Revised Detailed Project Description

Title

Improving Care for Women and Girls who have undergone Female Genital Mutilation (FGM): Qualitative Evidence Synthesis

Qualitative Evidence Synthesis: Proposal Summary

Background

Female Genital Mutilation (FGM) refers to all procedures that involve the partial or total removal of the external female genitalia or other injury to the female genital organs for non-medical reasons (1). FGM is associated with significant negative medical, psychological, sexual and social consequences and, though illegal, is a growing problem in the UK. In 2014, a National FGM Prevention Programme was initiated and there is a strong policy drive across the NHS to improve the identification and care of women and girls have who undergone FGM. There are currently only 14 specialist FGM clinics in England and Wales, hence many women lack access to appropriate services. Currently, women with FGM are identified primarily in the context of maternity services where care can be highly variable, dependent on the interests of individual staff, and often exclusively medically-focused (rather than addressing other health needs). There is a lack of information on FGM care in non-maternity settings. Evidence indicates that health professionals lack confidence around FGM, and that, even when trained, they do not always follow guidance. Reasons for this are unclear. Research suggests that women/girls experience significant barriers to seeking and receiving care, and are often unhappy with care received. Recent guidelines suggest that NHS care for women/girls who have undergone FGM should comprise a multi-agency approach and should include services that address their multiple and complex health needs. There is a recognised lack of coherent evidence with which to inform service development however, with no intervention studies currently available that could illuminate service design. In order to address this gap and to lay the foundations for future research in this area, we propose to undertake 2 systematic reviews of relevant qualitative evidence.

Aim

To synthesise evidence on experiences, needs, barriers and facilitators around seeking and providing FGM-related care from the perspectives of: (i) women and girls who have undergone FGM, and (ii) health professionals.

Methods

A thematic synthesis approach will be adopted. All steps will involve two or more reviewers. A systematic search of published literature will be conducted including 7 databases and hand searching of reference lists. We will also search for relevant grey literature and unpublished research reports using established grey literature databases. We will include papers from high income OECD countries (as these are most relevant to a UK context), with no date or language restrictions. Papers will be critically appraised and data extracted using JBI-QARI tools and NVivo software. Findings will be synthesised using inductive thematic analysis. Confidence in the review findings will be assessed by the CERQUAL approach. The reviews will be conducted sequentially and reported separately following ENTREQ guidelines. However, a discussion section of the final project report will compare, contrast and integrate both sets of review findings to generate recommendations for policy, practice and training. PPI involvement is integral throughout.

Dissemination

A stakeholder event will inform recommendations which will be used to produce a report, publications and a best practice guide.

Background

Introduction: FGM - What is the Problem?

Female Genital Mutilation (FGM) refers to all procedures that involve the partial or total removal of the external female genitalia or other injury to the female genital organs for non-medical reasons (1). FGM is associated with significant negative physical, psychological and sexual health consequences. FGM is practised in 28 countries across North and sub-Saharan Africa and in parts of the Middle East. In a context of increased migration to the UK from these countries, the need to address FGM within the NHS is already significant and is expected to increase (2-4). Evidence suggests that women and girls who have undergone FGM experience many barriers to accessing appropriate care within the UK (5). Likewise, research suggests that health professionals lack knowledge, experience and confidence in addressing FGM-related issues (6). FGM-related services in England and Wales are reported to be fragmented and highly variable, lacking clear referral or care pathways, and difficult for women/girls to access (4, 7, 8). FGM therefore, presents a significant and growing health issue for the NHS and there is a need to develop more and better services in this area (7). This proposal seeks to inform the development of new models of FGM-related health service delivery and staff training through syntheses of evidence regarding the views and experiences of service provision and quality of care from the perspectives of: (i) women/girls who have undergone FGM and, (ii) health professionals.

Size of the Problem

Estimates of women and girls within England and Wales who have undergone FGM show that it is a significant problem, with over 137,000 women/girls directly affected (3):

- 10,000 girls under 15 years,
- 103,000 women and girls aged 15-49 years
- 24,000 women over 50 years.

These figures are expected to increase as detection rates improve. For example, latest figures show that, in a 4 month period - September 2014 to January 2015 - over 2,600 patients (in whom FGM was first identified) were treated in the NHS (9). Additionally, it is estimated that approximately 60,000 girls aged 0-14 years have been born to mothers who have undergone FGM and may themselves be at risk of the procedure (3). Latest figures show that all major urban areas in the UK will have significant populations affected by FGM, with most areas of the country affected to some extent (3).

