Appendix 1: FSRH Clinical Guideline Development Process

Who has developed the guideline?

This guideline is produced by the Clinical Effectiveness Unit (CEU) with support from the Clinical Effectiveness Committee (CEC) of the Faculty of Sexual & Reproductive Healthcare (FSRH). The FSRH is a registered charitable organisation which funds the development of its own clinical guidelines. NHS Lothian is contracted to host the CEU in the Chalmers Centre and to provide the CEU’s services using ring-fenced funding from the FSRH. No other external funding is received. Chalmers Centre supports the CEU in terms of accommodation, facilities, education, training and clinical advice for the members’ enquiry service. As an organisation, NHS Lothian has no editorial influence over CEU guidelines, although staff members may be invited to join the CEU’s multidisciplinary guideline development groups (GDGs) in an individual professional capacity.

Development of the guideline was led by the secretariat (CEU staff) and involved the intended users of the guidelines (contraception providers) and patient/service user representatives as part of a multidisciplinary group. The scope of the guideline was informed by a scoping survey conducted among FSRH members and among service users from two sexual and reproductive health services (Oxfordshire Sexual Health Services, Oxford/Banbury, England and Aneurin Bevan University Health Board, Newport/Blackwood, Wales) across the UK. The first draft of the guideline was produced based on the final scope of the guideline agreed by the GDG. The first draft of the guideline (version 0.1) was reviewed by the GDG in person and a revised draft guideline (version 0.2) was produced in response to comments received, after which it was sent to international and UK-based external independent reviewers suggested by the GDG at the face-to-face meeting. A further revision generated a version of the draft guideline (version 0.3) which was placed on the FSRH website for public consultation between 14 December 2018 and 21 January 2019. The revised draft guideline (version 0.4) was sent to the GDG for final comments and to reach consensus on the recommendations (details of this process are given later).

Below is the list of contributors involved in the development of this clinical guideline.

Guideline development group (GDG) secretariat

- Dr Chelsea Morroni
- Dr Sarah Hardman
- Professor Sharon Cameron
- Mrs Valerie Warner Findlay

Deputy Director, Clinical Effectiveness Unit
Co-Director, Clinical Effectiveness Unit
Co-Director, Clinical Effectiveness Unit
Researcher, Clinical Effectiveness Unit

Multidisciplinary group

- Patient Representative 1
- Ms Janet Dearden
- Professor Fiona Denison
- Dr Rachel d’Souza

Registered Nurse and Clinical Team Leader, Lancashire Care NHS Foundation Trust (Blackburn with Darwen); Nurse Representative, Clinical Effectiveness Committee, FSRH
Professor of Translational Obstetrics, University of Edinburgh MRC Centre for Reproductive Health, Queens Medical Research Institute (Edinburgh)
Consultant in Sexual and Reproductive Health, Margaret Pyke Centre (London)
### Multidisciplinary group

<table>
<thead>
<tr>
<th>Name</th>
<th>Affiliation</th>
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<tbody>
<tr>
<td>Dr Lucinda Farmer</td>
<td>Specialty Doctor, Unity Sexual Health (Bristol), Chair of General Training Committee, FSRH</td>
</tr>
<tr>
<td>Dr Annabel Forsythe</td>
<td>Specialty Registrar, Community Sexual and Reproductive Healthcare, Oxfordshire Sexual Health Services (Oxford and Banbury)</td>
</tr>
<tr>
<td>Ms Natika H Halil</td>
<td>Chief Executive of Family Planning Association (FPA)</td>
</tr>
<tr>
<td>Dr Vivian Iguyovwe</td>
<td>Associate Specialist, Camberwell Sexual Health Centre (London); Clinical Standards Committee Member, FSRH</td>
</tr>
<tr>
<td>Dr Susie Nickerson</td>
<td>General Practitioner Partner, Murrayfield Medical Centre (Edinburgh)</td>
</tr>
<tr>
<td>Dr Michelle Olver</td>
<td>Specialty Registrar, Community Sexual and Reproductive Health, Aneurin Bevan University Health Board (Newport/Blackwood)</td>
</tr>
<tr>
<td>Dr Amy Reimoser</td>
<td>Patient Representative; General Practitioner (West Sussex) and Specialty Doctor in Sexual and Reproductive Healthcare (Brighton)</td>
</tr>
<tr>
<td>Professor Rebecca Reynolds</td>
<td>Professor of Metabolic Medicine and Deputy Director Centre for Cardiovascular Science, Queen’s Medical Research Institute, University of Edinburgh (Edinburgh)</td>
</tr>
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</table>

*Patient Representative has chosen to remain anonymous.

