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Appendices

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 members of the FSRH and among service users from two sexual and reproductive health services (New Croft Centre, Newcastle upon Tyne Hospital NHS Foundation Trust and Chalmers Centre, Edinburgh NHS Lothian) 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 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 15 June and 13 July 2020. 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 Sarah Hardman	Co-Director, Clinical Effectiveness Unit
▶ Dr Chelsea Morroni	Deputy Director, Clinical Effectiveness Unit
▶ Dr Zhong Eric Chen	Researcher, Clinical Effectiveness Unit
▶ Mrs Valerie Warner Findlay	Researcher, Clinical Effectiveness Unit

Multidisciplinary group

▶ Dr Savita Brito-Mutunayagam	Specialist Registrar in Community SRH, Honorary Research Fellow (University of Aberdeen)
▶ Dr Rachel D'Souza	Consultant in SRH (Margaret Pyke Centre, London)

▶ Dr Cindy Farmer	Associate Specialist Doctor in SRH (Unity Sexual Health Services, Bristol), Chair of General Training Committee, FSRH
▶ Dr Katherine Gilmore	Specialist Registrar in Community SRH (Newcastle upon Tyne)
▶ Dr Debbie Hallott	General Practitioner (New Southgate Surgery, Wakefield)
▶ Ms Claire Nicol	Advance Nurse Practitioner (Chalmers Centre, Edinburgh)
▶ Dr Farah Paruk	General Practitioner (Leighton Road Surgery, London), Chair of Clinical Effectiveness Committee, FSRH
▶ Dr Katherine Weaver	Associate Specialist in SRH (Chalmers Centre, Edinburgh)
▶ Mrs Michelle Kivlin	Patient Representative
▶ Ms Eilidh MacIver	Patient Representative

Independent reviewers

▶ Clinical Associate Professor Deborah Bateson	Medical Director Family Planning (New South Wales, Australia)
▶ Dr Katie Boog	Consultant in Community SRH (NHS Fife)
▶ Professor Alison Edelman	Professor of Obstetrics and Gynecology (Oregon Health & Science University)
▶ Professor Oskari Heikinheimo	Professor, Department of Obstetrics and Gynecology (University of Helsinki)
▶ Associate Professor Raymond Li	Associate Professor in Obstetrics and Gynaecology, The University of Hong Kong) and Honorary Medical Consultant (The Family Planning Association of Hong Kong

Declaration of interests

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

▶ Clinical Associate Professor Deborah Bateson	I have provided independent clinical education on Implanon NXT at sessions which have been sponsored by MSD. I am involved in an investigator-initiated clinical study on midwife-led postpartum implants which is funded in part by MSD.
▶ Dr Katie Boog	I have received payment from Consilient Healthcare to lecture at contraception training events where Consilient had no influence on the content of the talks.
▶ Professor Alison Edelman	I have received honoraria from Merck as a Trainer; no funds directly received since 2016. I have also received funding from Merck for an investigator-initiated project since December 2016 for which I am the Principal Investigator.

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▶ Dr Cindy Farmer	I have received honoraria from MSD to speak at the FSRH Current Choices lunchtime symposium. I am clinical lead in the development of the FSRH complex implant removal qualification.
▶ Professor Oskari Heikinheimo	I have served occasionally on advisory boards for Bayer AG, Exelgyn SAS, Gedeon Richter, Sandoz A/S and Vifor Pharma, and have designed and lectured at educational events for these companies.

Patient involvement

Service users from two sexual and reproductive health services (New Croft Centre, Newcastle upon Tyne Hospital NHS Foundation Trust and Chalmers Centre, Edinburgh NHS Lothian) across the UK were involved in providing feedback on the scope of the guideline.

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 the 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 17 February 2019. The evidence identified up to this point was used to develop the first draft of the guideline. The searches were re-run up to 3 March 2020 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 from the search were screened by title and abstract and full-text copies were obtained if the articles addressed the 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 recommendations

The recommendations are graded (A, B, C, D and Good Practice Point) according to the level of evidence upon which they are based (see later). 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.

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.

Classification of evidence levels and grades of recommendations

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.

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Classification of evidence levels			Grades of recommendations
1++	High-quality systematic reviews or meta-analysis of randomised controlled trials (RCTs) or RCTs with a very low risk of bias.	A	At least one systematic review, meta-analysis or RCT rated as 1++, and directly applicable to the target population; *or* 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.
1+	Well-conducted systematic reviews or meta-analysis of RCTs or RCTs with a low risk of bias.		
1-	Systematic reviews or meta-analysis of RCTs or RCTs with a high risk of bias.		
2++	High-quality systematic reviews of case-control or cohort studies or high-quality case-control or cohort studies with a very low risk of confounding, bias or chance and a high probability that the relationship is causal.	B	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+.
2+	Well-conducted case-control or cohort studies with a low risk of confounding, bias or chance and a moderate probability that the relationship is causal.	C	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++.
2-	Case-control or cohort studies with a high risk of confounding, bias or chance and a significant risk that the relationship is not causal.	D	Evidence level 3 or 4; *or* Extrapolated evidence from studies rated as 2+.
3	Non-analytical studies (eg, case report, case series).		
4	Expert opinions.	✓	Good Practice Points based on the clinical experience of the guideline development group.*

*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.