Health Consequences of FGM

FGM is associated with significant negative physical, psychological and sexual health sequelae (10). In the short term, these include infection, urinary retention or injury to other tissues (e.g. vaginal fistulae). In the longer term, they include psychological problems, post-traumatic stress disorder, painful intercourse and other sexual problems, relationship problems, chronic pain, chronic infections, infertility and complications in childbirth. It is essential that affected women and girls have access to services that can identify and meet these multiple complex health needs, and that include mental as well as physical healthcare provision (7, 11).

Costs of FGM

There is a lack of data on the economic burden of FGM or on the costs of different models of health service provision.

Legal and Policy Context of FGM

FGM has been illegal in the UK since 1985 and is considered a form of abuse (12) (FGM performed outside the UK on UK nationals or residents was criminalized through an additional Act in 2003). In 2014, the UK

Government published a declaration to end FGM, and initiated a National FGM Prevention Programme. A series of policy changes have been introduced as part of this programme: mandatory recording, mandatory reporting and use of an FGM Risk Information System (RIS).

Acute NHS Trusts have had to record all cases of FGM within an FGM Prevalence Database since April 2014. This database has now been re-named the FGM Enhanced Dataset (an Information Standard - SCCI2026). The Information Standard requires clinicians across all NHS healthcare settings to record in clinical notes when patients with FGM are identified, and what type it is (patient consent is not required). It became mandatory for all Acute Trusts to collect and submit the FGM Enhanced Dataset from July 2015 and all Mental Health Trusts and GPs from October 2015. Community services within Mental Health Trusts can also participate. Sexual Health and GUM clinics do not need to submit FGM information to HSCIC (but the legal obligation to appropriately share information for safeguarding purposes still applies).

In addition to mandatory recording, from October 2015, a new statutory duty has been introduced through the Serious Crime Act requiring all regulated health professionals to report cases of FGM in girls under the age of 18 to the police (known as ‘mandatory reporting’). In addition, a new national health system, the FGM Risk Information System (FGM RIS) was introduced in 2015, aiming to support safeguarding of girls up to 18 years. The system allows health professionals to add an indicator on a girl’s electronic summary care record to highlight that she may be at risk. This information can then be confidentially shared amongst health professionals. To set the indicator, professionals are required to seek parental consent.

These measures signal a new policy drive across the NHS to address FGM prevention (as well as care) and to significantly improve the identification of women and girls have who undergone FGM (4, 7, 11). However, all of the above measures place an additional burden of work upon health professionals and require additional training and support to understand the legal complexities, the logistics of how to use the systems, the sensitivities of discussing FGM with patients/communities and greater awareness of local safeguarding pathways. The ways in which these changes will impact upon the experience of healthcare delivery from a patient or professional’s perspective are, as yet, unclear. However, examining the existing evidence base on FGM, will help to identify some of the potential implications of these new policies for practice and future research.

FGM-Related Service Provision

Currently, there is limited evidence regarding the availability and accessibility of FGM-related care across the UK. However, there are strong indications that it is it poorly coordinated and sub-optimal (7).

Maternity Services

Traditionally, FGM-related care within the NHS has been provided mainly in the context of maternity services. Specialist clinics run by specialist midwives have been established in a limited number of maternity services, which provide medical interventions as well as access to counselling and other psychological services. The majority of maternity services do not offer this specialist provision however (PPI/Research Advisory Group Opinion). In these non-specialist settings, care tends to be focused primarily on medical management (for example, de-infibulation) with limited attention to other health needs or to considering the FGM prevention agenda (7, 13). Accurate information on the accessibility and quality of FGM related care within maternity services is difficult to estimate as there are no up to date statistics available. A 2006 national survey (now somewhat out of date) of Heads of Midwifery (87% response rate) suggested that FGM specialist service provision is inadequate and highly varied across the country. For example, the survey showed that only 11.7% of maternity services could provide access to specialist gynecological services, only 3.9% provided specialist antenatal clinics and only 14.3% had provided additional training for midwives (14).

The picture may have improved since then, however a 2013 audit (a retrospective obstetric notes review) of a large Central London teaching hospital gives cause for concern. This hospital had clear FGM-related protocols and policies as well as a staff training programme, but the audit revealed significant gaps in the provision of safe and appropriate care (15).