The FSRH CEU wishes to acknowledge the contribution made by Ms Claire Nicol who worked on the literature review for the sections on contraceptive efficacy with raised BMI.

### Independent reviewers

<table>
<thead>
<tr>
<th>Name</th>
<th>Affiliation</th>
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<tbody>
<tr>
<td>Professor Jan Brynhildsen</td>
<td>Professor and Consultant of Obstetrics and Gynecology, Department of Clinical and Experimental Medicine (Linköping University)</td>
</tr>
<tr>
<td>Professor Alison Edelman</td>
<td>Professor of Obstetrics and Gynecology (Oregon Health &amp; Science University)</td>
</tr>
<tr>
<td>Dr Louise Massey (UK)</td>
<td>Consultant in Sexual and Reproductive Health (Aneurin Bevan University Health Board)</td>
</tr>
<tr>
<td>Dr Rachel Pryke (UK)</td>
<td>General Practitioner (Winyates Health Centre)</td>
</tr>
<tr>
<td>Professor Carolyn Westhoff</td>
<td>Professor of Reproductive Health in the Department of Obstetrics and Gynecology, Professor of Population and Family Health and Epidemiology (Columbia University Medical Center)</td>
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### Declaration of interests

None of the individuals involved had competing interests that prevented their active participation in the development of this guideline.

### Patient involvement

Service users from two sexual and reproductive health services (Oxfordshire Sexual Health Services, Oxford/Banbury, England and Aneurin Bevan University Health Board, Newport/Blackwood, Wales) across the UK were involved in providing feedback on the scope of the
guideline. Mrs Jolene West, lay representative, assisted the FSRH CEU with the content of the surveys given to service users.

Two patient representatives were involved consistently throughout the development process. They provided valuable feedback on multiple drafts of the guideline; their input informed and supported content and the development of recommendations.

Public consultation contributors
We would like to thank the contributors who provided their valuable feedback during the public consultation.

Guideline development methodology
This FSRH guideline was developed in accordance with the standard methodology for developing FSRH clinical guidelines (outlined in the FSRH’s Framework for Clinical Guideline Development which can be accessed here). The methodology used in the development of this guideline has been accredited by the National Institute for Health and Care Excellence (NICE).

Systematic review of evidence
A systematic review of the literature was conducted to identify evidence to answer the clinical questions formulated and agreed by the GDG. Searches were performed using relevant medical subject headings and free-text terms using the following databases: PubMed, EMBASE, Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews, the Cumulative Index to Nursing and Allied Health Literature (CINAHL) and POPLINE®. Further, the National Guideline Clearinghouse (NGC) and Scottish Intercollegiate Guideline Network (SIGN) were also used to identify relevant guidelines produced by other organisations; these guidelines were checked to identify missing evidence. No language restrictions were applied to the searches.

Search date: The databases were initially searched up to 11 November 2017. The evidence identified up to this point was used to develop the first draft of the guideline. The searches were re-run up to 27 August 2018 to check additional evidence published since the initial search. Any evidence published after this date was not considered for inclusion.

Search strategy: The literature search was performed separately for the different subcategories covered in this clinical guideline.

Articles identified in the search were screened by title and abstract and full-text copies were obtained if the articles addressed clinical questions relevant to the guideline. A full critical appraisal of each article was conducted. Studies that did not report relevant outcomes or were not relevant to the clinical questions were excluded.

Synthesis of evidence and making clinical recommendation
The recommendations are graded (A, B, C, D and Good Practice Point) according to the level of evidence upon which they are based. The highest level of evidence that may be available depends on the type of clinical question asked. The CEU adopts the comprehensive methodology developed by the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) (http://www.gradeworkinggroup.org/) to assess the strength of the evidence collated and for generating recommendations from evidence.
The evidence used in this guideline was graded using the scheme below and the recommendations formulated in a similar fashion with a standardised grading scheme.

