FACULTY OF SEXUAL & REPRODUCTIVE HEALTHCARE

ROYAL COLLEGE OF OBSTETRICIANS & GYNAECOLOGISTS

Faculty of Sexual & Reproductive Healthcare Clinical Guidance

Progestogen-only Implants

Clinical Effectiveness Unit
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DETAILS OF CHANGES TO ORIGINAL GUIDANCE DOCUMENT

In September 2008, Schering-Plough, the manufacturer of the progestogen-only implant (Implanon®), updated the Summary of Product Characteristics (SPC) and issued revised insertion site guidance, details of which are included in this website version of the Clinical Effectiveness Unit (CEU) Guidance Document (p. 6).

The print version of this CEU Guidance Document (issued in April 2008) contained some inconsistencies that the CEU has corrected in this version. These corrections are to Table 2 (p. 6), the Summary Points (p. 11) and to Question 10 (p. 13) pertaining to the use of progestogen-only implants following abortion.

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FACULTY OF SEXUAL & REPRODUCTIVE HEALTHCARE
ROYAL COLLEGE OF OBSTETRICIANS & GYNAECOLOGISTS

Faculty of Sexual and Reproductive Healthcare Clinical Effectiveness Unit

A unit funded by the FSRH and supported by the University of Aberdeen to provide guidance on evidence-based practice

FSRH Guidance (April 2008) Progestogen-only Implants

(Date of planned revision 2013)

Purpose and scope

This Guidance provides evidence-based recommendations and good practice points for clinicians on the use of progestogen-only implants. Currently the only progestogen implant licensed for use as contraception in the UK is the etonogestrel (ENG) implant (Implanon®).[1]

This Guidance focuses on the evidence directly relating to the ENG implant (from hereon referred to as the 'progestogen-only implant'). However, where there is limited evidence, extrapolation of data from other progestogen implants (Norplant® and Jadelle®) has been used. Relevant recommendations from the guideline on long-acting reversible contraception (LARC) published in 2005 by the National Institute for Health and Clinical Excellence (NICE) are reproduced in this Guidance.[2]

This document is not intended to serve alone as a standard of medical care, as this should be determined individually based on available clinical information. This Guidance has been systematically developed using the standard methodology outlined in the Appendix to this document.

Background

Implanon comprises a single subdermal rod and is licensed for 3 years' use. Each implant contains 68 mg ENG dispersed in a membrane of ethylene vinyl acetate.

Other progestogen-only implants (not available in the UK) include: Norplant, a six-rod (36 mg each) levonorgestrel (LNG) implant whose use was discontinued in the UK in 1999; and Jadelle, which comprises two rods each containing 75 mg LNG. Both these implants are licensed for 5 years' continuous use. UK clinicians may still see women with these implants, in particular women who are continuing with their use and/or who had these implants inserted outside the UK.

Which women are eligible to use progestogen-only implants?

The *UK Medical Eligibility Criteria for Contraceptive Use* (UKMEC) provides evidence-based recommendations to allow couples to select the most appropriate method of contraception without imposing unnecessary restrictions.[3] For most women, the progestogen-only implant is a safe option. There are few circumstances where UKMEC recommendations suggest that the theoretical or proven risks usually outweigh the advantages of using the method (UKMEC 3) or that use of the method represents an unacceptable health risk (UKMEC 4) (Table 1). The only UKMEC Category 4 is current breast cancer.[3]

1 Health professionals should be familiar with the UK Medical Eligibility Criteria for progestogen-only implant use (Good Practice Point).

What should a clinician assess when considering use of a progestogen-only implant?

In order to advise on eligibility for use of a progestogen-only implant, the clinician should take a medical history (as outlined in Box 1) and refer to the recommendations in

Box 1: Appropriate information to document when inserting subdermal implants (adapted from *Service Standards for Record Keeping*)[37]

DOCUMENTATION REQUIRED WHEN INSERTING SUBDERMAL IMPLANTS

Medical history and clinical assessment
- Age
- Previous contraception used and problems encountered including emergency contraception
- Menstrual history including date of last menstrual period (LMP)
- Any serious illness/gynaecological problems/surgery
- Allergies
- Medication – prescribed/non-prescribed/complementary
- Coital history

Information, advice and counselling
- Contraceptive choices discussed
- Risks/benefits/uncertainties discussed
- Mode of action and efficacy of implant
- Duration of use
- Effects on bleeding pattern
- Effects at insertion site
- Explanation of insertion and removal procedure
- Consent obtained
- Leaflet given – including manufacturer's PIL

Details of insertion procedure
- Name of assistant (if any)
- Local anaesthesia used
- Site of insertion (i.e. which arm and where)
- Type of implant inserted, batch number and expiry date
- Implant palpable after insertion
- Problems encountered, if any, and actions taken

Post-insertion follow-up advice
- After care instructions for insertion site
- Special instructions (if any) (e.g. additional contraception for 7 days)
- Follow-up date if arranged (to discuss any problems, acceptability, etc.)

Follow-up
- Problems encountered (if any) and actions taken
- Implant palpable in subdermal position
- If removal is planned, alternative contraception discussed and/or other issues discussed

Details of removal
- Reason for removal
- Alternative contraception method advised/provided (if any)
- Name of assistant if present
- Local anaesthesia used

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Table 1 *UK Medical Eligibility Criteria for Contraceptive Use* for progestogen-only implant use[3]