FGM-Services in Non-Maternity Settings

There is a lack of evidence on FGM management in non-maternity settings. However the view of the expert PPI/Research Advisory Group for this project is that communication about, or management of, FGM in non-maternity settings is currently very poor, with a lack of clear referral or care pathways, and with health professionals lacking confidence and experience around FGM. Access to any non-maternity focused specialist FGM services is, therefore, limited and highly variable across the country. A report in March 2014 suggests that there are just 14 specialist FGM clinics across the UK. Many of these are actually based within maternity services and referral pathways from other services are not well established. Moreover, the majority of these specialist clinics (n=9) are located in London, with the remaining 5 based in other urban areas (7, 16). Many FGM-affected communities therefore, currently do not have access to specialist services, particularly those living in rural areas. This situation creates inequalities in access to care, as highlighted by a recent report: *"women and girls from affected communities living in low prevalence areas are likely to be more isolated and in greater need of targeted support"* (2:page 1).

FGM Service Development

In the current policy and legislative climate (with a renewed focus on prevention as well as care), health professionals across **all** sectors, especially primary and maternity care, are required to be knowledgeable about FGM and to have the requisite skills to deal with affected women/girls and communities in a sensitive and appropriate manner (4, 7). This is particularly important in order to ensure that healthcare encounters are not only focused on supporting women/girls who are living with the consequences of FGM, but can also be used to address the sensitive issue of prevention (7). To achieve this agenda, health professionals need a high level of skill and awareness of women/girls' needs, problems with, and experiences of, FGM (13). To this end, several professional and multi-agency guidelines have recently been published calling for greater levels of specialist and holistic service provision, clearly delineated FGM-related care pathways and clear referral pathways, backed up by enhanced training of health professionals (4, 7, 8, 11, 17, 18). Currently, Local Authorities and Clinical Commissioning Groups (CCGs) in England and Wales are being required to respond to commissioning guidance around FGM which calls for a comprehensive multi-agency approach for FGM prevention and care (4). The guidance recommends that FGM services broaden their focus to include provision for mental as well as physical healthcare (4). The guidance points out that there is *"limited awareness of how to commission services in this area",* but nonetheless calls for services to be *"sensitive and appropriate*" (4:page 2).

Evidence Explaining Why this Research is Needed and Why Now

Currently, there are limited resources to inform FGM-related service development. Much of the existing body of research relates to understanding the practice of FGM (19), the prevention of FGM (20-22) and the psycho-social and clinical consequences of FGM (10, 23-25). Evidence on the effectiveness of different models of care for FGM is currently lacking. A Cochrane systematic review on interventions for improving (clinical and psychosocial) outcomes for pregnant women who have experienced FGM found no RCTs or quasi-experimental studies (26). A recent expert commentary on FGM identified key gaps in the evidence on clinical management and on models of service delivery (27). In the absence of high quality evidence on the clinical or cost-effectiveness of different types of service provision, decision making around FGM services must be informed by other forms of evidence (27). Hence, this project proposes to bring together existing qualitative evidence on lay and professional experiences of, and perspectives on, FGM care, and to relate this to the UK context. In doing so, it would provide a vital resource for evidence informed FGM-related service development and training. Qualitative research can provide insights into factors influencing service acceptability, appropriateness and meaningfulness, and on micro and macro level organizational and contextual issues that influence service use and delivery (28-30). Qualitative evidence syntheses around FGM would generate rich data and deep understanding with which to inform new service initiatives and the content and structure of staff training resources (31, 32).

Understanding Stakeholder Perspectives to Inform Service Development and Training

Given the complexity of service development and the sensitivity of FGM, it is imperative to take into the account the views of all stakeholders. We propose therefore, to examine the experiences of women and girls who have undergone FGM and healthcare professionals in two separate systematic reviews, and then bring these together to generate key recommendations for policy and practice.