<table>
<thead>
<tr>
<th>Classification of evidence levels</th>
<th>Grades of recommendations</th>
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<tbody>
<tr>
<td>1++</td>
<td>At least one systematic review, meta-analysis or RCT rated as 1++, and directly applicable to the target population; or</td>
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<tr>
<td>1+</td>
<td>A systematic review of RCTs or a body of evidence consisting principally of studies rated as 1+, directly applicable to the target population and demonstrating overall consistency of results.</td>
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<tr>
<td>1-</td>
<td>A body of evidence including studies rated as 1++, directly applicable to the target population and demonstrating overall consistency of results.</td>
</tr>
<tr>
<td>2++</td>
<td>A body of evidence including studies rated as 2++ directly applicable to the target population and demonstrating overall consistency of results; or Extrapolated evidence from studies rated as 1++ or 1+.</td>
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<tr>
<td>2+</td>
<td>A body of evidence including studies rated as 2+ directly applicable to the target population and demonstrating overall consistency of results; or Extrapolated evidence from studies rated as 2++.</td>
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<tr>
<td>2-</td>
<td>Evidence level 3 or 4; or Extrapolated evidence from studies rated as 2+.</td>
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<tr>
<td>3</td>
<td>Good Practice Points based on the clinical experience of the guideline development group.*</td>
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<td>4</td>
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*On the occasion when the GDG finds there is an important practical point that they wish to emphasise but for which there is not, nor is there likely to be, any research evidence. This will typically be where some aspect of treatment is regarded as such sound clinical practice that nobody is likely to question it. It must be emphasised that these are NOT an alternative to evidence-based recommendations, and should only be used where there is no alternative means of highlighting the issue.
Considerations when making recommendations
FSRH clinical guidelines are produced primarily to recommend safe and appropriate clinical practice in relation to the provision of different contraceptive methods. Therefore, when formulating the recommendations, the GDG takes into consideration the health benefits, side effects and other risks associated with implementing the recommendations, based on the available evidence and expert opinion. Further, the GDG takes into consideration the different financial and organisational barriers that healthcare practitioners and services may face in the implementation of recommendations to ensure that the recommendations are realistic and achievable.

Reaching consensus on the recommendations
When further revisions based on public consultation feedback have been made, members of the GDG were asked to complete a form to indicate whether they agree or disagree with the recommendations proposed. The consensus process is as follows:

► Consensus will be reached when 80% of the GDG members agree with the recommendation.
► Recommendations where consensus is not reached will be redrafted in the light of any feedback.
► The recommendation consensus form will be sent again for all recommendations. Consensus will be reached when 80% of the GDG members agree with the recommendation.
► If consensus is not reached on certain recommendations, these will be redrafted once more.
► If after one more round of consultation, consensus is still not reached, the recommendation will be taken to the CEC for final decision.
► Any group member who is not content with the decision can choose to have their disagreement noted within the guideline.

Updating this guideline
Clinical guidelines are routinely due for update 5 years after publication. The decision as to whether update of a guideline is required will be based on the availability of new evidence published since its publication. Updates may also be triggered by the emergence of evidence expected to have an important impact on the recommendations. The final decision on whether to carry out a full or partial clinical guideline update is taken by the CEU in consultation with the CEC of the FSRH.
Questions for continuing professional development

The following multiple choice questions (MCQ) have only one correct answer and have been developed for continuing professional development (CPD). The answers to the questions and information on claiming CPD points can be found in the ‘members-only section’ of the FSRH website (www.fsrh.org).

1. When considering oral emergency contraception (EC) in women with body mass index (BMI) >30 kg/m², which of the following statements is true?
   a) A double-dose of ulipristal acetate emergency contraception (UPA-EC) could be considered
   b) A double-dose of levonorgestrel emergency contraception (LNG-EC) could be considered
   c) UPA-EC is not recommended
   d) LNG-EC is not recommended

2. When considering contraception in a woman with BMI ≥30–34 kg/m², which of the following is UKMEC Category 3?
   a) Combined hormonal contraception (CHC) if there is a history of bariatric surgery
   b) Progestogen-only implant (IMP) if obesity is one of multiple risk factors for cardiovascular disease (CVD)
   c) Progestogen-only injectable (depot medroxyprogesterone acetate (DMPA)) if obesity is one of multiple risk factors for CVD
   d) Progestogen-only pill (POP) if there is a history of bariatric surgery

3. When considering contraceptive effectiveness, which of the following statements is true?
   a) The FSRH recommends that healthcare providers replace IMP earlier in women weighing >149 kg
   b) The FSRH recommends a shortened interval between doses of DMPA in women weighing >90 kg
   c) The FSRH advises that there may be a possible reduction in combined hormonal patch effectiveness in women weighing >90 kg
   d) The FSRH advises doubling the dose of POP in women weighing >149 kg

4. Which of the following statements is false? Obesity is associated with increased risk of...
   a) Diabetes
   b) Venous thromboembolism (VTE)
   c) Endometrial cancer
   d) Epilepsy

5. Which of the following statements regarding POP in women with obesity is true?
   a) There is evidence to support a dose of more than one pill per day
   b) POP may be used safely by women with additional risk factors for CVD
   c) Use of POP is UKMEC 3 after bariatric surgery
   d) Use of POP increases VTE risk and is therefore not recommended