UKMEC 1 (A condition for which there is *no restriction* for the use of the contraceptive method)	UKMEC 2 (A condition for which the *advantages of using the method generally outweigh the theoretical or proven risks)*
Age *menarche to >45 years* **Parity** *nulliparous and parous* **Breastfeeding** **Postpartum** **Post-abortion** *immediately first- and second-trimester, and post-septic* **Past ectopic pregnancy** **History of pelvic surgery** **Smoking** **Obesity** **Hypertension** **History of high blood pressure during pregnancy** **Family history of VTE** *in a first-degree relative aged <45 years or ≥45 years* **Major surgery without prolonged immobilisation** **Minor surgery without immobilisation** **Immobility (unrelated to surgery)** *(e.g. wheelchair use, debilitating illness)* **Varicose veins** **Superficial thrombophlebitis** **Valvular and congenital heart disease** *uncomplicated and complicated by pulmonary hypertension, atrial fibrillation, history of subacute bacterial endocarditis* **Non-migrainous headaches** *mild or severe* **Epilepsy** *and not using liver enzyme-inducers* **Depressive disorders** **Endometriosis** **Benign ovarian tumour** **Severe dysmenorrhoea** **Gestational trophoblastic neoplasia** *when hCG is normal* **Cervical ectropion** **Cervical intraepithelial neoplasia** **Breast disease** *benign breast disease or a family history of breast cancer* **Endometrial or ovarian cancer** **Uterine fibroids** *with or without distortion of the uterine cavity* **PID** *current; or past history of, with or without subsequent pregnancy* **STI** *current, vaginitis or increased risk of STI* **HIV/AIDS** *risk of HIV/AIDS, current HIV not using antiretroviral therapy* **Schistosomiasis, pelvic and non-pelvic tuberculosis, malaria** **Diabetes** *history of gestational disease* **Thyroid disorders** **History of cholestasis** *pregnancy related* **Viral hepatitis** *carrier* **Inflammatory bowel disease** **Anaemias** *thalassaemia, sickle cell disease, iron deficiency* **Raynaud's disease** *primary and secondary without lupus anticoagulant* **Non-liver enzyme-inducing antibiotics** *(some antiretrovirals)*	**Multiple risk factors for arterial cardiovascular disease** **Hypertension** *vascular disease* **Past history of VTE** **Major surgery with prolonged immobilisation** **Known thrombogenic mutations** **Current and history of ischaemic heart disease** *(initiation)* **Stroke** *(initiation)* **Known hyperlipidaemias** **Migraine headaches** *without aura in women any age; with aura at any age (initiation); past history of migraine with aura at any age* **Vaginal bleeding** *unsuspicious irregular, heavy or prolonged* **Cervical cancer** **Breast disease** *undiagnosed mass; carriers of known gene mutations associated with breast cancer (e.g. BRCA1)* **HIV/AIDS** *current HIV using antiretroviral therapy; or current AIDS and using HAART* **Diabetes** *NIDDM and IDDM, non-vascular disease; with nephropathy/retinopathy/neuropathy; or other vascular disease or diabetes of >20 years' duration* **Gallbladder disease** *symptomatic treated by cholecystectomy, medically treated or current; asymptomatic* **History of cholestasis** *past COC-related* **Cirrhosis** mild compensated disease **Raynaud's disease** *secondary with lupus anticoagulant and thus a tendency to thrombosis* **Highly active antiretroviral therapy (HAART)**
UKMEC 3 (A condition where the *theoretical or proven risks usually outweigh the advantages* of using the method) (NB. The provision of a method to a woman with a condition given a UKMEC Category 3 requires expert clinical judgement and/or referral to a specialist contraceptive provider since use of the method is not usually recommended unless other methods are not available or not acceptable.)	
Current VTE *on anticoagulants* **Current/arising ischaemic heart disease** *(continuation)* **Stroke** *(continuation)* **Migraine headaches** *with aura at any age (continuation)* **Unexplained vaginal bleeding** *suspicious for serious condition* **Gestational trophoblastic neoplasia** *when hCG is abnormal* **Breast disease** *past history of breast cancer and no evidence of recurrence for 5 years* **Viral hepatitis** *active disease* **Cirrhosis** *severe decompensated disease* **Liver tumours** *benign and malignant* **Drugs which induce liver enzymes** [*e.g. rifampicin, rifabutin, St John's Wort, griseofulvin, and certain anticonvulsants (phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine)*]	
UKMEC 4 (A condition which represents an *unacceptable health risk* if the contraceptive method is used)	
Breast disease *current breast cancer*	

Initiation *= Starting a method of contraception by a woman with a specific medical condition.*
Continuation *= Continuation with a method already being used by a woman who develops a new medical condition.*
COC, combined oral contraceptive; HAART, highly active antiretroviral therapy; hCG, human chorionic gonadotrophin; IDDM, insulin-dependent diabetes mellitus; NIDDM, non-insulin-dependent diabetes mellitus; STI, sexually transmitted infection; VTE, vascular thromboembolism.

the UKMEC (reproduced in Table 1).[3] Individual assessment of risk of sexually transmitted infections (STIs) will inform decisions about the additional need for condoms and/or appropriate testing for STIs.

2 A medical history (including sexual history) together with consideration of the recommendations in the UKMEC should be used to assess the appropriateness of the progestogen-only implant (Good Practice Point).

What information should be given to a woman when counselling her about a progestogen-only implant?

Each woman choosing a contraceptive method should be given oral and written information (e.g. fpa leaflet) as part of routine counselling. The clinician should discuss the topics outlined in the following paragraphs.

Mode of action

The progestogen-only implant is a LARC. The primary mode of action is prevention of ovulation.[4] In addition, implants also alter cervical mucus, thus preventing sperm penetration, and inhibit normal endometrial development.[4]

3 Women should be informed that the primary mode of action of the progestogen-only implant is prevention of ovulation (Grade B).

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Duration of use

The progestogen-only implant is licensed for 3 years' use.[1] Evidence confirms that the dose of ENG is sufficient to suppress ovulation in most cycles for 3 years.[5–7]

Women who have LNG implants (Norplant and Jadelle) inserted outside the UK may attend for removal. These implants are licensed for 5 years' use.