Health Professional Perspectives

An initial scoping literature search has found three existing systematic reviews on health professional perspectives around FGM (6, 33, 34). These have identified a significant lack of knowledge, confidence and competence around FGM and have concluded that more and better training is required. These reviews provide useful evidence but still leave gaps in our understanding. Two issues in particular are problematic. First, the reviews have primarily focused on quantitative evidence and, whilst highlighting trends, have been unable to provide a more nuanced picture of barriers and facilitators of service provision. The need to consider wider factors in understanding health professionals' practice is illustrated by a recent study (cited above) of FGM management in a large London maternity unit (15). This found that, in spite of the existence of protocols, guidelines and training, clinical care for women/girls with FGM was sub-optimal (15). The maternity unit had access to a FGM specialist service, but 41% of women with FGM were not identified until they arrived in the labour ward. Hence, even though a specialist service existed, it was not being optimally used to benefit women with FGM, and a significant percentage of opportunities were missed to provide women with specialist care. Similar findings were reported from a study in a maternity unit in Switzerland where, in spite of staff training and the existence of clear guidelines, FGM was correctly identified and managed in only 34 (26.4%) of 129 cases reviewed (35). The reasons for this lack of adherence to protocols are unclear – hence we suggest that reviewing the related qualitative evidence may shed greater light on organizational and personal factors that may influence health professionals' views and behavior in this area (36-46). Second, the existing reviews on health professionals have all taken a multi-context (or 'lumping') approach to the evidence (47, 48) and have included research from high and low income settings across the world. Many key themes from these reviews therefore are drawn from evidence from very different contexts and are not easily transferable to a UK or high income setting. For example, the UK has a strong, well-resourced public health system and FGM is primarily found within its migrant populations. FGM care and its challenges in a UK setting will, therefore, be linked to other challenges around providing care for migrant populations (such as lack of familiarity with cultural norms, NHS systems or communication issues). This is a very different situation compared with countries where health systems are weak, where FGM is more prevalent, where health providers may have greater exposure to, and indeed, may even be complicit in, FGM. In order to address these dual shortcomings of the existing reviews, the proposed systematic review of health professionals will focus specifically on qualitative evidence and will only include evidence from high income OECD contexts.

Perspectives of Women/Girls who have undergone FGM

An initial scoping literature search found no systematic reviews of women/girls' views and experiences on FGM-related health-seeking or of FGM-related healthcare, although several primary studies have been published on this topic (49-56). This is a key gap. In the UK context, evidence suggests that several barriers to FGM-related care-seeking exist from the perspective of women/girls. Some of these relate to accessibility in terms of not knowing where to go or who to speak to, and not being aware of any specialist provision (5). Understanding the nature of these barriers is critical for staff training and for service development in terms of promoting timely use of services and also for prevention. For example, the latest Commissioning Guidelines (2015) state that "*there is recognition that, if services were on offer and known to exist, many more women may seek support and care in advance of marriage and/or having sex. Consideration must be given to an effective and sustainable structure for the future*" (4:page 10).

Other barriers highlighted in existing research relate more directly to quality of care such as feeling judged or misunderstood or feeling unable to communicate about FGM related problems (5, 57-60). There is an urgent need, therefore, to bring the UK qualitative evidence together and to combine it with relevant evidence from other high income countries facing similar challenges in order generate a more in-depth understanding of factors affecting service use, effective communication and perceived quality of care. A synthesis of this evidence would inform training initiatives and would clearly show which aspects of service provision are considered important from the perspective of affected women/girls. It would also highlight gaps where future research is needed.

Reviews in Progress

An initial scoping literature search has identified two published protocols of reviews in progress. One seeks to assess health professionals' knowledge and clinical competence, but is including only quantitative evidence (61). The other seeks to assess the effect of providing educational interventions to girls and women living with FGM on their body image and care seeking behaviour (62). There are very different topics to the reviews set out in this proposal.

Conclusion: Need for Evidence Synthesis

In conclusion, NHS organizations are being required to develop specialist care and support for women/girls who have undergone FGM. Legal reporting requirements and the need to address prevention means that many health professionals previously unfamiliar with FGM will increasingly be required to encounter it within their everyday practice and require additional training (7, 13). Current FGM-related services are unevenly distributed across the country, are poorly coordinated and deliver care of unknown quality. A spokesperson for the national FGM Clinical Group (Yana Richens) recently stated that: "*the care provided to women, both in the UK and internationally, tends to be anecdotal and is not all evidenced based….All care provided to women impacted by FGM needs to be consistent, based on clear evidence and delivered by trained health care professionals, who have access to evidence-based guidelines"* (63). This proposal to undertake separate systematic reviews of the qualitative research on lay and provider experiences around FGM-care would produce essential insights to inform decision making, training, practice and policy in this area.