6. Which of the following statements regarding CHC is true?
   a) CHC is not recommended in women with BMI ≥35 kg/m² due to increased risk of contraceptive failure
   b) CHC is safe in women with BMI ≥35 kg/m² as long as they have undergone bariatric surgery
   c) The combined patch or ring are regarded as safer options than combined oral contraception (COC) in women with BMI ≥35 kg/m²
   d) Use of COC is UKMEC 2 for women with BMI 30–34 kg/m² who have no other risk factors for CVD
7 Which of the following statements regarding use of DMPA by women with obesity is true?
   a) Benefits of use of DMPA generally outweigh risks for women with multiple risk factors for CVD
   b) The negative effect of DMPA on bone mineral density (BMD) is countered by the protective effect of higher BMI on BMD
   c) Teenagers who are overweight may be at increased risk of weight gain with DMPA use compared with teenagers who are not overweight
   d) Evidence suggests that effectiveness of DMPA may be reduced by increased BMI

8 Which of the following statements regarding use of IMP by women with obesity is true?
   a) IMP is safe and may be used where there are multiple risk factors for CVD
   b) Evidence supports a reduction in effectiveness and IMP should be replaced early
   c) Evidence suggests removal is likely to be more difficult if the arm circumference is >30 cm
   d) Inadvertent intramuscular insertion is more common in women with BMI >30 kg/m²

9 Which of the following statements regarding VTE risk is true?
   a) The baseline risk of VTE in healthy women of reproductive age is in the range of 6–11 events per 10 000 women per year.
   b) The risk of VTE is 8–10-fold higher in women with obesity compared to women without obesity
   c) The VTE risk associated with CHC use is the same as that in the immediate postpartum period
   d) VTE risk increases significantly with age, irrespective of BMI

10 After bariatric surgery, which of the following statements is true?
    a) Use of DMPA is UKMEC 4 due to the increased risk of osteoporosis
    b) The combined vaginal ring could be more effective than COC
    c) Use of POP is UKMEC4 due to risk of malabsorption
    d) Use of COC is UKMEC 4 due to risk of VTE

Auditable outcomes

<table>
<thead>
<tr>
<th>Auditable outcome</th>
<th>Target</th>
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<tbody>
<tr>
<td>Percentage of women with body mass index (BMI) ≥30 kg/m² requiring emergency contraception (EC) who (subject to eligibility):</td>
<td></td>
</tr>
<tr>
<td>1. Are advised that a copper intrauterine device is the most effective method of EC</td>
<td>97%</td>
</tr>
<tr>
<td>2. Are advised that oral EC could be less effective because of their higher BMI</td>
<td></td>
</tr>
<tr>
<td>Percentage of women taking weight-loss medication and using or requesting oral contraception (including oral EC) who are informed regarding a potential reduction in effectiveness associated with vomiting and/or diarrhoea</td>
<td>97%</td>
</tr>
<tr>
<td>Percentage of women who have undergone bariatric surgery (or are about to undergo bariatric surgery) who are informed regarding a potential reduction in effectiveness of oral contraception</td>
<td>97%</td>
</tr>
</tbody>
</table>
Comments and feedback on published guideline

All comments on this published guideline can be sent directly to the Clinical Effectiveness Unit (CEU) of the Faculty of Sexual & Reproductive Healthcare (FSRH) via the FSRH website (www.fsrh.org).

The CEU may not respond individually to all feedback. However, the CEU will review all comments and provide an anonymised summary of comments and responses, which are reviewed by the Clinical Effectiveness Committee (CEC) and any necessary amendments made subsequently.

The Faculty of Sexual & Reproductive Healthcare (FSRH) is the largest UK professional membership organisation working in the field of sexual and reproductive health (SRH). We support healthcare professionals to deliver high-quality healthcare including access to contraception. We provide our 15,000 doctor and nurse members with NICE-accredited evidence-based clinical guidance, including the UKMEC, the gold standard in safe contraceptive prescription, as well as clinical and service standards.

The FSRH provides a range of qualifications and training courses in SRH, and we oversee the Community Sexual and Reproductive Healthcare (CSRH) Specialty Training Programme to train consultant leaders in this field. We deliver SRH-focused conferences and events, provide members with clinical advice and publish *BMJ Sexual & Reproductive Health* – a leading international journal. As a Faculty of the Royal College of Obstetricians and Gynaecologists (RCOG) in the UK, we work in close partnership with the College but are independently governed.

The FSRH provides an important voice for UK SRH professionals. We believe it is a human right for women and men to have access to the full range of contraceptive methods and SRH services throughout their lives. To help to achieve this we also work to influence policy and public opinion working with national and local governments, politicians, commissioners, policymakers, the media and patient groups. Our goal is to promote and maintain high standards of professional practice in SRH as a way towards realising our vision of holistic SRH care for all.

www.fsrh.org