy in most situations.

Implications of a conditional recommendation:

For clients – Most people in this situation would want the recommended course of action, but many would not.

For clinicians – Different choices will be appropriate for different clients, who will require assistance in arriving at a management decision consistent with their values and preferences.

For policy-makers – Policy-making will require substantial debate and involvement of many stakeholders.

15 WHO handbook for guideline development, 2nd ed. Geneva: World Health Organization; 2014 (http://www.who.int/kms/handbook_2nd_ed.pdf).

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