Overall Research Aim

To undertake two separate systematic reviews of qualitative evidence in order to understand the experiences, needs, barriers and facilitators around seeking and providing FGM-related care from the perspectives of: (i) women and girls who have undergone FGM, and (ii) health professionals. Review results will be integrated in a final report: (i) to make recommendations for NHS training, service development and improvement, (ii) to pinpoint key dimensions of quality of care that can be operationalised for use in future service improvement evaluations or patient reported outcome measures, and (iii) to identify areas where further research is required.

Aim of Review 1 (Experiences of Women and Girls who have undergone FGM)
To explore the experiences of FGM-related healthcare across the life course for women and girls who have undergone FGM.

Objectives of Review 1
From the perspective of women and girls who have undergone FGM: -

- to illuminate factors that influence FGM-related healthcare seeking and access to health services across the lifecourse
- to explore how quality of care is perceived and experienced in different healthcare settings and with different groups of healthcare professionals
- to characterise and explain elements of service provision considered important for the provision of acceptable and appropriate healthcare
- to describe factors perceived to influence open discussion and communication around FGM (including prevention) with health professionals

Aim of Review 2 (Experiences of Health Professionals around FGM Care)
To explore the views on, and experiences of, all cadres of health professionals in providing care for women/girls who have undergone FGM.

Objectives of Review 2
From the perspective of health professionals: -

- to explore how quality of care for women/girls who have undergone FGM is perceived in different healthcare settings and amongst different professional groups
- to characterise and explain elements of service provision considered important for the provision of high quality care to women/girls who have undergone FGM
- to illuminate factors perceived to facilitate or hinder appropriate provision of care for women and girls who have undergone FGM
- to identify processes and practices perceived to influence open discussion and communication around FGM (including prevention) with women/girls from affected communities

Research Design

The two proposed systematic reviews will be syntheses of qualitative research evidence, conducted using a thematic synthesis approach (31), and will follow the guidance set out by the Cochrane Qualitative and Implementation Methods Group (64, 65). The overall design for each review will be the same and will be reported as per ENTREQ Guidelines (66). A final project report will critically compare and consider the findings of each review and bring these together to identify key recommendations for policy and practice.

Methodology

The research aims and objectives have been constructed to identify insights about lay/health professional experiences of FGM-related healthcare and perceived appropriateness and acceptability of services. As noted above, these are questions best answered by qualitative research (28, 29) – hence the specific focus on qualitative evidence. Indeed, it is increasingly recognized that qualitative evidence syntheses have an essential role to play in understanding barriers and facilitators of service initiatives (65, 67). An initial scoping of the literature has identified a lack of intervention studies around FGM (26). As per the MRC complex interventions guidance, a first step in developing new interventions or evaluation measures is to conduct a systematic review of the evidence (30). The proposed qualitative systematic reviews will, therefore, yield essential insights for future research and intervention development in this area.

There are many possible approaches to qualitative evidence synthesis, with most discussions in this area characterizing the different types along a continuum between aggregation and interpretation (68). Where the purpose of a synthesis is to generate new theoretical insights, a highly interpretive approach such as meta-ethnography may be most suitable, informed by an idealist epistemological stance. However, where the purpose is to inform policy or practice a more aggregative or thematic approach informed by a realist epistemology is often advocated (69). The latter is also suggested in cases where the existing evidence is likely to be descriptive (as in much health services research) rather than highly theoretical or conceptual (31). An initial scoping of the literature suggests that this is the case for the proposed syntheses. A thematic synthesis approach involves using thematic analysis techniques to identify key themes from primary research studies (70, 71). Synthesis involves an iterative and inductive process of grouping themes into overarching categories and exploring the similarities, differences and relationships between them. Thematic synthesis explicitly aims to move beyond generating a list of descriptive themes (as would be the case in meta-aggregation) in order to identify new, higher order, analytical insights that can contribute to new understandings of a phenomenon. Review recommendations however are clearly formulated to inform policy and practice. As such, it is considered the most suitable approach for the two proposed systematic reviews (64).

Methods

Literature Searching and Study Selection

A systematic search of published literature will be conducted across databases that cover relevant disciplinary areas (including Medline, Embase, ASSIA, PsycINFO, CINAHL, POPLINE, Web of Science) using index-term and text-based searches. Key MeSH terms are: *exp Circumcision, Female/ exp Genitalia, Female/ and exp Medicine, Traditional/*. We will also search for relevant grey literature, for example, theses and unpublished research reports using established grey literature databases, websites and repositories (see Appendix 1 for a full description of the search strategy). Hand searching of reference lists and citation searching will be employed to complement the structured searches. Searches will be set to include “in process” searching which includes literature either in the process of being assigned a MeSH subject heading, or which has not been assigned because it does not fit existing terms.