4 Women can be advised that the duration of use for the progestogen-only implant is 3 years (Grade C).

Contraceptive efficacy

Serum ENG concentrations rise within 8 hours of insertion of an implant.[5,7] Serum ENG at 8 hours post-insertion (266 pg/ml) is higher than the concentration after 1 year of use (196 pg/ml) when ovulation is notably rare.[1] Ovulation is likely to be inhibited quickly following insertion.

Randomisation of women in contraceptive studies is problematic thus evidence on contraceptive efficacy is generally from observational studies. Non-comparative studies[8–11] observed no pregnancies with progestogen-only implant use; in the largest multicentre study[11] data were collected for 1200 woman-years. Nevertheless, pregnancies during progestogen-only implant use have been reported in Australian post-marketing surveillance[12,13] and in reports to the UK Medicines and Healthcare Products Regulatory Agency (MHRA).[14] The overall pregnancy rate reported in the National Institute for Health and Clinical Excellence (NICE) guideline on LARC was <1 in 1000 over 3 years of use.[2]

Pregnancies in implant users are not usually true method failures, but arise after incorrect timing of insertion, unrecognised non-insertion or drug interactions.[13] A recent case report documented a likely true method failure resulting in an ectopic pregnancy.[15] Ovulation is inhibited in most cycles throughout the 3 years of use therefore the risk of ectopic pregnancy is reduced in comparison with that for women not using contraception. Only two other ectopic pregnancies have been reported.[16,17] Women who have experienced a previous ectopic pregnancy may have unrestricted use of progestogen-only implants (UKMEC 1).[3]

There have been concerns that efficacy of progestogen-only implants may be reduced in women with a body mass index (BMI) >30 kg/m^2. However, a meta-analysis of clinical trials reported no pregnancies at 1 year among implant users weighing ≥70 kg (n = 78).[18] UKMEC recommends that women with a BMI >30 kg/m^2 can use a progestogen-only implant without restriction (UKMEC 1).[3]

5 Women should be advised that the pregnancy rate associated with use of a progestogen-only implant is very low (<1 in 1000 over 3 years) (Grade B).

6 Women should be advised that the overall risk of ectopic pregnancy is reduced when using progestogen-only implants when compared to using no contraception (Grade B).

7 Women with a BMI >30 kg/m^2 can use a progestogen-only implant without restriction and without a reduction in contraceptive efficacy for the duration of the licensed use (Grade C).

Return of fertility

Following removal of the progestogen-only implant, concentrations of ENG are undetectable after a mean of 6 days (range, 1–10 days).[7] Ovulation[5,9,11,18] and fertility[19] return within 3 months of removal. A meta-analysis reported return of ovulation within 3 weeks in 94% of women.[18]

8 Women should be informed that there is no evidence of a delay in return of fertility following removal of a progestogen-only implant (Grade B).

Side effects

Bleeding

Altered bleeding patterns are common among women using progestogen-only implants. A retrospective study found that 25% of women discontinued implant use within 1 year; the majority (62%) discontinued because of bleeding problems.[20] A non-comparative study showed that bleeding changes were more prominent in the first 3 months following insertion.[9] A retrospective case review in the UK reported a cumulative rate of removal because of bleeding problems of 12% (17/107) at 3 years; bleeding changes were reported in 26% of all women. Changes included: prolonged bleeding (31%), oligomenorrhoea/amenorrhoea (27%) and irregular bleeding (13%). Good cycle control was reported in 28% of women at 3 years.[10] A similar study in Mexico[8] (n = 417) reported cumulative bleeding changes at 3 years including: amenorrhoea (14%), prolonged bleeding (16%), infrequent bleeding (4%) and frequent bleeding (1%). At 3 years the proportion of women with bleeding problems was less than in earlier years; however, there was a dropout rate of 39% in this trial.

9 Women should be informed about the likely bleeding patterns that may occur with a progestogen-only implant (Grade C).

10 Women should be advised that 20% of users will have no bleeding, while almost 50% will have infrequent, frequent or prolonged bleeding and that bleeding patterns are likely to remain irregular (Grade C).

Weight change

Retrospective studies[8–10,21] have reported that some women experience weight gain while using progestogen-only implants. Cumulative weight gain up to 3 years' use ranged from 2.8% to 12.7%. Weight fluctuation in women of reproductive age is common; there is no evidence to support a causal association between progestogen-only implants and weight change.[2]

Mood change

Non-comparative studies have reported mood changes with use of progestogen-only implants.[8–10,21] Two studies in women completing the licensed duration of use[8,10] indicated that at 3 years 11% and 10%, respectively, of women experienced mood changes. Mood changes (positive or negative) were not defined in the majority of studies.

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Loss of libido

Non-comparative studies have reported loss of libido in fewer than 6% of users of progestogen-only implants.[8,10,21]

11 Women should be advised that there is no evidence of a causal association between use of a progestogen-only implant and weight change, mood change or loss of libido (Grade C).

Acne

Data from one non-comparative study indicated that acne occurred or worsened in 13% (80/635) of progestogen-only implant users (but also improved in 13%).[11] Other studies have similarly reported the occurrence or worsening of acne in women using implants.[8,9,21] Nevertheless, women may be advised that there are no known interactions between progestogen-only implants and any established acne treatments. Thus, the presence of a progestogen-only implant does not preclude the use of effective acne therapy.

12 Women should be advised that acne may improve, occur or worsen during the use of a progestogen-only implant (Grade C).

Headache

A retrospective study conducted in Switzerland reported headaches in 4% (12/306) of progestogen-only implant users at follow-up (mean duration, 11.4 months).[21] In a UK study (n = 132), 1% of women reported headaches as an unwanted side effect at 3 years' follow-up.[10] A higher proportion of women reported headaches in two retrospective studies: 24% (78/330) over 2 years' follow-up in the USA[9] and 25% (n = 417) over 3 years in Mexico.[8] However, headache is a common symptom in the general population and a causal relationship cannot be confirmed. Women of any age who develop migraine with aura during use of progestogen-only implants are given an UKMEC Category 3 rating. A woman continuing the method may need expert clinical judgement (and/or referral to a specialist contraceptive provider) as this is a condition where the theoretical or proven risks usually outweigh the advantages of using the method.

