

# Category: Clinical Guidance Statement C-Gyn 1 Female Genital Mutilation/Cutting (FGM/C)

This statement has been developed by the C-Gyn 1 Female Genital Mutilation-Cutting (FGM/C) Statement Development Panel (SDP) and approved by the Women's Health Committee (WHC) and associated working groups, RANZCOG Council and Board (**Appendix A**), **Appendix B**). Conflict of Interest disclosures have been received from all members of this committee (**Appendix C**)

Disclaimer: This information is intended to provide general advice to practitioners. This information should not be relied on as a substitute for proper assessment with respect to the particular circumstances of each case and the needs of any patient. This document reflects emerging clinical and scientific advances as of the date issued and is subject to change. The document has been prepared having regard to general circumstances (Appendix D).

Objectives:	To provide clinical advice which supports the provision of culturally competent <sup>i</sup> healthcare to women (including adolescent girls) <sup>ii</sup> impacted by FGM/C.
Target audience:	This statement was developed primarily for use by registered health
	professionals and women''' who have experienced FGM/C.
	See: RANZCOG's Interim statement on gendered language (below)
Background:	The statement was first published in March 1994 and reviewed in July 2010 and November 2017 respectively. The most recent update to this statement following updated evidence-based processes, was approved by the WHC in March 2023 (Appendix C). The next review of this statement will be due in March 2028.
Funding:	The development and review of this statement was funded by RANZCOG.

<sup>&</sup>lt;sup>i</sup> For the purposes of this Clinical Guidance Statement, RANZCOG defines 'cultural competency as 'a reciprocal relationship between service provision and the meeting of cultural needs... occurring at an organisational, systemic and individual level'. <u>See RANZCOG Statement on Cultural Competency (WPI-20)</u>.

<sup>&</sup>lt;sup>ii</sup> The content in this Clinical Guidance Statement may apply to both adult women and adolescent girls. The statement will refer to women (including adolescent girls) hereinafter as 'women'.

<sup>&</sup>lt;sup>iii</sup> RANZCOG currently uses the term 'woman' in its documents to include all individuals needing obstetric and gynaecological healthcare, regardless of their gender identity. The College is firmly committed to inclusion of all individuals needing O&G care, as well as all its members providing care, regardless of their gender identity.

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# 1. Plain language summary

FGM/C refers to the partial or full removal of external female genitalia or other injury to the female genital organs for non-medical reasons.<sup>1</sup> FGM/C has no health benefits, results in harm and is a violation of the human rights of women and girls. As a result, it is against the law to perform FGM/C in Australia and Aotearoa New Zealand.

This statement provides registered health professionals and women with updated, evidence-based recommendations on the management of FGM/C during pregnancy and where short and long-term health impacts occur for women who are not pregnant and living with FGM/C in Australia and Aotearoa New Zealand.

# 2. Purpose and scope

In 2022, RANZCOG established a Statement Development Panel (SDP) to update an existing statement on FGM/C. The SDP determined the scope of this Clinical Guidance Statement would include women who are not pregnant, who are pregnant and who are in labour. Raising awareness, advocacy and prevention of FGM/C practices were deemed out of scope for this statement.

The methodology used to develop this Clinical Guidance Statement is detailed in Methods.

# 3. Terminology

There are four types of FGM/C:

- Type I Partial or total removal of the clitoris (clitoridectomy) and/or the prepuce
- **Type II** Partial or total removal of the clitoris and the labia minora, with or without excision of the labia majora (excision)

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

The following terms are used throughout this Clinical Guidance Statement and their definitions are provided below.<sup>1</sup>

- **Infibulation:** The 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:** 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 a midline incision across the scar tissue that covers the vaginal introitus until the external urethral meatus, and eventually the clitoris, are visible. The cut edges are then sutured apart, which allows the introitus to remain open.
- **Reinfibulation:** A procedure done to narrow the vaginal opening after deinfibulation.

The terminology used in this statement is relevant to the clinical care and management of FGM/C. The language was approved by the SDP and does not reflect all terminology used to refer to FGM/C. Women may use other terms in reference to FGM/C and it is important for clinicians to be aware of this. An extensive list of terms by country and language can be found in the following report, published by Family Planning Victoria-Improving the health care of women and girls affected by female genital mutilation/cutting- A national approach to service coordination (2014).

# Advice about language

## Language

It is important for clinicians to use appropriate language when providing clinical care to women who have experienced FGM/C. The following resource may be helpful:

- Female Genital Mutilation, South Australia Maternal, Neonatal & Gynaecology Community of Practice 2018. See pp. 9-10- <u>Sensitive language and history taking</u>.
- NETFA Best Practice Guide for Working with Communities Affected by FGM/C, Multicultural Centre for Women's Health (MCWH). See pp. 6- <u>Why words matter: a note on terminology</u>.

# 4. Executive summary

The Clinical Guidance Statement covers the management of FGM/C experienced by women who are not pregnant, women who are pregnant and women who are in labour. In particular, it provides evidence-based recommendations concerning Type III FGM/C, in addition to several Good Practice Points with respect to coordinated care of women impacted by all types of FGM/C and associated short and long-term health issues.

It is a serious crime in Australia and Aotearoa New Zealand to perform FGM/C. This includes but is not limited to cutting or removing genital tissue without clinical need. It is also illegal to facilitate FGM/C (i.e., taking a female child/adolescent or woman overseas for the purpose of having FGM/C undertaken). For healthcare professionals, reinfibulation (by request of the woman and/or family members) after a deinfibulation procedure has been performed is against the law.

# List of recommendations

Recommendation 1	Evidence based recommendation
Weak/Conditional	
Women who are pregnant with	Гуре III FGM/C may be offered deinfibulation during pregnancy to improve
obstetric outcomes, including re	duced rates of caesarean section and postpartum haemorrhage (PPH).
Recommendation 2	Evidence based recommendation
Weak/Conditional	
Women who are pregnant with	-GM/C Type III may be offered either antenatal or intrapartum
deinfibulation. The choice of pro	cedure timing may depend on additional factors such as a woman's
preference, geographic location,	intended place of birth and clinician experience.
Good Practice Point 1	
Consideration should be given to	establishing centres of expertise in caring for women with FGM/C by
providing multidisciplinary, cultu	rally appropriate, and trauma-informed care.
Good Practice Point 2	
Deinfibulation may be offered to	women living with Type III FGM/C, particularly to those affected by health
complications of FGM/C, such as	dysuria, recurrent UTIs or dyspareunia.
Good Practice Point 3	
Discussion of the benefits and ris	sks of deinfibulation should include information regarding the anatomical,
physiological, and cosmetic char	ges that can be expected after the procedure (i.e., expected labial
appearance, faster micturition, i	ncreased vaginal discharge).
Women with FGM/C should be a	ppropriately informed about the risks of clitoral reconstruction and the lack
of strong evidence regarding pol	ential denetits.

# 5. Introduction

# Rationale

There are many health impacts from FGM/C. Haemorrhage, pain, shock, genital tissue swelling, traumarelated injuries from resistance may occur immediately following the procedure. Longer term gynaecological outcomes may include genital tissue damage (resulting in chronic vulvar and clitoral pain); vaginal discharge and itching; menstrual problems including dysmenorrhea; genital tract infections (i.e., bacterial vaginosis (BV); painful urination; sexual pain and decreased sexual satisfaction, desire, and arousal; decreased lubrication and anorgasmia. Longer term obstetric outcomes may include increased risk of needing episiotomy and caesarean section; PPH; obstetric tears/lacerations; risks of difficult labour and dystocia; risks of stillbirth and early neonatal death. Long-term psychological side effects are also noted, including PTSD, anxiety disorders and depression and social consequences such as experiences of stigma and social isolation.