Alerts will be set on all the major databases so that any new studies can be identified immediately and added into the review, on an on-going basis (i.e. searching will be an iterative rather than one-off process). In addition, alerts will be set up for key authors and citations through each individual database.

We will also regularly seek recommendations to identify research that is ongoing or not yet published from the Research Advisory Group. The literature search will be presented in a flow diagram as per PRISMA Guidelines (72).

Titles and abstracts will be independently screened for inclusion by 2 reviewers, with any discrepancies resolved by recourse to a third reviewer. Studies considered for inclusion will be retrieved as full text articles and independently screened by 2 reviewers. As above, any discrepancies of opinion will be resolved through discussion with a third reviewer. Final decisions about inclusion will be agreed by the whole review team, and reasons for exclusion will be documented. Foreign language studies that meet the eligibility criteria will be included. Abstracts will be translated to determine eligibility. Where they are deemed to be eligible, the full text will be retrieved, translated and then further assessed for final eligibility.

Inclusion Criteria

Population

Review 1: Women and girls who have undergone any form of FGM – as defined by WHO (1).
Review 2: Any cadre of healthcare professionals or healthcare students who are involved in the care of women/girls who have undergone FGM.

Phenomenon of Interest

Review 1: experiences of FGM-related healthcare across the life course.
Review 2: views on, and experiences of, providing care for women/girls who have undergone FGM.

Context/Setting

The reviews will be limited to studies that have been undertaken in high income OECD country settings (73). The OECD grouping includes the majority of countries with healthcare services that share similar social/political values and levels of resourcing to the UK and therefore whose research findings could be transferable to the UK. In addition, in terms of migration, high income OECD countries tend to be 'destination' countries and share a need and a challenge to adapt their health services to the needs of communities who practise FGM. 'High income' will be defined according to World Bank criteria (74). Both reviews will include studies from any healthcare setting, sector or context within a high income OECD country.

Study Design

Any type of qualitative study and any type of mixed methods study that reports qualitative findings.

Language

The review will include papers in any language.

Date

No date limit.

Exclusion Criteria

Context

Studies relating to middle and low income countries or non-OECD high income countries.

Participants

Review 1: Studies not related to women or girls' experiences of healthcare or health professionals.
Review 2: Studies that do not include the views/experiences of healthcare professionals or students

Study Design

Quantitative study designs and papers that do not report empirical research (e.g. commentaries or opinion pieces).

Assessment of Sufficiency of Evidence

Following the literature search and study selection stages (as described above), an assessment will be made of the sufficiency of evidence for each review. There is no established guidance on this process for qualitative evidence syntheses. The issue will be discussed by the project team and the project advisory group. If concerns are identified, the NIHR will be notified.

Quality Assessment

The role of critical appraisal in qualitative evidence synthesis is contested and there is lack of agreement over: (i) the appropriateness of excluding studies, (ii) the potential impact (or not) of excluding eligible papers on review outcomes, and, (iii) the criteria on which quality should be established (75-78). For these reasons, the team proposes to take an inclusive approach to critical appraisal, using the appraisal process to enable an in-depth understanding of each paper and to facilitate a critical, questioning approach to the study findings (79). Studies will not be excluded on the basis of quality, rather, the quality assessment will be used: (i) to judge the relative contribution of each study to the overall synthesis, and, (ii) to assess the methodological rigour of each study as part of a process of assessing confidence in the review findings (80). The quality of included studies will be assessed independently by 2 reviewers using the Joanna Briggs Institute Qualitative Assessment and Review Instrument (JBI-QARI) (81, 82). This tool has been found to be more coherent and more sensitive to assessment of validity than other commonly used tools (83).

Data Extraction and Management

Details of each of the included studies will be extracted using a Joanna Briggs Institute data extraction template, including details of the phenomenon of interest, population, context, study methodology, methods, and outcomes of significance to the review questions and specific objectives (81, 84). If studies lack relevant detail, authors will be contacted to provide further information. Findings from the studies will be extracted, following the approach described by Thomas & Harden (2008) (31). Here, the entire ‘results’ or ‘findings’ sections in study reports will be considered to constitute the ‘findings’ of a primary research study. These sections will be entered into NVivo software and then analysed. Data extraction will primarily be undertaken by one reviewer, however a second and third reviewer will extract findings from a sub-sample of papers (20% each) and the team will have regular meetings to cross-check for inter-rater reliability and to ensure consistency of approach.