13 Women should be advised that there is no evidence of a causal association between use of a progestogen-only implant and headache (Grade C).

14 Women of any age with a history of migraine (with or without aura) may use progestogen-only implants (Grade C).

15 Women who develop new symptoms of migraine without aura while using progestogen-only implants may continue the method (UKMEC 2) (Grade C).

16 Women who develop new symptoms of migraine with aura while using progestogen-only implants should be advised to seek medical advice, as investigation may be appropriate. Continued use of progestogen-only implants may be considered (UKMEC 3) (Grade C).

Discontinuation

LARC methods are designed for women who want effective contraception administered less than once per month and with a prolonged duration of continued use. Most methods of contraception can be discontinued without the aid of a health professional. Women can choose to stop contraception at any time, however women need to seek help for removal of implants. Requiring assistance may mean that women have to postpone implant removal.[2]

Discontinuation among implant users has been reported to be up to 43% within 3 years.[8–10,20,21] Most women who discontinue do so because of irregular bleeding (33%); less than 10% discontinue because of other (non-bleeding) side effects.[2]

17 Clinicians should be aware that early discontinuation (up to 43% within 3 years) of progestogen-only implants is common (Grade C).

Health concerns

Venous thromboembolism

Venous thromboembolism (VTE) is uncommon in women of reproductive age, with an incidence usually quoted as approximately 5 per 100 000 woman-years.[22] A recent review which combined findings from more than 30 studies suggested that the incidence of VTE in the general population of women of reproductive age is higher than the generally quoted figure (i.e. around 50 per 100 000 woman-years).[23] This estimate remains controversial but may mean that the additional risk attributable to contraceptive use is smaller than previously thought.

Few studies have been large enough to evaluate the risk of VTE with progestogen-only contraception. A World Health Organization (WHO) Collaborative Study collected data from Africa, Asia, Europe and Latin America to evaluate the risks with use of oral and injectable progestogen-only contraception.[24] Although limited by small numbers and inherent bias, the data suggest that there is little or no increase in risk of VTE associated with use of these progestogen-only methods. No specific data on VTE risk with progestogen-only implants were found.

18 Women should be informed that evidence suggests there is little or no increase in risk of venous thromboembolism associated with use of a progestogen-only implant (Grade C).

Bone mineral density

Most concerns regarding bone mineral density (BMD) relate to long-term use of progestogen-only injectable contraception. An open prospective study found no change in BMD at the lumbar spine, femoral neck or distal radius in women (aged 18 to 40 years) who had used either a progestogen-only implant or an intrauterine device (IUD) for 2 years.[25] BMD was significantly lower in the mid-shaft of the ulna, but not in the distal radius, after 18 months of progestogen-only implant use in women aged 19 to 43 years.[26] Although a statistically significant reduction was seen, a clinically significant mean decrease in BMD of one standard deviation was not reached.

19 Women should be informed that there is no evidence of a clinically significant effect on bone mineral density with use of a progestogen-only implant (Grade B).

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Breast cancer

The Collaborative Group on Hormonal Factors in Breast Cancer undertook a re-analysis of 54 studies to investigate the relationship between breast cancer and hormonal contraceptives.[27] Progestogen-only methods were used by just over 2% of the women studied. Progestogen-only implants are not specifically highlighted. There are insufficient data to make an evidence-based recommendation concerning the effect of progestogen-only implants on breast cancer risk. Nevertheless, as for other progestogen-only methods, any attributable risk (if any) is likely to be very small.

Drug interactions

The Summary of Product Characteristics (SPC) for the progestogen-only implant recommends additional contraceptive protection while using a liver enzyme-inducing drug and for 28 days after its cessation.[1] The efficacy of progestogen-only implants is *not reduced* with non-liver enzyme-inducing antibiotics.[28]

20 Women using liver enzyme-inducing drugs short term (<3 weeks) may choose to continue with a progestogen-only implant. Additional contraceptive protection, such as condoms, should be used and until 4 weeks after the liver enzyme-inducing drug has been stopped. Information should be given on the use of alternative contraception if liver enzyme-inducing drugs are to be used long term (Good Practice Point).

21 Women should be informed that the efficacy of a progestogen-only implant is not reduced by non-liver enzyme-inducing antibiotics and that additional contraceptive protection is not required (Grade C).

Non-contraceptive benefits

NICE LARC guidelines do not specifically mention any non-contraceptive benefits of progestogen-only implants.[3] In common with other methods which suppress ovulation, progestogen-only implants may improve dysmenorrhoea[29] and the symptoms of endometriosis. Up to 20% of women using a progestogen-only implant will be amenorrhoeic, which some may perceive as a benefit.

When can a progestogen-only implant be safely inserted?

Recommendations for the safe insertion of progestogen-only implants are outlined in Table 2.

Insertion of progestogen-only implants in special circumstances

Postpartum

The SPC[1] for the progestogen-only implant recommends insertion between Days 21 and 28 postpartum. Women who are postpartum (following vaginal or operative delivery, breastfeeding or bottle-feeding) may choose to use a progestogen-only implant without restriction (UKMEC 1).[3] A cohort study compared changes in breast milk volume and composition in women who elected to use a progestogen implant or a copper-bearing IUD at 6 weeks postpartum.[30] There were no significant differences between the groups. Follow-up at 3 years in the same cohort of women revealed no differences in infant development and no treatment-related side effects.[31]

A progestogen-only implant may be inserted before Day 21 postpartum if this is more convenient for the woman. This early insertion may cause bleeding and is outside the terms of the product licence.

22 Progestogen-only implants can safely be used by women who are breastfeeding (Grade C).

23 Women can have a progestogen-only implant inserted up to and including Day 21 postpartum with immediate contraceptive protection. If inserted after Day 21 then condoms or abstinence should be advised for 7 days (Grade C).