A 2012 survey of 396 RANZCOG Fellows, Diplomates and Trainees reported that 75% of respondents had seen up to five women who had an FGM/C procedure in the preceding five years.<sup>2</sup> Reinfibulation, also known as resuturing, is an illegal practice in both Australia and Aotearoa New Zealand, however the same survey found 21% of respondents had been asked to re-suture the labia following childbirth.<sup>2</sup>

## Background epidemiology

Approximately 200 million women of reproductive age have experienced FGM/C across 30 countries in 3 WHO regions (Africa, Middle East and Asia), with a prevalence of 37% in women and 8% among adolescent girls.<sup>3</sup> FGM/C is an illegal practice in all states and territories of Australia and in Aotearoa New Zealand. However, it is estimated that 53,000 women born elsewhere but living in Australia in 2017 had undergone

FGM/C during their lifetime—a rate of 4.3 per 1,000 girls and women in Australia, or 0.4% of Australia's overall female population.<sup>4</sup>

# 6. Methods

The statement was developed according to approved RANZCOG processes, available in the <u>Manual for</u> <u>Developing and Updating Clinical Guidance Statements</u>.

Following these processes, the Research and Policy Team conducted an initial search for relevant guidelines published within three years. The WHO Guideline on the Management of Health Complications from Female Genital Mutilation (2016) and the systematic review commissioned to inform the guideline were identified as most recent.

The search terms used to retrieve publications in the WHO commissioned systematic review were then applied to undertake an updated electronic search of MEDLINE and CENTRAL on 11<sup>th</sup> October 2022 for literature published since 2015.

Reference lists of identified studies were screened for additional studies to include. The evidence retrieved in the database search, reference lists and searches of evidence included in Australian and Aotearoa New Zealand FGM/C Guidelines were used to inform the Evidence to Decision (EtD) domains where possible.

Assessment of the rigour, certainty and quality of the evidence was performed using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach.

Phrasing for recommendations differs according to the strength of evidence- further explanation of recommendation types and classifications can be found in the <u>Manual for Developing and Updating Clinical</u> <u>Guidance Statements for RANZCOG</u>.

## Search strategy

- "Female genital mutilation" OR "female circumcision" OR "FGM" OR "FGM/C" OR "Genital cutting" AND "deinfibulation" OR "reconstruction" OR "surgical reversal" OR "surg\*"
- Limited to publications 2015-2022

# Other sources of evidence

Systematic reviews commissioned by the WHO to inform the 2016 Guideline formed the basis for the literature search.<sup>5-7</sup> An additional search using the initial search terms in MEDLINE and CENTRAL was performed on 11<sup>th</sup> October 2022. 512 studies published since the most recent literature search done by the WHO were identified. Two of these studies met the eligibility criteria and were included.<sup>8, 9</sup> The following clinical practice guidelines and protocols were also reviewed:

- Female Genital Mutilation and its Management, Green Top Guideline 2015.<sup>10</sup>
- Female Genital Mutilation, South Australia Maternal, Neonatal & Gynaecology Community of Practice 2018.<sup>11</sup>
- Improving the health care of women and girls affected by female genital mutilation/cutting- A national approach to service coordination, Family Planning Victoria 2014.<sup>12</sup>
- SOGC Clinical Guideline No. 395 Female Genital Cutting 2020.<sup>13</sup>

Subsequently, resources from the National Education Toolkit for Female Genital Mutilation/Cutting Awareness (NETFA) were reviewed as complementary material but were not included within this analysis.

# 7. Clinical Questions and Recommendations

Detailed Evidence to Decision summaries for each clinical question, including the study results, absolute effect estimates and certainity of the evidence for the reported outcomes, can be found in Appendix E- Evidence profiles.

# **Clinical Question 1**

For women who have FGM/C identified during pregnancy, what are the obstetric outcomes if deinfibulation is offered, compared to no surgical interventions or management of sequelae only?

 $\mathbf{P}^{\mathbf{iv}}$  Women who have FGM/C identified during pregnancy

I- Deinfibulation

**C-** Other non-surgical interventions (i.e., use of dilators) or symptomatic management (i.e., treatment of infections)

O- Intrapartum outcomes, perineal trauma, delivery type, birthing experience as reported by patient

## Summary of evidence:

A systematic review of four observational studies<sup>7</sup> was used to inform this recommendation. A greater proportion of women with Type III FGM/C who did not undergo deinfibulation had a caesarean section delivery or PPH than those who had deinfibulation (uncertain at what point during their pregnancy). Little to no difference was found in episiotomy, prolonged second stage labour (>120mins) and Apgar score >5 at 1 minute.

A cohort study of nulliparous Somali born women who were migrants to Norway was published since the above systematic review.<sup>9</sup> This cohort study reports a higher rate of Obstetric Anal Sphincter Injury (OASIS) in women who had not had deinfibulation compared to those who had had deinfibulation during the antenatal period or prior to the pregnancy.

## Recommendation 1

## Evidence based recommendation

## Weak/Conditional

Women who are pregnant with type III FGM/C may be offered deinfibulation during pregnancy to improve obstetric outcomes, including reduced rates of caesarean section and postpartum haemorrhage (PPH).

## Good Practice Point 1

Consideration should be given to establishing centres of expertise in caring for women with FGM/C by providing multidisciplinary and culturally appropriate care.

## **Clinical Question 2**

For women who have FGM/C identified during pregnancy, what are the obstetric outcomes if deinfibulation is offered during the second trimester, compared to the intrapartum period if indicated?

**P** Pregnant women who have FGM/C identified during pregnancy

I Offer deinfibulation in antenatal period (second trimester)

 ${\bf C}$  Defer to labour and deinfibulation only if indicated

<sup>&</sup>lt;sup>iv</sup> Please note, PICO is a framework for developing a focused clinical question. The letters stand for **P**opulation, Intervention, **C**omparator, **O**utcome. See <u>RANZCOG Manual on Developing and Updating Clinical Guidance Statements</u> – pp. 10 for further detail.

**O** Perineal trauma/tearing; obstetric complications; outcome based on timing of deinfibulation; type of delivery

## Summary of evidence:

A systematic review including two case-control studies found little to no difference in the duration of labour, proportion of perineal lacerations, PPH and episiotomy between women with Type III FGM/C who had antenatal deinfibulation compared to those having intrapartum deinfibulation.<sup>6</sup>

Two publications using the same cohort of nulliparous Somali born women who were migrants to Norway were published since the above systematic review.<sup>8, 9</sup>

Migrant women from Sub-Saharan Africa living in high-income countries generally have higher rates of caesarean section than non-migrant women living in those countries. Poor maternal health, cultural and social factors, low quality of care, aspects of migration, language skills, length of residence, and FGM/C were reported as contributing factors.<sup>14</sup>

Nulliparous Somali women in the observational study who had antenatal deinfibulation had a greater risk of OASIS than deinfibulation during labour.<sup>9</sup> The authors present three theories for this: 1) new scar tissue formed by the deinfibulation procedure may itself increase the vulnerability of the perineum; 2) those with antenatal deinfibulation may have had more extensive infibulations than other women so might present a persisting greater risk of OASIS; 3) women who had antenatal deinfibulation had episiotomy less frequently (as they may have been deemed lower risk) and thus may have had less protection.

The greater risk of PPH with antenatal deinfibulation may be secondary to the greater risk of OASIS in this group.

The overall rate of OASIS among women with Type III FGM/C was 11%, compared with 10% among type I-II FGM/C, and 15% among Somali women without FGM/C.<sup>9</sup> A very high rate of OASIS injury was found in the women having an instrumental birth in this study - this may be secondary to language skills of the migrant women - optimal protection of the perineum requires good communication between the woman and the registered health professional providing care in labour.

### Recommendation 1

Evidence based recommendation

## Weak/Conditional

Women who are pregnant with FGM/C Type III may be offered either antenatal or intrapartum deinfibulation. The choice of procedure timing may depend on additional factors such as a woman's preference, geographic location, intended place of birth and clinician experience.

## **Clinical Question 3**

# Does deinfibulation (including surgical reversal) compared to no treatment of FGM/C have better long-term outcomes among women with FGM/C who are not pregnant?

**P** Adolescent girls and women who are not pregnant, living with Types 1-4 of FGM/C who experience shortand long-term sequalae, such as narrow vagina, inclusion cysts, chronic infection etc.

I Deinfibulation or reversal procedures (including surgical interventions)

**C** No surgical intervention or treatment of FGM/C

**O** Dyspareunia; risk of tearing/tissue damage; infection risk/incidence; problems with urination; psychological issues- PTSD etc.; bacterial vaginosis; menstrual disorders (dysmenorrhea, amenorrhea etc.); gynecological complications; infertility; scar tissue and keloids; development of fistula/fistulae.