Synthesis within each Review

Synthesis will follow the principles of inductive thematic analysis (70, 71), and will comprise 4 stages: (i) intensive and repeated reading of all the included studies to gain an overall picture of their context and key findings, (ii) free line by line coding of the findings of the primary studies, (iii) organisation of free codes into related areas to identify ‘descriptive themes’ and to identify the relationships between them, and (iv) the development of higher order ‘analytical themes’ which constitute the key findings of the review. If appropriate, this latter stage may involve the development of models or frameworks to identify and display relationships between, and patterns within, the analytical themes. Where possible, the analytical themes will be formulated as ‘directive’ findings indicating clear messages and/or suggesting clear lines of action for policy and practice (81). The synthesis stage will involve two reviewers, working together, who will be assisted in formulating emerging interpretations through regular meetings with other research team members. The preliminary synthesis will also be shared at a meeting of the Research Advisory Group.

Assessment of Confidence: CERQUAL

Assessment of confidence in each of the review findings will be undertaken using the CerQual approach (80). CerQual is a relatively new, transparent method for assessing confidence in the findings in qualitative evidence syntheses - akin to the GRADE approach for establishing confidence in evidence of effectiveness for each outcome in a quantitative review (85). The assessment of confidence in the evidence for an individual review finding considers four elements: (i) methodological limitations (the extent to which there are problems in the design or conduct of primary studies that contributed to evidence of a review finding); (ii) relevance (the extent to which the body of evidence from the primary studies supporting a review finding is applicable to the context specified in the review question); (iii) coherence (whether the finding is well grounded in data from the primary studies and can provide a convincing explanation for pattern found in the data); and (iv) adequacy of data (an overall determination of the degree of richness and quantity of data supporting a review finding) (80:2-4). Based on the assessment, each review finding will be assigned one of four levels of confidence: high, moderate, low and very low.

Reporting and Integration across Reviews

Each review will be reported separately and will follow the ENTREQ Statement Guidelines to enhance transparency in reporting qualitative evidence synthesis (66). Both reviews will be included in an overall project report which will include a final discussion section in which findings from both reviews will be summarized, compared, contrasted and critically discussed. The key foci of the existing body of research will be clearly mapped and key gaps identified. Where possible and where relevant, key issues will be identified for which a comparison or synthesis of findings from both reviews can provide greater explanatory power or enable new insights to emerge. The construction of recommendations for the final reports will be based upon a highly consultative process, involving all research team members and the Research Advisory Group. The recommendations will pay particular attention to the relevance of the review findings in the context of mandatory reporting, the FGM RIS and mandatory recording.

Registration with PROSPERO

Both review proposals have been registered separately with the PROSPERO database and will be updated on progression (86, 87).

Project Outputs

The outputs of this project will be two qualitative systematic review reports, with clear recommendations for staff training, policy, practice and future research. There will also be a final project report which brings the findings from Review 1 and Review 2 together in order to generate new insights into the care of women/girls who have undergone FGM and to identify overarching recommendations. In particular, the review findings will be discussed in light of recent UK policy changes around mandatory reporting/recording and implications for future research and service development will be addressed. In addition, through a process of knowledge translation (see below), the review findings will be formulated into best practice guidelines and publications for different stakeholder groups.

Project Contributions

Review 1: (Perspectives and Experiences of Women/Girls who have Undergone FGM)

The outcomes of this review will make several important contributions. First, it will add new knowledge in terms of identifying key aspects of service delivery and care that are valued by women/girls who have undergone FGM. This information can be used to inform service design and the development of patient reported outcome measures regarding quality of care. Second, the review findings can be used in best practice guidelines and training for health professionals to improve quality of care in service delivery. Third, the review will identify factors that influence FGM-related care seeking and will point to ways in which services can address these factors to promote timely care and to promote early communication about FGM for the protection of future generations. Finally, the review will identify key gaps in current knowledge and will inform a future research agenda to improve women/girls' experiences of FGM-related care.