Following abortion or miscarriage

The SPC for the progestogen-only implant suggests that an implant can be inserted immediately following a first-trimester abortion but should be delayed until between Days 21 and 28 following second-trimester abortion.[1] The UKMEC supports the use of progestogen-only implants immediately following abortion (first trimester, second trimester and septic abortion) (UKMEC 1).[3]

The Royal College of Obstetricians and Gynaecologists (RCOG)[32] and the LARC guideline[2] both recommend initiation of contraception immediately following abortion. In keeping with general insertion (Table 2), if the progestogen-only implant is inserted >5 days after abortion or miscarriage then condoms or abstinence is advised for 7 days.

24 A progestogen-only implant can be inserted immediately following surgical abortion or (second part of) medical abortion or miscarriage; no additional contraception is required. If inserted >5 days after abortion or miscarriage then condoms or abstinence should be advised for 7 days (Grade C).

Implant insertion

Training requirements

All doctors offering progestogen-only implant insertion should hold the Letter of Competence in Subdermal Contraceptive Implants (LoC SDI) from the Faculty of Sexual and Reproductive Healthcare (FSRH). Nurses are strongly advised to obtain accreditation from the Royal College of Nursing (RCN) after completion of the RCN training guidance.[33] Accreditation involves: demonstration of skills required for counselling for implants, knowledge of issues relevant to implant use, problem management, and observation of insertion and removal. In addition, a minimum number of supervised insertions and removals, as specified by the FSRH/RCN should be completed. Evidence of maintaining skills should be sought by re-certifying according to the FSRH/RCN guidelines and attending regular updates.

25 Health professionals who insert (and remove) progestogen-only implants should be appropriately trained, maintain competence and attend regular updates (Grade C).

Emergency services for insertions and removals

The FSRH *Service Standards for Resuscitation in Sexual Health Services*[34] recommends training and regular

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Table 2 Recommendations for timing of insertion of a progestogen-only implant as long-term contraception

Circumstances when progestogen-only implant is to be inserted	Recommendations for timing of insertion
General insertion	Ideally, an implant should be inserted between Days 1 and 5 (inclusive) of a normal menstrual cycle. No additional contraception is required. An implant can be inserted at any other time in the menstrual cycle if the clinician is reasonably certain that the woman is not pregnant and that there is no risk of conception. Additional contraception (barrier method or abstinence) should be advised for 7 days after insertion. If the woman is amenorrhoeic, the clinician must be reasonably certain that the woman is not pregnant and that there is no risk of conception; additional contraception should be used for 7 days.
Postpartum	An implant can be inserted up to Day 21 postpartum with immediate contraceptive cover. If inserted after Day 21, then condoms or abstinence should be advised for 7 days. Insertion can be prior to Day 21 but bleeding may be a problem (unlicensed use).
Following miscarriage or abortion	Can be inserted up to Day 5 following surgical abortion, second part of medical abortion or miscarriage. No additional contraception is required. If inserted beyond 5 days after abortion or miscarriage then additional contraception is required for 7 days.
Switching from another method of contraception	
Combined hormonal contraception (CHC)	Can be inserted immediately if CHC has been used consistently and correctly or if the clinician is reasonably certain that the woman is not pregnant and that there is no risk of conception. No additional contraception is required.
Progestogen-only pill (POP)	Can be inserted immediately if POP has been used consistently and correctly or if the clinician is reasonably certain that the woman is not pregnant and that there is no risk of conception. No additional contraception is required.
Progestogen-only implant	Can be inserted immediately on removal of previous implant if the woman attends at or within the licensed duration of use (3 years) without the need for additional contraception. If removal or replacement occurs beyond the licensed duration, a new implant may be inserted at the removal of the previous implant if the clinician is reasonably certain that the woman is not pregnant and that there is no risk of conception. Additional contraception is required for 7 days.
Progestogen-only injectable	Should be inserted when the repeat injection is due (or up to 14 weeks since last injection). No additional contraception is required.
Levonorgestrel-releasing intrauterine system (LNG-IUS)	Can be inserted immediately if LNG-IUS was used consistently and correctly or if the clinician is reasonably certain that the woman is not pregnant. As bleeding with the LNG-IUS may not reflect ovarian activity the LNG-IUS should be continued for at least 7 days.
Copper-bearing intrauterine device (IUD)	Can be inserted immediately if IUD was used consistently and correctly or if the clinician is reasonably certain that the woman is not pregnant. The IUD should be continued for at least 7 days, unless the implant is fitted within the first 5 days of the menstrual cycle.
Barrier method (i.e. male condom, female condom, cap or diaphragm)	Can be inserted immediately if barrier method has been used consistently and correctly or if the clinician is reasonably certain that the woman is not pregnant and that there is no risk of conception. If the woman is amenorrhoeic or it has been more than 5 days since menstrual bleeding started, additional contraception should be continued for 7 days.

updates in resuscitation for all staff dealing with emergencies that may arise during implant procedures. The recommendations for emergency resuscitation, emergency packs and service standards are summarised in Table 3.[34]

26 Emergency equipment must be available in all settings where subdermal contraception is inserted/removed and local referral protocols must be in place for women who require further medical input (Grade C).

Practical procedures for implants

Insertion site

The manufacturer of Implanon now recommends that the implant is inserted 8–10 cm above the medial epicondyle of the humerus, instead of 6–8 cm above the elbow crease in the groove between the biceps and triceps.

Aseptic precautions and sterile gloves

Aseptic precautions for the insertion (and removal) of progestogen-only implants are as follows:[1]

- Clean skin with antiseptic solution and apply a dressing towel
- Use sterile gloves.

27 An aseptic technique should be used for the insertion and removal of a progestogen-only implant (Good Practice Point).