## Summary of evidence

Only observational studies were identified.

Studies compare operative procedures (deinfibulation, excision of cysts, or clitoral reconstruction) to no surgery. No studies comparing these procedures to other non-surgical interventions were identified. Differences in study methodology, procedure, and outcome measure preclude any meta synthesis of results.

The WHO did not make a recommendation regarding clitoral reconstruction in their 2016 guideline citing a lack of evidence, methodological concerns in the available evidence, and unacceptably high complication rates.

A 2021 systematic review by Nzinga et al included five observational studies reporting on sexual functioning after FGM/C.<sup>15</sup> The sexual function scores assessed using the Female Sexual Function Index (FSFI) of women with any type of FGM/C, were compared to the sexual function of women without FGM/C. There was a significant decrease in the total FSFI scores of women with any type of FGM/C compared to women without FGM/C.

A 2020 systematic review by Lurie et al reported on painful gynaecological complications of FGM/C.<sup>16</sup> Pooled analyses after adjustment for study design found that FGM/C was associated with dyspareunia and dysuria. There was insufficient evidence to conclude that there was an association between FGM/C and dysmenorrhea.

**Deinfibulation:** Case series data of 40 cases of deinfibulation in a US hospital found no intraoperative or postoperative complications were reported.<sup>17</sup> 32 patients (80%) were reached for follow-up. All patients followed up, and their husbands, were satisfied with the results, felt their appearance had improved, and were sexually satisfied (no validated tool used to assess this). 94% stated they would highly recommend it to others.

Catania et al (2007) reported a case series of 15 women undergoing deinfibulation at an Italian hospital.<sup>18</sup> All women were satisfied at follow-up several months after the operation (variable follow-up times) with the improvement in quality of life (reduction of dysmenorrhea, reduction of urinary and vaginal infections, and improvement in flow of urination and menstrual flux), however, this improvement was not measured using a validated tool and quality of life was not measured at baseline.

Krause et al (2011) reported a prospective cohort of 18 patients undergoing deinfibulation with a CO2 laser.<sup>19</sup> Patients were asked to complete the validated Female Sexual Function Index (FSFI) tool before and six months after their operation. No intraoperative complications were noted. Two of the 18 women experienced a UTI in the postoperative course, and one woman experienced prolonged wound healing requiring repeated outpatient appointments. Female sexual function improves after surgical deinfibulation in the domains desire, arousal, satisfaction, and pain, whereas lubrication and orgasm remained unchanged.

**Excision of cysts:** Berg et al (2017) conducted a systematic review of observational studies.<sup>20</sup> Thirteen studies of excision of cysts (not further described but likely to be clitoral or labial) were included. No intraoperative or postoperative complications were reported in the included studies. There were no recurrences of cysts at 1–6 years of follow-up (k = 6, n = 97), the anatomical appearance was good at 1–7 months of follow-up (4 studies, n = 4), and women's sexual life had improved (on self-report, no assessment tool used) at 1–7 months of follow up (6 studies, n = 49). One included study used the non-validated Kasr El Aini sexual assessment questionnaire and found women having an isolated excision of cyst procedure only without other procedures experienced a worsening of their sex score (76.7 to 63.0).<sup>21</sup>

**Clitoral reconstruction:** Auricchio et al (2021) conducted the most recent systematic review of clitoral reconstruction for FGM/C.<sup>22</sup> Eight studies were included in this review (n = 3063). Studies differed in their reconstruction technique. On average, studies reported 5% of patient had moderate postoperative complications (partial graft necrosis, haematoma, suture failure, moderate fever). Vulvar pain and dyspareunia before and after surgery were reported in two studies, the largest of which had a 71% loss to follow up rate at one year, half of patients reported an improvement of pain. Sexual function was reported in all the included studies and represented the primary indication for reconstructive surgery in most patients who suffered FGM/C. Only two of the included studies assessed sexual function using a validated scale (FSFI), both studies reported improvements in five or six of the six parameters. Three studies assessed self-image before and after surgery. One study used a validated tool (the Female Genital Self-Image Scale (FGSIS)) and reported statistically significant improvement.

## Good Practice Points 2 & 3

Deinfibulation may be offered to women living with Type III FGM/C, particularly those with health complications from FGM/C, such as dysuria, recurrent UTIs or dyspareunia. Women presenting with mental health concerns should be offered a referral to mental health services for review and appropriate care.

Discussion of the benefits and risks of the procedure should include information regarding the anatomical and physiological changes that can be expected after deinfibulation (i.e., expected labial appearance, faster micturition, increased vaginal discharge).

Women with FGM/C should be appropriately informed about the benefits and risks of clitoral reconstruction and the lack of evidence regarding potential benefits.

# 8. Legal and ethical implications

In Australia and Aotearoa New Zealand, the practice of FGM/C is unlawful.<sup>23, 24</sup> In addition to the prohibition of these practices, registered health professionals in all states and territories of Australia are mandated by law to report any risk or confirmation of FGM/C in a child to relevant authorities such as Child Protection. This includes if a child is likely to be taken to another country to have FGM/C. Risk assessment is a complex process and practitioners should refer to the policies, procedures, and processes relevant to their health service. Furthermore, the legal definition of a child varies substantially across jurisdictions and practitioners should consult the legislation relevant to the state or territory of practice. The following table summarises current<sup>v</sup> mandatory reporting legislation by jurisdiction.

Jurisdiction	Act	Summary
VIC	Children, Youth and Families Act 2005	s183 & 4- Professionals such as education staff, police, medical and nursing staff are mandated to report FGM/C to Child Protection, if they form a 'belief on reasonable grounds that a child is in <b>need</b> <b>of protection</b> '
NSW	Children Legislation Amendment Act 2009	S23 and s27- All health professionals in NSW are mandatory reporters and must report if a child who is <b>under the age of 16</b> 'has been or is at risk of being <b>physically abused or ill-treated</b> ' to Family and Community Services (Child Protection Helpline and NSW Education Program on FGM).
QLD	Health Act 1937 (Qld)	S76K Requires all medical practitioners to notify one of the Director-General's designated officers if they suspect on reasonable grounds the 'maltreatment or

<sup>v</sup> Accurate at publication in March 2023

		neglect of a child in such a manner as to subject or be likely to <b>subject a child to unnecessary injury</b> , suffering or dangers'
SA	Children's Protection Act 1993	All health professionals to report to the Child Abuse Report Line (Department for Education and Child Development- Families SA) if 'they have <b>a reasonable</b> <b>concern that a child is at risk of significant harm</b> '. It is up to the department to determine whether there are reasonable grounds for investigation/intervention.
WA	Children and Community Services Act 2004	FGM/C is not specifically mentioned, however the Department of Child Protection and Family Support have stated mandatory reporting of FGM would fall under this Act, however it <b>is noted as physical, not</b> <b>sexual abuse</b> . In any case, when FGM/C is identified, a healthcare professional must make a child protection notification to the local CPFS District Office.
TAS	Children, Young Persons and Their Families Act 1997	Broad range of mandatory reporting duties for four classical forms of child abuse and neglect. FGM/C is covered by Section 3(1)(2)- reporting is mandated if 'the injured person has suffered, or is likely to suffer, <b>physical or psychological harm detrimental to the</b> <b>person's wellbeing</b> '.
NT	Community Welfare Act 1983 (No 76)	Section 4(3) (e)- specifically references FGM/C. A person, including healthcare professionals, 'who believes, on reasonable grounds, that a child has suffered or is suffering maltreatment'. Maltreatment can include if 'he or she has <b>suffered a physical injury</b> <b>causing temporary or permanent disfigurement or</b> <b>serious pain</b> or has <b>suffered impairment of a bodily</b> <b>function or the normal reserve/flexibility of a bodily</b> <b>function</b> , inflicted or allowed to be inflicted <b>by a</b> <b>parent, guardian or person having custody</b> or where there is substantial risk of suffering such as injury or impairment'
ACT	Children and Young People Act 2008 (ACT)	Requires health professionals to report to ACT Care & Protection Services, if, in the course of their professional work (whether paid or unpaid), they form a reasonable belief that a child or young person (birth to 17 years) has <b>experiences or is experiencing</b> <b>non-accidental physical injury</b> .
Aotearoa New Zealand	Crimes Act 1961 (Section 204A (1-7))	There is no law in Aotearoa New Zealand that makes the reporting of abuse of children, adults, or the elderly mandatory. However, a 1996 amendment to the Crimes Act states it is illegal to perform "any medical or surgical procedure or mutilation of the vagina or clitoris of any person" for reasons of "culture, religion, custom or practice". This includes FGM/C. It is also against the law to perform FGM/C even if a woman requests it to be done.
		In 2020, an update to the Crimes Act 1961 (Section 204A) resulted in a replacement of the definition of female genital mutilation to assert the difference between FGM/C and cosmetic/enhancement procedures. It also added nurses, registered midwives and trainee health professionals to the list of professions whereby subsection 2- <i>Subject to subsection (3), every one is liable to imprisonment for a term not exceeding 7 years who performs, or causes to be performed, on any other person, any act involving female genital mutilation- <b>does not</b> apply to (in respect of any medical or surgical procedure that is performed on any person).</i>