Review 2: (Health Professional Perspectives and Experiences of FGM-related Service Provision)
The outcomes of this review will, likewise, make several important contributions. First, it will provide new knowledge regarding which aspects of service design are considered important by health providers and why. It will identify factors considered to promote or hinder communication and care around FGM and will identify suggestions for service improvements. These insights can be used to inform service design and training as well as best practice information guidelines. Second, the review findings will identify key gaps in current knowledge and will inform a future research agenda to improve FGM-related service delivery.

Dissemination

Dissemination will have two phases ensuring that the project findings reach a wide range of UK stakeholders (e.g. health professionals, commissioners, educators) and, therefore, have the potential to influence service development/education initiatives across the country. Dissemination activities will be carefully targeted to meet the particular needs of different stakeholder groups and recommendations will be tailored to be target-group specific. Tailoring of information and recommendations will be facilitated by using a phased and consultative approach – as described below.

First, there will be a stakeholder engagement event, inviting a wide range of national stakeholders (including researchers, educators, clinicians, commissioners and community organisations). The review findings will be presented and there will be round-table discussions on key implications for practice, policy, education and research. This event will include specific discussion on the implications of the review findings in the context of recent policy changes around FGM in the UK. The recommendations and discussions from this event will feed into the next phase.

Phase two will involve production of outputs aimed at various audiences, as described below:

- ACADEMIC COMMUNITY: (i) one paper based on each of the reviews (i.e. two in total) published in open access international peer reviewed journals (such as BMC Women's Health); (ii) conference presentations (e.g. RCN research conference, RCM annual conference, RCGP annual conference).
- HEALTH PROFESSIONALS: (i) best practice information sheet highlighting the key review findings, with suggestions/top tips on providing appropriate care, (ii) short articles in professional 'trade' journals (e.g. Nursing Standard, GP weekly) with wide readership.
- FGM-RELATED COMMISSIONERS/POLICY MAKERS: short summary report highlighting key findings from both reviews and recommendations for service delivery and training initiatives.
- FGM-RELATED COMMUNITY ORGANISATIONS: (i) plain English short summary report, highlighting review findings and key action points relevant to community advocacy and action, (ii) short report in Mojatu's regular publication and available through its website (Mojatu is the community organization led by one of the co-applicants, Valentine Nkoyo).

Additional knowledge mobilization will be facilitated through the professional networks of the research team and the Research Advisory Group which includes representatives from a range of different health professional groups, academics, educationalists, FGM-related professional leads, community organizations, NHS commissioners and, importantly, a member of the national FGM clinical group.

Next Steps

Based on the review findings, the research team aims to develop future research proposals in this area. The collaborative and consultative process of conducting the review will build new knowledge networks around

FGM, bringing together a wide range of stakeholders and building capacity within the NHS and community organisations for future participatory initiatives in developing service provision/research around FGM.

Project Management

The project will be managed and led by the Principal Investigator (PI), Dr. Catrin Evans. A project Gantt Chart will be developed and key milestones identified. Dr. Evans will work closely with a full time experienced Research Assistant (RA) who will be appointed to undertake many of the project activities. Training for team members less familiar with systematic reviewing will be provided.

Approval by Ethics Committee

This project does not involve collection of any primary data or access of any data bases containing patient information. Ethical approval is not required.

Patient and Public Involvement (PPI)

Patient/public involvement is built into every stage of this project and has been key to the development of this proposal. By adopting a participatory collaborative approach to this project, we anticipate that it will engage with, and involve, relevant community members and groups at every stage of the review, reflecting their views, needs and issues – and drawing upon their skills, networks and expertise. Relevant training on systematic review principles and processes will be provided to the various PPI representatives.

Plan of Investigation and Timetable

Months	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**
Tasks													
Training in systematic review principles and processes	■	■											
Review 1&2 **Literature search**	■	■											
Review 1&2 **Screening & selection of papers**	■	■											
Review 1&2 **Assessment of sufficiency of evidence (review cut-off point)**		■											
Review 1 **Quality assessment**		■	■										
Review 1 **Data extraction**			■										
Review 1 **Synthesis**				■									
Review 1 **Report writing**					■								
Interim Progress Report						■							
Review 2 **Quality assessment**						■	■						
Review 2 **Data extraction**							■						
Review 2 **Synthesis**								■					
Review 2 **Report writing**									■				
Final synthesis & report writing										■	■		
Stakeholder dissemination event												■	■
Dissemination												■	■
Project Team Meetings	■	■	■	■	■	■	■	■	■	■	■	■	■
Project Advisory Group Meetings	■					■						■	

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