Local anaesthesia

The SPC[1] for the progestogen-only implant states that for insertion 2 ml (1%) lidocaine should be injected just under the skin along the 'insertion canal'. For removal, 0.5–1 ml (1%) lidocaine should be injected at the site.

28 Appropriate anaesthesia should be injected prior to insertion and removal of a progestogen-only implant (Good Practice Point).

Antibiotic prophylaxis for implant procedures

Use of prophylactic antibiotics for the prevention of endocarditis for progestogen-only implant insertion or removal is not recommended for women at risk of subacute bacterial endocarditis.[1,35,36] Women with valvular or congenital heart disease (complicated or uncomplicated) have unrestricted use of progestogen-only implants (UKMEC 1). The Clinical Effectiveness Unit could find no reports of bacterial endocarditis following insertion of a progestogen-only implant.

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Table 3 Emergencies and insertion of subdermal implants: resuscitation measures and contents of an emergency pack (adapted from *Service Standards for Resuscitation in Sexual Health Services*)[34]

Basic resuscitation measures	Equipment	Medication
• Display clear algorithms regarding emergency procedures and emergency telephone numbers • Adequate training of all staff in basic life support • Abandon procedure, lower head and/or raise legs • Assistant to monitor pulse and blood pressure • Ensure clear airway • Arrange transfer if no improvement	**Essential** • Sphygmomanometer • Pocket mask and one-way valve • Appropriate selection of needles and syringes, tape, latex-free gloves, sharps box, scissors, saline flush **Desirable** (accessible if available) • Oxygen mask with reservoir bag • Automated external defibrillator • Suction • Adjustable couch with easy access	**Essential** • Atropine for intravenous use (0.6 mg/ml) for the management of persistent bradycardia • Adrenaline for intramuscular use 1:1000 (1 mg/ml) for the management of anaphylaxis **Desirable** • Diazepam

29 Use of prophylactic antibiotics to prevent endocarditis is not recommended for progestogen-only implant insertion or removal (Good Practice Point).

Documentation

Recommendations from the FSRH for record keeping specific to progestogen-only implant insertion are summarised in Box 1.[37]

What information should be given to implant users about continuation and follow-up?

Follow-up

30 Women using implants should be advised that no routine follow-up is required, but that they can return at any time to discuss problems or if they want to change their contraceptive method (Grade C).

Signs and symptoms requiring medical attention

A progestogen-only implant should be palpable by the woman after insertion. Women should be advised to return if: they cannot feel their implant; they notice any change to the shape of the implant; it appears to have broken; or there are any changes to the skin (such as a rash) or pain around the site of the implant. If a woman develops problems (such as problematic vaginal bleeding, pregnancy, VTE, ischaemic heart disease, stroke, migraine with aura, breast cancer, active viral hepatitis, severe decompensated cirrhosis, or liver tumours) while using a progestogen-only implant the continued use of the method should be reviewed.[3]

31 Women using a progestogen-only implant should be advised to return if: they cannot feel their implant or it appears to have changed shape; they notice any change to the skin or pain around the site of the implant; they become pregnant; or they develop any condition which may contraindicate continuation of the method (Good Practice Point).

Reducing the risk of STIs

Progestogen-only implants do not provide protection against STIs and women using this method should be informed about safer sex.

32 If a woman chooses a progestogen-only implant and is at higher risk of STIs (aged <25 years, or >25 years with a new sexual partner, or more than one partner in the last year) she should be advised to use condoms in addition (Grade C).

Managing problems associated with progestogen-only implant use

Problematic bleeding

STIs represent a common cause of problematic bleeding in women of reproductive age. A clinician should consider a woman's risk of STIs if she presents with intermenstrual or postcoital bleeding.

The *UK Selected Practice Recommendations for Contraceptive Use*[38] and the 2005 WHO version[39] provide recommendations on the management of menstrual abnormalities while using progestogen-only implants. In women with persistent problematic bleeding (or with bleeding after a period of amenorrhoea) gynaecological pathology should be excluded. If a woman does not wish treatment or if treatment fails then the implant should be removed and other contraceptive methods discussed.

Data relating to management of bleeding problems associated with ENG implants are limited.[2] Data extrapolated from LNG-only implants provide some evidence of beneficial effects on bleeding patterns of mefenamic acid or ethinylestradiol (alone or as an oral contraceptive).[40–43] It is biologically plausible that the same will be true for any progestogen-only implant. There is no evidence to support the use of vitamin E or aspirin, and limited evidence for non-steroidal anti-inflammatory drugs other than mefenamic acid.[44,45]

Research suggests that doxycycline and mifepristone may also be beneficial,[46–49] however neither is used in UK clinical practice.

33 Women who experience problematic bleeding while using a progestogen-only implant should have a sexual history taken to establish STI risk and/or be investigated for gynaecological pathology if clinically indicated (Grade C).

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34 Women who experience problematic bleeding while using a progestogen-only implant and who have had gynaecological pathology excluded may be offered mefenamic acid or ethinylestradiol (alone or as an oral contraceptive) for treatment (Grade C).

Pregnancy

The SPC and NICE LARC guideline recommend that if a pregnancy occurs, the implant should be removed.[1,2] There is no known harm to the woman, the course of her pregnancy, or the fetus if pregnancy occurs while using an implant.[3,50] However, LARC[2] suggests that, theoretically, virilisation of the fetus might occur. A case report described spontaneous full-term labour with normal delivery of a healthy baby in a woman with a progestogen-only implant *in situ*.[51] If pregnancy is to be terminated then the implant may be retained. However, the woman may wish to choose another method if there is an apparent true method failure.

35 There is no evidence of a teratogenic effect of a progestogen-only implant, but if a user becomes pregnant and continues with the pregnancy then the implant should be removed (Grade C).