**NB:** This information was captured from jurisdictional information obtained from Australian and Aotearoa New Zealand data sources, accessed online. The following publications were additionally used as reference documents:

- <u>Child Abuse and Neglect: A Socio-legal Study of Mandatory Reporting in Australia- Report for the Tasmanian</u> <u>Government (Mathews, B et al 2015)</u> was additionally used as a reference document.

- <u>Improving the health care of women and girls affected by female genital mutilation/cutting: A national approach to</u> <u>service coordination</u>, *Family Planning Victoria 2014* 

- New Zealand Nurses Organisation- Reporting Abuse- Actual or suspected: Frequently Asked Questions

- FGM & the NZ Law, Webpage- accessed online on 23<sup>rd</sup> January 2023. <u>https://fgm.co.nz/fgm-nz-law/</u>

# 9. Recommendations for future research

This Clinical Guidance Statement identified a gap in available, current, and accessible research on the following topics:

- Obstetric and gynaecological care for women who have been impacted by FGM/C.
- Accurate prevalence data of FGM/C in Australia and Aotearoa New Zealand.
- Acceptability studies for deinfibulation.
- Access to continuity of care/r and early referral on a woman's uptake of deinfibulation during pregnancy to improve obstetric outcomes.
- Study methods which discern if women's sexual satisfaction as a measure was reported in the presence of a partner/husband.
- Disaggregated data collection to understand the association between socio-cultural/ demographic factors and health status for women affected by FGM/C.

# 10. References

1. (WHO) WHO. WHO guidelines on the management of health complications from female genital mutilation. Geneva, Switzerland: Research DoRHa; 2016.

2. Moeed SM, Grover SR. Female genital mutilation/cutting (FGM/C): Survey of RANZCOG Fellows, Diplomates & Trainees and FGM/C prevention and education program workers in Australia and New Zealand. Australian and New Zealand Journal of Obstetrics and Gynaecology. 2012;52(6):523-7.

3. Farouki L, El-Dirani Z, Abdulrahim S, Akl C, Akik C, McCall SJ. The global prevalence of female genital mutilation/cutting: A systematic review and meta-analysis of national, regional, facility, and school-based studies. PLoS Med. 2022;19(9):e1004061.

4. Health Alo, Welfare. Discussion of female genital mutilation/cutting data in Australia. Canberra: AIHW, 2019.

5. Effa E, Ojo O, Ihesie A, Meremikwu MM. Deinfibulation for treating urologic complications of type III female genital mutilation: A systematic review. Int J Gynaecol Obstet. 2017;136 Suppl 1:30-3.

6. Esu E, Udo A, Okusanya BO, Agamse D, Meremikwu MM. Antepartum or intrapartum deinfibulation for childbirth in women with type III female genital mutilation: A systematic review and meta-analysis. Int J Gynaecol Obstet. 2017;136 Suppl 1:21-9.

7. Okusanya BO, Oduwole O, Nwachuku N, Meremikwu MM. Deinfibulation for preventing or treating complications in women living with type III female genital mutilation: A systematic review and meta-analysis. Int J Gynaecol Obstet. 2017;136 Suppl 1:13-20.

8. Taraldsen S, Vangen S, Øian P, Sørbye IK. Female genital mutilation/cutting, timing of deinfibulation, and risk of cesarean section. Acta Obstet Gynecol Scand. 2021;100(4):587-95.

9. Taraldsen S, Vangen S, Øian P, Sørbye IK. Risk of obstetric anal sphincter injury associated with female genital mutilation/cutting and timing of deinfibulation. Acta Obstet Gynecol Scand. 2022;101(10):1163-73.
10. Gynaecologists RCoOa. Female Genital Mutilation and its Management. Green-top Guideline No 532015. p. 26.

 Female Genital Mutilation. In: Department for Health and Wellbeing GoSA, editor. 2018. p. 21.
 Jordan L, Neophytou K, James C. Improving the health care of women and girls affected by female genital mutilation/ cutting: A national approach to service coordination Family Planning Victoria, 2014.

 Perron L, Senikas V, Burnett M, Davis V. Guideline No. 395-Female Genital Cutting. Journal of Obstetrics and Gynaecology Canada. 2020;42(2):204-17.e2.

14. Merry L, Vangen S, Small R. Caesarean births among migrant women in high-income countries. Best Pract Res Clin Obstet Gynaecol. 2016;32:88-99.

15. Nzinga AM, De Andrade Castanheira S, Hermann J, Feipel V, Kipula AJ, Bertuit J. Consequences of Female Genital Mutilation on Women's Sexual Health - Systematic Review and Meta-Analysis. J Sex Med. 2021;18(4):750-60.

16. Lurie JM, Weidman A, Huynh S, Delgado D, Easthausen I, Kaur G. Painful gynecologic and obstetric complications of female genital mutilation/cutting: A systematic review and meta-analysis. PLoS Med. 2020;17(3):e1003088.

17. Nour NM, Michels KB, Bryant AE. Defibulation to treat female genital cutting: effect on symptoms and sexual function. Obstet Gynecol. 2006;108(1):55-60.

18. Catania L, Abdulcadir O, Puppo V, Verde JB, Abdulcadir J, Abdulcadir D. Pleasure and orgasm in women with Female Genital Mutilation/Cutting (FGM/C). J Sex Med. 2007;4(6):1666-78.

19. Krause E, Brandner S, Mueller MD, Kuhn A. Out of Eastern Africa: defibulation and sexual function in woman with female genital mutilation. J Sex Med. 2011;8(5):1420-5.

20. Berg RC, Taraldsen S, Said MA, Sørbye IK, Vangen S. The effectiveness of surgical interventions for women with FGM/C: a systematic review. Bjog. 2018;125(3):278-87.

21. Thabet SM, Thabet AS. Defective sexuality and female circumcision: the cause and the possible management. J Obstet Gynaecol Res. 2003;29(1):12-9.

22. Auricchio V, Garzon S, Pomini P, Laganà AS, Casarin J, Cromi A, et al. Clitoral reconstructive surgery after female genital mutilation: A systematic review. Sex Reprod Healthc. 2021;29:100619.

23. Crimes (Definition of Female Genital Mutilation) Amendment Act, Stat. 53 (7 August 2020, 2020).

24. (NETFA). Multicultural Centre for Women's Health (MCWH); 2023 [cited 2023 10/02]. Available from: https://netfa.com.au/what-is-female-genital-mutilation-or-cutting/australian-law/.

25. Dawson AJ, Turkmani S, Varol N, Nanayakkara S, Sullivan E, Homer CS. Midwives' experiences of caring for women with female genital mutilation: Insights and ways forward for practice in Australia. Women Birth. 2015;28(3):207-14.

