Title Registration Form
Campbell Collaboration Social Welfare Coordinating Group

Title identification no. (This no. will be provided to you by the social welfare managing editor after you submit the title registration).	SW2009-12
Approval date	December 16, 2009

1. Title of review

Interventions to reduce the prevalence of female genital mutilation/cutting in African countries

2. Background and objective of this review

Female genital mutilation/cutting (FGM/C) is practised in more than 28 countries in Africa and in some countries in the Middle East and Asia. It is rooted in religious, personal and societal beliefs within a frame of psycho-sexual and social issues such as control of women's sexuality and family honour. These are, in turn, enforced by community mechanisms. There is great variation in FGM/C prevalence between and within countries, reflecting ethnicity and tradition. FGM/C is associated with numerous immediate and long term health risks and has a range of psychological, social, and sexual consequences. It is recognized by the WHO as a violation of the human rights of girls and women.

A definite decline in the prevalence of FGM/C has not been observed in spite of legislation against FGM/C in many African countries and in most Western countries that receive immigrants from countries where FGM/C is practised. Interventions to reduce the prevalence of FGM/C have used several approaches. For example, some are based on human rights frameworks while others involve training health workers as change agents, creating alternative rites and attempting to facilitate comprehensive social development. These interventions have targeted stakeholders at individual, interpersonal, community and national levels. Reported outcomes are mostly related to knowledge, attitudes, intentions and behaviours. Few studies appear to measure and report the effects of these interventions on the prevalence of FGM/C. All intervention studies identified by our systematic review earlier this year were carried out in African countries.

The research questions are:
1. What is the effectiveness of interventions to reduce the prevalence of FGM/C compared to no or any other intervention?
2. How do factors related to the continuance and discontinuance of FGM/C help explain the effectiveness of interventions designed to reduce the prevalence of FGM/C?

3. Define the population

Research questions 1 and 2: Girls and young women at risk of FGM/C, other members of communities practising FGM/C (e.g. men, religious leaders, circumcisers) and communities practising FGM/C. The review will include studies conducted in African countries.

4. Define the intervention/s

Research question 1: Interventions may consist of any activities designed to reduce the prevalence of FGM/C. These could include advocacy, education and social development in various forms (e.g., from brief educational interventions that target specific groups, such as health workers or students, to more comprehensive approaches that target whole communities practicing FGM/C). An intervention will be included if the description of the intervention was adequate to allow the review authors to establish that it aimed to reduce the prevalence of FGM/C. We will include both interventions to reduce the prevalence of FGM/C that are compared to no intervention and such interventions compared to other active comparisons.

5. Outcome/s

Research question 1:
- Primary outcomes: Prevalence of FGM/C; behaviours related to FGM/C (e.g. telling others not to cut their daughter/s).
- Secondary outcomes: Intentions regarding FGM/C; beliefs/attitudes regarding FGM/C; knowledge/awareness about FGM/C.

Research question 2:
- Primary variables: Factors that are perceived by stakeholders (see section 3 above) as related to the continuance and discontinuance of FGM/C, e.g. beliefs, attitudes about why FGM/C continues.
- Secondary variables: Sociodemographic characteristics of stakeholders endorsing and opposing FGM/C, e.g. gender, ethnicity, education, religious affiliation.

6. Methodology

Study designs:
- Research question 1: Randomized controlled trials, quasi-randomized controlled trials, controlled before-and-after studies, and interrupted time series designs will be included. One group pretest – posttest, posttest-only, and qualitative studies will be excluded.
- Research question 2: Observational quantitative studies will be included. We will also include qualitative studies, defined as studies that have used qualitative methods for data collection and analysis.

Control/comparison:
- Research question 1: No or any other intervention.

Data collection:
- Research question 1: Prevalence can be measured by physical examination, or self-report (interview or questionnaire); behaviours can be measured by observation or self-report. All other outcomes must be measured through self-report questionnaire or interview. We will accept any scale used to measure the outcomes of interest and, where possible, will report the validity of any measures / scales used.
- Research question 2: The outcomes must be collected through self-report questionnaire, interview or focus group discussions. We accept any scale used to measure the outcomes of interest.

Follow-up:
- Research question 1: As far as possible, the longest duration of follow-up for individuals included in the study will be used.

7. Review team

Lead reviewer This is the person who develops and co-ordinates the review team, discusses and assigns roles for individual members of the review team, liaises with the editorial base and takes responsibility for the on-going updates of the review	Name: Eva Denison Title: Researcher Affiliation: The Norwegian Knowledge Centre for the Health Services Address: P. O. Box 7004 St. Olavsplass City: Oslo State, Province or County: Postal Code: N-0130 Country: Norway Phone: +47 46 40 04 96 Mobile: +47 41 20 93 10 Email: Eva.Denison@nokc.no
Co-author There should be at least one co-author	Name: Rigmor C Berg Email: Rigmor.Berg@nokc.no Affiliation: The Norwegian Knowledge Centre for the Health Services
Co-author	Name: Simon Lewin Email: Simon.Lewin@nokc.no Affiliation: The Norwegian Knowledge Centre for the Health Services
Co-author	Name: Jan Odgaard-Jensen Email: Jan.Odgaard-Jensen@nokc.no Affiliation: The Norwegian Knowledge Centre for the Health Services

8. Roles and responsibilities

Please give brief description of content and methodological expertise within the review team. It is recommended to have at least one person on the review team who has content expertise, at least one person who has methodological expertise and at least one person who has statistical expertise. It is also

recommended to have one person with information retrieval expertise. Please note that this is the *recommended optimal* review team composition.

- *Content*: Eva Denison, Rigmor Berg. Eva Denison has several years of primary research experience in behavioural medicine. She has contributed to a published systematic review and is currently working on several reviews, including mixed methods syntheses. Rigmor C. Berg has several years of primary research experience in sexual health. She has contributed to several published quantitative reviews and also has experience in conducting mixed methods syntheses.

- *Systematic review methods*: Simon Lewin, Rigmor Berg, Jan Odgaard-Jensen, Eva Denison. Simon Lewin is an editor for the Cochrane Effective Practice and Organisation of Care Review Group and the Cochrane Consumers and Communication Review Group. He has contributed to several published reviews and also has experience in conducting syntheses of qualitative studies.

- *Statistical analysis*: Jan Odgaard-Jensen. Jan Odgaard-Jensen is a statistical editor/advisor for the Cochrane Effective Practice and Organisation of Care Review Group and the Cochrane Methodology Review Group. He has contributed with statistical support to several published systematic reviews. He has also experience in analysis of data from primary research.

- *Information retrieval*: Research librarians at the Norwegian Knowledge Centre for the Health Sciences.

9. Potential conflicts of interest

Denison and Berg are authors of a systematic review of the effectiveness of interventions to reduce the prevalence of female genital mutilation/cutting that was published at the Norwegian Knowledge Centre for the Health Services in November 2009. Odgaard-Jensen was the statistical expert in the review.

10. Support

No.

11. Funding

We have got a USD 100,000 grant from The International Initiative for Impact Evaluation (3ie) in August 2009 for carrying out the proposed review.

11. Preliminary timeframe

We intend to submit a draft protocol no later than end of January 2010, pending approval by 3ie (who requests a draft protocol by the end of December 2009).

Title registration submission date: December 8 2009.

Title registration approval date: 16 Dec.