Implant removal and replacement

Women who return on schedule for implant removal or replacement do not need to: abstain from sexual intercourse prior to removal, use additional contraceptive protection, or use emergency contraception if sexual intercourse has occurred. However, immediately after the implant has been removed, clinicians should assume that fertility has been restored and the woman will need effective contraception if pregnancy is not desired.

When a woman wishes to continue with this method of contraception a replacement implant may be inserted through the same incision by which the previous implant was removed.[1] Removal/replacement should be conducted under aseptic conditions as for insertion. Appropriate local anaesthesia as outlined above should also be used.

36 Women should be advised that fertility may return immediately after progestogen-only implant removal and effective contraception is required if pregnancy is not desired (Grade B).

37 Women who do not wish to have a pregnancy can be reassured that abstinence, additional contraceptive protection or emergency contraception is not necessary prior to implant removal as long as they return within 3 years, have immediate replacement or immediately start another method of contraception (Good Practice Point).

Complications with removal

The incidence of complications at implant removal is low (1.3%).[52] Complications include broken implant, migration of implant, and difficulty locating the implant. If the implant cannot be palpated, methods such as ultrasound or magnetic resonance imaging can be used.[1,53,54] Once the implant is located, a potentially difficult removal should be conducted in close liaison with a radiology department or experienced ultrasonographer.[54,55]

38 If difficulty arises with progestogen-only implant removal (due to deep insertion, failed insertion or migration) it should be localised by ultrasound before being removed. Deeply inserted implants often need to be removed by an expert (Good Practice Point).

Cost-effectiveness

Increasing the uptake of LARC methods such as the progestogen-only implant will reduce unintended pregnancies.[2] Long-term use of the progestogen-only implant is highly cost-effective. The implant is more cost-effective than combined oral contraception (even at 1 year of use) or progestogen-only injectables. The IUD is more cost-effective than the implant, but the incremental cost-effectiveness ratio decreases over time. The implant is more cost-effective than the levonorgestrel-releasing intrauterine system (LNG-IUS) with up to 3 years of use, after which the LNG-IUS becomes more cost-effective.[2]

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APPENDIX: DEVELOPMENT OF CEU GUIDANCE

This Guidance was developed by the Clinical Effectiveness Unit (CEU) (**Dr Gillian Penney**, Acting Unit Director at the time of Guidance preparation; **Dr Susan Brechin**, Current Unit Director; **Ms Lisa Allerton** and **Ms Gillian Stephen**, Research Assistants) on behalf of the Faculty of Sexual and Reproductive Healthcare (FSRH) with a multidisciplinary group of health professionals comprising: **Dr Lesley Bacon**, Consultant in Sexual and Reproductive Health, Department of Sexual and Reproductive Health Care, Lewisham Primary Care Trust, South East London; **Dr Amanda Britton** (FSRH Council Representative/General Practitioner, Contraception and Sexual Health, Basingstoke, Hants Primary Care Trust; **Dr Lesley Craig**, Associate Specialist in Sexual and Reproductive Health, Square 13, Golden Square, NHS Grampian; **Dr Alyson Elliman**, FSRH Honorary Secretary/Consultant in Family Planning, Croydon Primary Care Trust; **Dr Marian Everett**, FSRH Education Committee/Consultant in Sexual and Reproductive Health, Conifer House, Hull Primary Care Trust; **Mrs Julie Gallagher**, Clinical Lead/Senior Nurse, Palatine Centre, Manchester Primary Care Trust; **Dr Val Godfree**, FSRH Clinical Standards Committee/Director of Family Planning and Reproductive Health Care, Chapel Street Clinic, Chichester, West Sussex Primary Care Trust; **Dr Helen Ribbans**, Consultant in Sexual and Reproductive Health, Burnley General Hospital, East Lancashire Primary Care Trust (Burnley) and East Lancashire Primary Care Trust; **Dr Sam Rowlands**, Freelance Specialist in Contraception and Reproductive Health and Visiting Senior Lecturer, Warwick Medical School. Written feedback was received from: **Ms Rebecca French**, Senior Research Fellow, Margaret Pyke Centre, University College London, London; **Dr Diana Mansour**, Deputy Medical Director, Graingerville Clinic, Newcastle upon Tyne Primary Care Trust; **Ms Toni Belfield** (User Representative), Director of Information, fpa, London; and from the FSRH Clinical Effectiveness Committee. This Guidance was independently peer reviewed by **Professor Carolyn Westhoff,** New York-Presbyterian Hospital, Columbia University, New York, NY, USA.

No competing interests were noted by members of the multidisciplinary group.

CEU Guidance is developed in collaboration with the Clinical Effectiveness Committee of the FSRH. The CEU Guidance development process employs standard methodology and makes use of systematic literature review and a multidisciplinary group of professionals. The multidisciplinary group is identified by the CEU for their expertise in the topic area and typically includes clinicians working in family planning, sexual and reproductive health care, general practice, other allied specialities, and user representation. In addition, the aim is to include a representative from the FSRH Clinical Effectiveness Committee, the FSRH Education Committee and FSRH Council in the multidisciplinary group.

Evidence is identified using a systematic literature review and electronic searches are performed for: MEDLINE (CD Ovid version) (1996–2007); EMBASE (1996–2007); PubMed (1996–2007); The Cochrane Library (to 2007) and the US National Guideline Clearing House. The searches are performed using relevant medical subject headings (MeSH), terms and text words. The Cochrane Library is searched for systematic reviews, meta-analyses and controlled trials relevant to progestogen-only implants. Previously existing guidelines from the FSRH (formerly the Faculty of Family Planning and Reproductive Health Care), the Royal College of Obstetricians and Gynaecologists (RCOG), the World Health Organization, and the British Association for Sexual Health and HIV, and reference lists of identified publications, are also searched. Similar search strategies have been used in the development of other national guidelines. Selected key publications are appraised using standard methodological checklists similar to those used by the National Institute for Health and Clinical Excellence (NICE). All papers are graded according to the Grades of Recommendations Assessment, Development and Evaluation (GRADE) system. Recommendations are graded as in the table below, using a scheme similar to that adopted by the RCOG and other guideline development organisations. The clinical recommendations within this Guidance are based on evidence whenever possible. Summary evidence tables are available on request from the CEU. An outline of the Guidance development process is given in the table on the inside back cover of this Guidance document. Feedback on Guidance documents should be directed to the CEU via e-mail (ceu.guidance@abdn.ac.uk).