# 11. Links to relevant College Statements

- Cultural Competency (WPI-20)
- Evidence-based Medicine, Obstetrics and Gynaecology (C-Gen 15)
- Consent and Provision of Information to Patients in Australia regarding proposed treatment (C-Gen 2a)
- Consent and Provision of Information to Patients in New Zealand regarding proposed treatment (C-Gen 2a)
- Provision of routine intrapartum care in the absence of pregnancy complications <u>(C-Obs 31)</u>- Under Review

# 12. Links to relevant Consumer resources

- <u>Best Practice Guide for Working with Communities Affected by FGM/C</u>, Multicultural Centre for Women's Health
- National Education Toolkit for FGM/C Awareness- Find Support, accessed online. See <u>https://netfa.com.au/find-support/</u>
- Female Genital Mutilation in New Zealand- Communities affected by FGM, accessed online. Seehttps://fgm.co.nz/communities/
- The Forum of Australian Services for Survivors of Torture and Trauma- Services Available, accessed online. See <u>Members FASSTT</u>

# 13.Links to relevant ATMs and learning modules

- RANZCOG- Female Genital Mutilation (FGM) Module: Acquire
- Culturally Responsive Health Project (TRUE Relationships and Reproductive Health QLD)-'Introduction to Female Genital Mutilation/Cutting/Circumcision': <u>online course</u>

# 14.Useful links/support groups

- The Royal Women's Hospital Victoria- Deinfibulation Technique and Timing Guideline, published 2020. Permission has been sought to reproduce this content. See Appendix F- Additional Practical Advice: Deinfibulation technique (illustration).
- Female Genital Mutilation in New Zealand- Health Professionals, accessed online. See<u>https://fgm.co.nz/resources/health-professionals/</u>
- Female Genital Mutilation in New Zealand- Child Protection Professionals, accessed online. Seehttps://fgm.co.nz/resources/child-protection-professionals/
- Oranga Tamariki (Ministry for Children) Practice Centre- Female genital mutilation Guidance, accessed online. See- Female genital mutilation | Practice Centre | Oranga Tamariki
- True Relationships and Health (Queensland), published 2019. Accessed online- <u>Female genital</u> <u>mutilation/cutting/circumcision (FGM/C) for Health Professionals- Factsheet: Culturally responsive</u> <u>health</u>.

# Appendices

# Appendix A: Women's Health Committee Membership

Name	Position on Committee
Dr Scott White	Chair
Dr Gillian Gibson	Deputy Chair, Gynaecology
Dr Anna Clare	Deputy Chair, Obstetrics
Associate Professor Amanda Henry	Member and Councillor
Dr Samantha Scherman	Member and Councillor
Dr Marilla Druitt	Member and Councillor
Dr Frank O'Keeffe	Member and Councillor
Dr Kasia Siwicki	Member and Councillor
Dr Jessica Caudwell-Hall	Member and Councillor
Dr Sue Belgrave	Member and Councillor
Dr Marilyn Clarke	Aboriginal and Torres Strait Islander Representative
Professor Kirsten Black	SRHSIG Chair
Dr Nisha Khot	Member and SIMG Representative
Dr Judith Gardiner	Diplomate Representative
Dr Angela Brown	Midwifery Representative, Australia
Ms Adrienne Priday	Midwifery Representative, Aotearoa New Zealand
Ms Leigh Toomey	Community Representative
Dr Rania Abdou	Trainee Representative
Dr Philip Suisted	Māori Representative
Prof Caroline De Costa	Co-opted member (ANZJOG member)
Dr Steve Resnick	Co-opted member

# Appendix B: Statement Development Panel Membership

Name	Position on Committee
Dr Angela Brown	Chair
Dr Deepa Gopinath	Member (CU)
Dr Murad Al-Aker	Member (CGO)
Dr Pari Gurusamy	Member
Dr Rania Abdou	Member
Dr Gillian Gallagher	Member
Dr Divya Viswanathan	Member
Dr Zahrah Ali	Member
Ms Leigh Toomey	Member, Consumer representative

Research & Policy Team <sup>vi</sup>	Position
Professor Cindy Farquhar	Dean of Research & Policy
Ms Jinty Wilson	Head of Research & Policy
Ms Katie Coulthard	Senior Coordinator, Research & Policy

<sup>&</sup>lt;sup>vi</sup> RANZCOG wish to acknowledge the contribution of the technical support provided by the University of Auckland (Dr Karyn Anderson, Ms Marian Showell) who have supported the identification and appraisal of evidence.



## Appendix C: Overview of the development and review process for this statement

*i.* Declaration of interest process and management

Declaring interests is essential in order to prevent any potential conflict between the private interests of members, and their duties as part of RANZCOG Women's Health Committee or working groups.

A declaration of interest form specific to guidelines and statements (approved by the RANZCOG Board in September 2012). All members of the Statement Development Panels, Statement and Guideline Advisory Group (SaGG) and Women's Health Committee were required to declare their relevant interests in writing on this form prior to participating in the review of this statement. Dr Divya Viswanathan, SDP member, disclosed involvement as a board member of Zonta Brisbane East (branch of Zonta International- registered charity). This involvement is non-financial.

Members were required to update their information as soon as they become aware of any changes to their interests and there was also a standing agenda item at each meeting where declarations of interest were called for and recorded as part of the meeting minutes.

There were no significant real or perceived conflicts of interest that required management during the process of updating this statement.

## *ii.* Steps in developing and updating this statement

This statement was developed in **March 1994** by the C-Gyn 1 FGM/C Statement Development Panel, a working group established by the Women's Health Committee. It was most recently reviewed by the Women's Health Committee in **March 2023**. The Women's Health Committee carried out the following steps in reviewing this statement:

- Declarations of interest were sought from all members prior to reviewing this statement.
- Structured clinical questions were developed and agreed upon.
- An updated literature search to answer the clinical questions was undertaken.
- At the February 2023 meeting of the Women's Health Committee, the existing consensusbased recommendations were reviewed and updated (where appropriate) based on the available body of evidence and clinical expertise, as set out in the Methodology section below.

RANZCOG statements are developed according to the standards of the Australian National Health and Medical Research Council (NHMRC), which includes the use of GRADE methodology. The Evidence to Decision framework embedded within the MAGIC (Making GRADE the Irresistible Choice) digital platform (<u>https://magicevidence.org</u>) is used to publish the updated statement recommendations. The recommendations published by RANZCOG are approved by the RANZCOG Women's Health Committee, Council and Board respectively. The processes used to develop RANZCOG clinical guidance statements are described in detail at: <u>https://ranzcog.edu.au/wp-</u> <u>content/uploads/2022/08/Manual-for-developing-and-updating-clinical-guidance-statements.pdf</u>

## *iii.* Developing recommendations using GRADE methodology

The relevant GRADE assessments for each recommendation are presented within the online platform used to structure the Clinical Guidance Statement

(MAGICapp; https://magicevidence.org/magicapp/).





# Appendix D: Full Disclaimer

## Purpose

This Statement has been developed to provide general advice to registered health professionals about women's health issues concerning FGM/C and should not be relied on as a substitute for proper assessment with respect to the particular circumstances of each case and the needs of any person. It is the responsibility of each practitioner to have regard to the particular circumstances of each case. Clinical management should be responsive to the needs of the individual person and the particular circumstances of each case.

## Quality of information

The information available in this statement is intended as a guide and provided for information purposes only. The information is based on the Australian/New Zealand context using the best available evidence and information at the time of preparation. While the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) has endeavoured to ensure that information is accurate and current at the time of preparation, it takes no responsibility for matters arising from changed circumstances or information or material that may have become subsequently available. The use of this information is entirely at your own risk and responsibility.

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## Exclusion of warranties

To the maximum extent permitted by law, RANZCOG makes no representation, endorsement or warranty of any kind, expressed or implied in relation to the materials within or referred to throughout this statement being in any way inaccurate, out of context, incomplete or unavailable for all expenses, losses, damages and costs incurred.



These terms and conditions will be constructed according to and are governed by the laws of Victoria, Australia.



# Appendix E- Evidence profiles

## **Clinical Question 1**

## For women who have FGM/C identified during pregnancy, what are the obstetric outcomes if deinfibulation is offered compared to no surgical interventions or management of sequelae only?

PICO (2.3.1) Population: Women who have FGM-C identified during pregnancy

Intervention: Deinfibulation

Comparator: Other non-surgical interventions (ie. use of dilators) or symptomatic management (ie. treatment of infections)

<b>Outcome</b> Timeframe	Study results and measurements	Absolute effect estimates Other non- surgical interventions or symptomatic management	<b>Certainty of the Evidence</b> (Quality of evidence)	Plain language summary
Episiotomy - deinfibulation vs no deinfibulation among type III FGM in pregnancy	Odds ratio: 0.31 (CI 95% 0.09 - 1.1) Based on data from 431 participants in 2 studies <sup>1</sup>	357         147           per 1000         per 1000           Difference:         210 fewer per 1000           (CI 95% 309 fewer - 22 more)         22 more)	<b>Very low</b> Due to serious risk of bias <sup>2</sup>	Okusanya et al 2017 Systematic Review We are uncertain whether dein fibulation improves or worsen episiotomy- dein fibulation vs no dein fibulation among type iii fgm in pregnancy
Caesarean delivery - deinfibulation vs no deinfibulation among type III FGM in pregnancy	Odds ratio: 0.19 (CI 95% 0.09 - 0.39) Based on data from 491 participants in 2 studies	588         213           per 1000         per 1000           Difference: 375 fewer per 1000         (CI 95% 474 fewer - 230 fewer)	<b>Very low</b> Due to serious risk of bias <sup>3</sup>	Okusan ya et al 2017 Systematic Review We are uncertain whether deinfibulation increases or decreases caesarean delivery - deinfibulation vs no deinfibulation among type iii fgm in pregnancy
Postpartum haemorrhage - deinfibulation vs no deinfibulation among type III FGM in pregnancy	Odds ratio: 0.31 (CI 95% 0.12 - 0.83) Based on data from 253 participants in 1 studies	500         237           per 1000         per 1000           Difference:         263 fewer per 1000           (CI 95% 393 fewer - 46 fewer)	<b>Very low</b> Due to serious risk of bias <sup>4</sup>	Okusan ya et al 2017 Systematic Review We are uncertain whether deinfibulation improves or worsen postpartum haemorrhage- deinfibulation vs no deinfibulation among type iii fgm in pregnancy
Prolonged second stage (>120mins) - deinfibulation vs no deinfibulation among type III FGM in pregnancy	Odds ratio: 0.54 (CI 95% 0.06 - 4.56) Based on data from 241 participants in 1 studies	71         40           per 1000         per 1000           Difference: 31 fewer per 1000         (CI 95% 66 fewer - 187 more)	<b>Very low</b> Due to serious risk of bias <sup>5</sup>	Okusan ya et al 2017 Systematic Review We are uncertain whether deinfibulation improves or worsen prolonged second stage (>120mins) - deinfibulation vs no deinfibulation among type iii fgm in pregnancy
Apgar score less than 7 at 1 minute - deinfibulation vs no deinfibulation among type III FGM in pregnancy	Odds ratio: 0.56 (CI 95% 0.19 - 1.7) Based on data from 499 participants in 2 studies	105         62           per 1000         per 1000           Difference: 43 fewer per 1000         (CI 95% 83 fewer - 61 more)	<b>Very low</b> Due to serious risk of bias <sup>6</sup>	Okusanya et al 2017 Systematic Review We are uncertain whether deinfibulation increases or decreases apgar score less than 7 at 1 minute - deinfibulation vs no deinfibulation among type iii fgm in pregnancy
OASIS injury - deinfibulation vs no deinfibulation	Odds ratio: 0.45 (CI 95% 0.25 - 0.83) Based on data from 624 participants in 1 studies <sup>7</sup>	200         101           per 1000         per 1000           Difference:         99 fewer per 1000           (CI 95% 141 fewer - 28 fewer)	Very low Due to serious imprecision <sup>8</sup>	Taraldsen et al 2022 - setting Norway We are uncertain whether deinfibulation improves or worsen oasis injury- deinfibulation vs no deinfibulation

Systematic review . Baseline/comparator Control arm of reference used for intervention . Supporting references [16]. 1.

2. Risk of Bias: serious.



## Evidence to Decision

## Benefits and harms

## Small net benefit, or little difference between alternatives

A systematic review of four observational studies (Okusanya et al 2017) was used to inform this recommendation. A greater proportion of women with type III FGM/C who did not undergo deinfibulation had a caesarean section delivery or postpartum haemorrhage than those who had deinfibulation (uncertain at what point during their pregnancy). Little to no difference was found in episiotomy, prolonged second stage (>120mins) and APGAR score >5 at 1 minute.

A cohort study of nulliparous Somali born women who were migrants to Norway (Taralden et al 2022) was published since the above systematic review. This cohort study reports a higher rate of OASIS injury in women who had not had deinfibulation compared to those who had had deinfibulation during the antenatal period or prior to the pregnancy.

Domain	Summary of judgement	Comment
Certainty of evidence	Very low.	Observational data only
Values and preferences	Substantial variability is expected or uncertain.	A systematic review on women's motivation for and experience with surgical interventions found that deinfibulation in relation to childbirth is perceived as facilitating an easier birth. <sup>20</sup>
Resources	Factor not considered.	Additional surgical resources used for deinfibulation may be offset by reduced caesarean section rate. No formal evidence to inform this was identified.
Equity	Important issues, or potential issues not investigated.	
Acceptability	No important issues with the recommended alternative.	Clinician acceptability would depend on adequate training to identify cases of type III FGM/C and perform deinfibulation procedures. Midwives surveyed in Australia described practice issues, including the development of rapport with women, working with interpreters, misunderstandings about the culture of women, inexperience with associated clinical procedures and
Feasibility	No important issues with the recommended alternative.	Deinfibulation assessed as 'Probably feasible'. Would require resources and training for health facilities.

Additional considerations



The WHO did not make a recommendation regarding clitoral reconstruction in their 2016 guideline citing a lack of evidence, methodological concerns in the available evidence, and unacceptably high complication rates.

A 2021 systematic review by Nzinga et al included five observational studies reporting on sexual functioning after FGM/C. The sexual function scores using the FSFI tool of women with any type of FGM/C, was compared to the sexual function of women without FGM/C. There was a significant decrease in the total FSFI scores of women with any type of FGM/C compared to women without FGM/C.

A 2020 systematic review by Lurie et al reported on painful gynaecological complications of FGM/C. Pooled analyses after adjustment for study design found that FGM/C was associated with dyspareunia (6,283 FGM/C and 3,382 non-FGM/C participants; pooled OR: 2.47; 95% confidence interval [CI]: 1.45–4.21; I 2 : 79%; p-value < 0.01), and dysuria (3,686 FGM/C and 3,482 non-FGM/C participants; pooled OR: 1.43; 95% CI: 1.17–1.75; I 2 : 0%; p-value = 0.01). There was insufficient evidence to conclude that there was an association between FGM/C and dysmenorrhea (7,349 FGM/C and 4,411 non-FGM/C participants; pooled OR: 1.66; 95% CI: 0.97-2.84; I 2 : 86%; p-value = 0.06), or urinary tract infection (4,493 FGM/C and 3,776 non-FGM/C participants; pooled OR: 2.11; 95% CI: 0.80-5.54; I 2 : 90%; p-value = 0.10).



## Clinical Question 2

For women who have FGM/C identified during pregnancy, what are the obstetric outcomes if deinfibulation is offered during the second trimester, compared to the intrapartum period if indicated?

#### PICO (2.2.1)

Population: Pregnant women who have FGM-C identified during pregnancy Intervention: Offer deinfibulation in antenatal period (second trimester) Comparator: Defer to labour and deinfibulation only if indicated

<b>Outcome</b> Timeframe	Study results and measurements	Absolute effect estimates Defer to labour Offer and deinfibulation deinfibulation in antenatal only if period (second indicated trimester)	Certainty of the Evidence (Quality of evidence)	Plain language summary
Duration of labour (>120mins)- antenatal deinfibulation vs intrapartum deinfibulation	Odds ratio: 0.6 (CI 95% 0.17 - 2.18) Based on data from 58 participants in 1 studies <sup>1</sup>	313         215           per 1000         per 1000           Difference: 98 fewer per 1000         (CI 95% 241 fewer - 185 more)	<b>Very low</b> Due to serious risk of bias, Due to serious imprecision <sup>2</sup>	Systematic review - Esu et al 2017 We are uncertain whether offer deinfibulation in antenatal period (second trimester) increases or decreases duration of labour (>120mins) - antenatal deinfibulation vs intrapartum deinfibulation
Perineal lacerations (2nd, 3rd, and 4th degree)- antepartum deinfibulation vs intrapartum deinfibulation	Odds ratio: 0.79 (Cl 95% 0.28 - 2.19) Based on data from 77 participants in 2 studies	<b>414 358</b> per 1000 per 1000 Difference: <b>56 fewer per 1000</b> (CI 95% 249 fewer - 193 more)	<b>Very low</b> Due to serious risk of bias <sup>3</sup>	Systematic review - Esu et al 2017 We are uncertain whether offer deinfibulation in antenatal period (second trimester) increases or decreases perineal lacerations (2nd, 3rd, and 4th degree) - antepartum deinfibulation vs intrapartum deinfibulation
Postpartum haemorrhage - antepartum deinfibulation vs intrapartum deinfibulation	Odds ratio: 1.06 (Cl 95% 0.33 - 3.39) Based on data from 58 participants in 1 studies	<b>438 452</b> per 1000 per 1000 Difference: <b>14 more per 1000</b> (CI 95% 233 fewer - 287 more)	<b>Very low</b> Due to serious risk of bias, Due to serious imprecision <sup>4</sup>	Systematic review - Esu et al 2017 We are uncertain whether offer deinfibulation in antenatal period (second trimester) increases or decreases postpartum haemorrhage- antepartum deinfibulation vs intrapartum deinfibulation
Episiotomy- antepartum deinfibulation vs intrapartum deinfibulation	Odds ratio: 0.94 (Cl 95% 0.34 - 2.58) Based on data from 77 participants in 2 studies	655         641           per 1000         per 1000           Difference:         14 fewer per 1000           (CI 95% 263 fewer - 175 more)	<b>Very low</b> Due to serious risk of bias, Due to serious in consistency <sup>5</sup>	Systematic review - Esu et al 2017 We are uncertain whether offer deinfibulation in antenatal period (second trimester) increases or decreases episiotomy - an teparlum deinfibulation vs intrapartum deinfibulation
APGAR score less than 5 at 1 minute - antepartum deinfibulation vs intrapartum deinfibulation	Odds ratio: 0.37 (Cl 95% 0.02 - 6.23) Based on data from 58 participants in 1 studies	63 24 per 1000 per 1000 Difference: <b>39 fewer per 1000</b> (CI 95% 62 fewer - 232 more)	<b>Very low</b> Due to serious risk of bias, Due to serious imprecision <sup>6</sup>	Systematic review - Esu et al 2017 We are uncertain whether offer deinfibulation in antenatal period (second trimester) improves or worsen apgar score less than 5 at 1 minute -



## Evidence to Decision

## Benefits and harms

## Small net benefit or little difference between alternatives

A systematic review including two case-control studies (Esu et al 2017) found little to no difference in the duration of labour, proportion of perineal lacerations, PPH and episiotomy between women with type III FGM/C who had antenatal deinfibulation compared to those having intrapartum deinfibulation.

Two publications using the same cohort of nulliparous Somali born women who were migrants to Norway (Taralden et al 2021; 2022) were published since the above systematic review.

Domain	Summary of judgement	Comment
Certainty of evidence	Very low.	Two observational studies only - both underpowered.
Values and preferences	Substantial variability is expected or uncertain.	A systematic review on women's motivation for and experience with surgical interventions found that deinfibulation in relation to childbirth is perceived as facilitating an easier birth, and women prefer to have the procedure performed during labour, rather than antenatally (Burg et al 2017b).
Resources	No important issues with the recommended alternative.	Similar staff time, and operative resources would be required for either procedure.
Equity	Important issues, or potential issues not investigated.	Refer to rationale section regarding specific circumstances in which antenatal deinfibulation should be preferred, as recommended by the WHO. This includes women with difficult access to healthcare facilities.
Acceptability	No important issues with the recommended alternative.	Assessed as 'probably acceptable' amongst providers of clinical care.
Feasibility	No important issues with the recommended alternative.	Deinfibulation in antenatal period assessed as 'probably feasible'

## Additional considerations

Migrant women from Sub-Saharan Africa living in high-income countries generally have higher rates of caesarean section than non-migrants living in those countries. Poor maternal health,



cultural and social factors, low quality of care, aspects of migration, language skills, length of residence, and FGM/C are contributing factors (Merry, Vangen & Small 2016).

Nulliparous Somali women in the observational study Taraldsen et al 2022 who had antenatal deinfibulation had a greater risk of OASIS than deinfibualtion during labour. The authors present three theories for this: 1) new scar tissue formed by the deinfibulation procedure may itself increase the vulnerability of the perineum; 2) those with antenatal deinfibulation may have had more extensive infibulations than other women so might present a persisting greater risk of OASIS; 3) women who had antenatal deinfibulation had episiotomy less frequently (as they may have been deemed lower risk) and thus may have had less protection.

The greater risk of PPH with antenatal deinfibulation may be secondary to the greater risk of OASIS in this group.

The overall rate of OASIS among women with type III FGM/C was 11.3%, compared with 10.2% among type I-II FGM/C, and 15.2% among Somali women without FGM/C. A very high rate of OASIS injury was found in the women having an instrumental birth in this study - this may be secondary to language skills of the migrant women - optimal protection of the perineum requires good communication between the woman and the birth attendant.



# **Clinical Question 3**

## Does deinfibulation (including surgical reversal) compared to no treatment of FGM/C have better long-

## term outcomes among women with FGM/C who are not pregnant?

PICO (2.1.1)

Propulation: Girls/adolescents and women who are not pregnant, living with Types 1-4 FGM-C who experience short- and long-term sequelae, such as narrow vagina, inclusion cycsts, chronic infection etc. Intervention: Deinfibulation or reversal procedures (including surgical interventions) Comparator: No surgical intervention or treatment of FGM-C

		Absolute effect estimates		
<b>Outcome</b> Timeframe	Study results and measurements	No surgical intervention or treatment of FGM-C	Certainty of the Evidence (Quality of evidence)	Plain language summary
Deinfibulation - urological outcomes	Based on data from participants in 0 studies <sup>1</sup>	A systematic review in vestigating the effects of deinfibulation on the prevention or treatment of recurrent urin ary tract infections (UTIs) and urin ary retention was commissioned by the WHO to inform their guideline on management of FGM-C. The authors of the commissioned review (Effa et al 2017) found no studies that met their inclusion criteria.		No studies were found by WHO that looked at deinfibulation - urological outcomes
Deinfibulation - complication rates	Based on data from participants in 2 studies <sup>2</sup>	Nour, Michels, & Bryant (2006) published a case series of 40 cases of deinfibulation at a US hospital. No intraoperative or postoperative complications were reported. Krause et al (2011) report a prospective cohort of 18 patients undergoing deinfibulation with a CO2 laser. No intraoperative complications were noted. Two of the 18 women experienced a UTI in the postoperative course, and one woman experienced prolonged wound healing requiring repeated outpatient appointments.	Very low Due to very serious risk of bias - loss to follow-up, variable follow- up length between and within studies, and use of unvalidated tools for outcome assessment. Due to serious imprecision (small number of cases in series) <sup>3</sup>	Summarized in Berg et al 2017 systematic review We are uncertain whether deinfibulation or reversal procedures improves or worsen deinfibulation - complication rates
Deinfibulation - satisfaction	Based on data from participants in 2 studies <sup>4</sup>	Nour, Michels, & Bryant (2006) published a case series of 40 cases of deinfibulation at a US hospital. All patients followed up (80%), and their husbands, were satisfied with the results, felt their appearance had improved. 94% stated they would highly recommend the procedure to others. Catania et al (2007) reported a case series of 15 women undergoing deinfibulation at an Italian hospital. All women were satisfied at follow-up several months after the operation, with improvement in quality of life (reduction of dy smenorthea, reduction of urinary and vaginal infections, and improvement in flow of urination and menstrual flux).	Very low Due to very serious risk of bias - variable follow-up length between and within studies, and use of unvalidated tools for outcome assessment. Due to serious imprecision (small number of cases in series) <sup>5</sup>	Summarized in Berg et al 2017 systematic review We are uncertain whether deinfibulation or reversal procedures improves or worsen deinfibulation - satisfaction
Deinfibulation - sexual functioning	Based on data from participants in 2 studies <sup>6</sup>	Nour, Michels, & Bryant (2006) published a case series of 40 cases of deinfibulation at a US hospital. All patients followed up (80%), and their husbands, were sexually satisfied. Krause et al (2011) report a prospective cohort of 18 patients undergoing deinfibulation with a CO2 laser. Patients were asked to complete the validated Female Sexual Function Index (FSFI) tool before and 6 months after their	Very low Due to very serious risk of bias - loss to follow-up, variable follow- up length between and within studies, and use of unvalidated tools for outcome assessment. Due to serious imprecision (small number of cases in series) <sup>7</sup>	Summarized in Berg et al 2017 systematic review We are uncertain whether deinfibulation or reversal procedures improves or worsen deinfibulation - sexual functioning



## Evidence to Decision

## **Benefits and harms**

## <u>Small net benefit, or little difference</u> <u>between alternatives</u>

Deinfibulation: Nour, Michels, & Bryant (2006) published a case series of 40 cases of deinfibulation at a US hospital. No intraoperative or postoperative complications were reported. 32 patients (80%) were reached for follow-up. All patients followed up, and their husbands, were satisfied with the results, felt their appearance had improved, and were sexually satisfied (no validated tool used to assess this). 94% stated they would highly recommend it to others.

Catania et al (2007) reported a case series of 15 women undergoing deinfibulation at an Italian hospital. All women were satisfied at follow-up several months after the operation (variable follow-up times) with the improvement in quality of life (reduction of dysmenorrhea, reduction of urinary and vaginal infections, and improvement in flow of urination and menstrual flux), however, this improvement was not measured using a validated tool and quality of life was not measured at baseline.

Krause et al (2011) reported a prospective cohort of 18 patients undergoing deinfibulation with a CO2 laser. Patients were asked to complete the validated Female Sexual Function Index (FSFI) tool before and 6 months after their operation. No intraoperative complications were noted. Two of the 18 women experienced a UTI in the postoperative course, and one woman experienced prolonged wound healing requiring repeated outpatient appointments. Female sexual function improves after surgical deinfibulation in the domains desire, arousal, satisfaction, and pain, whereas lubrication and orgasm remained unchanged.

**Excision of cysts:** Berg et al (2017) conducted a systematic review of observational studies. Thirteen studies of excision of cysts (not further described but likely to be clitoral or labial) were included. No intraoperative or postoperative complications were reported in the included studies. There were no recurrences of cysts at 1–6 years of follow-up (k = 6, n = 97), the anatomical appearance was good at 1–7 months of follow-up (4 studies, n = 4), and women's sexual life had improved (on self-report, no assessment tool used) at 1–7 months of follow up (6 studies, n = 49). One included study (Thabet et al 2003 - a before and after study from Egypt) used the non-validated Kasr El Aini sexual assessment questionnaire and found women having an isolated excision of cyst procedure only without other procedures experienced a worsening of their sex score (76.7 to 63.0).

**Clitoral reconstruction:** Auricchio et al (2021) conducted the most recent systematic review of clitoral reconstruction for FGM/C. Eight studies were included in this review (n = 3063). Studies differed in their reconstruction technique. On average studies reported 5.3% of patient had moderate postoperative complications (partial graft necrosis, haematoma, suture failure, moderate fever). Vulvar pain and dyspareunia before and after surgery were reported in two studies, the largest of which had a 71% loss to follow up rate at 1 year, half of patients reported an improvement of pain. Sexual function was reported in all the included studies and represented the primary indication for reconstructive surgery in most patients who suffered FGM/C. Only two of the included studies assessed sexual function using a validated scale (FSFI), both of these studies reported improvements in 5 or 6 of the 6 parameters. Three studies assessed self-image before and after surgery. One study used a validated tool (the Female Genital Self-Image Scale (FGSIS)) and reported statistically significant improvement.



Domain	Summary of judgement	Comment
Certainty of evidence	Very low	Quality and certainty assessed as 'Very Low'. All identified studies were observational. No comparative data. Identified studies frequently used un-validated tools for outcome measurement and had significant methodological flaws including large loss to follow-up.
Resources	Factor not considered	Economic evaluation was outside of the scope of this evidence review
Equity	Important issues, or potential issues not investigated	Deinfibulation assessed as 'probably increased equity'. As noted by the WHO Guideline committee, restoration of the anatomy and physiology through surgical correction should not only be seen as a treatment for health complications but also as an attempt to reinstate a violated human right, in particular the right to the highest attainable standard of health.
Acceptability	Important issues, or potential issues not investigated	Deinfibulation assessed as 'probably acceptable'.
Feasibility	Important issues, or potential issues not investigated	Deinfibulation assessed as 'probably feasible'. Providers conducting deinfibulation or other surgical correction procedures for FGM/C must be adequately trained on how to carry out the surgical procedure. Regional centres who specialise in this surgery could be established. Operating theatre time and resources would be required. Patients would be likely be added to existing elective gynaecological surgery waitlists



# Appendix F- Additional Practical Advice: Deinfibulation technique (illustration)

The following diagrams can be attributed to the *Deinfibulation Timing and Technique Guideline*, published by the Royal Women's Hospital Victoria, Australia. The guideline can be found at: <u>Deinfibulation Timing and Technique (worldssl.net)</u>. A request to obtain permission to adapt this copyrighted material was granted, as of 14/03/2023 and 24/04/2023 (RANZCOG addition to Figure 8).









## **De-infibulation at birth:**

Refer to the diagrams below



## Figure 5: Approach

When undertaking deinfibulation in the second stage of labour, the steps are the same as for the elective procedure, but some adjustment is required to compensate for the distension of the perineum as the baby's head descends.

Explain the procedure to the woman and elicit her co-operation as you work between and during contractions.







Suggested position if	Figure 8: Completing the delivery 1 The raw edges will retract as the head begins to crown. RANZCOG addition: If a medio-lateral episiotomy is required, the incision
mediolateral episiotomy is required.	position should be directed at 60 degrees to the midline.
	<ul> <li>Figure 9: Completing the delivery 2</li> <li>Control the birth of the emerging head with light downward pressure as usual, carefully monitoring perineal stretching throughout because: <ul> <li>Scarring from the infibulation may not stretch well</li> <li>There may be vaginal scarring which is not evident externally.</li> </ul> </li> </ul>
	Be prepared to perform an early medio-lateral episiotomy if there is any degree of tightness or evidence of severe scarring. A bilateral episiotomy is rarely needed nor recommended. Avoid downward midline incisions as these have the potential to extend to a 3rd or 4th degree tear.
(22) The second	<b>Figure 10: Repair after birth:</b> Suture the retracted tissue to promote haemostasis and prevent re-anastomosis of the raw wound edges. Use a fine, rapidly absorbed suture such as a 2/0 or 3/0 Vicryl Rapide on a small suture needle. A small number of interrupted sutures or a continuous suture will be adequate. Any extension of the anterior incision above the
	urethra may also be repaired at this time. Ensure that adequate analgesia is prescribed and provided and appropriate advice on wound management and body changes given to the woman.



Version	Date of Version	Pages revised / Brief Explanation of Revision
v1.0	September/ 1993	Details
V2.1	February/ 1998	WHC
V3.1	February/ 2000	WHC
V4.1	October/ 2000	MLC/WHC
V5.1	February/ 2003	MLC/WHC
V6.1	March/ 2006	MLC
V7.1	March/ 2010	WHC/RANZCOG Legal rep
V8.1	March/ 2013	WHC/Russell Kennedy Pty Ltd (statement split into two C-Gen 2a and C-Gen 2b)
V9.1	July/ 2016	WHC
V10.1	March/2020	Dr W Milford/WHC

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