Level of evidence	Evidence
Ia	Evidence obtained from meta-analysis of randomised trials
Ib	Evidence obtained from at least one randomised controlled trial
IIa	Evidence obtained from at least one well-designed controlled study, without randomisation
IIb	Evidence obtained from at least one other type of well-designed quasi-experimental study
III	Evidence obtained from well-designed non-experimental descriptive studies, correlation studies and case studies
IV	Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities

	Grades of Recommendations
A	Evidence based on randomised controlled trials
B	Evidence based on other robust experimental or observational studies
C	Evidence is limited but the advice relies on expert opinion and has the endorsement of respected authorities
✓	Good Practice Point where no evidence exists but where best practice is based on the clinical experience of the multidisciplinary group

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SUMMARY POINTS: PROGESTOGEN-ONLY IMPLANTS

CLINICAL ASSESSMENT

- A medical history (including sexual history) and clinical assessment together with consideration of the recommendations in the UK Medical Eligibility Criteria (UKMEC) should be used to assess the use of the progestogen-only implant.

POINTS TO COVER WHEN COUNSELLING PATIENTS

- The primary **mode of action** of the progestogen-only implant is prevention of ovulation.
- The **duration of use** for the progestogen-only implant is 3 years.
- A progestogen-only implant can be inserted on the days of surgical or second part of medical abortion or immediately following miscarriage: no additional contraception is required. If started **>5 days** after abortion or miscarriage, additional contraception is required for 7 days.
- The **ectopic pregnancy** risk is reduced with a progestogen-only implant compared to no use of contraception.
- Women with a **BMI >30 kg/m^2** can use progestogen-only implants without restriction or a reduction in contraceptive efficacy for the licensed duration of use.
- There is **no evidence of a delay in fertility** following removal of a progestogen-only implant.
- **Bleeding patterns** are likely to change during use of a progestogen-only implant. 20% of users will have no bleeding; almost 50% will have infrequent, frequent or prolonged bleeding. Bleeding patterns are likely to remain irregular over time.
- There is no causal association between the use of a progestogen-only implant and **weight change, mood change, loss of libido** or **headache.**
- **Acne** may improve, occur or worsen during use of a progestogen-only implant.
- Clinicians should be aware that **early discontinuation** of progestogen-only implants is common.
- There is little or no increase in risk of **venous thromboembolism** associated with use of a progestogen-only implant.
- There is no evidence of a clinically significant effect on **bone mineral density** with use of a progestogen-only implant.
- Women using **liver enzyme-inducing drugs *short term (<3 weeks)*** may continue with the progestogen-only implant. Additional contraception (e.g. condoms) should be used until 4 weeks after the liver enzyme-inducer has been stopped. An alternative contraceptive method should be chosen if liver enzyme-inducing drugs are to be used long-term.

INSERTION

- All women who are **postpartum (including breastfeeding women)** may use a progestogen-only implant without restriction.
- A progestogen-only implant can be inserted any time **postpartum** up to Day 21 with immediate contraceptive protection. If inserted **after Day 21**, then condoms or abstinence should be advised for **7 days.** (Use prior to Day 21 may be associated with bleeding and is outside the terms of the product licence.)
- A progestogen-only implant can be inserted on the days of **surgical or second part of medical abortion or immediately following miscarriage:** no additional contraception is required. If started >5 days after abortion or miscarriage, additional contraception is required for 7 days.
- **Health professionals** who insert and remove progestogen-only implants should be appropriately trained, should maintain competencies and attend regular updates.
- **Emergency equipment** must be available in all settings where subdermal contraception is inserted and removed and local referral protocols must be in place for women who require further medical input.
- An **aseptic technique** should be applied to **insertion and removal** of progestogen-only implants.
- Appropriate local **anaesthesia** should be injected prior to insertion and removal of progestogen-only implants.
- **Prophylactic antibiotics for endocarditis** for **insertion and removal** are not recommended.

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FOLLOW-UP

- **Routine follow-up visits are not required.** Women should be advised to return at any time to discuss problems or if they want to change their contraceptive method.
- Women should be **advised to specifically return** if they: cannot feel the implant; notice any change in shape or any changes to the skin around the site of the implant; experience any pain; become pregnant; or develop any condition that would contraindicate use.
- Woman at **higher risk for sexually transmitted infections (STIs)** (i.e. those aged <25 years, or aged >25 years with a new sexual partner, or more than one partner in the last year) should be advised to use condoms in addition to the implant.

PROBLEMS ASSOCIATED WITH USE

- A sexual history should be taken from women who experience unacceptable **bleeding** while using the progestogen-only implant to establish STI risk and/or be investigated for gynaecological pathology if clinically indicated.
- Women who experience **unacceptable bleeding** while using the progestogen-only implant who have had gynaecological problems excluded may be offered **mefenamic acid** or **ethinylestradiol** as a combined oral contraceptive pill as short-term treatment.
- There is no evidence of a **teratogenic effect** of a progestogen-only implant if a woman becomes pregnant.

REMOVAL

- **Fertility** is restored quickly after progestogen-only implant removal and effective contraception is required if pregnancy is not desired.
- Women should be advised that **abstinence, additional contraceptive protection or emergency contraception is not required** prior to progestogen-only implant removal if they return within 3 years and there is to be immediate replacement of another implant or they are starting another method of contraception.
- If **difficulty arises with progestogen-only implant removal** then the implant should be localised by ultrasound. Deeply inserted implants may need to be removed by an expert.

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Discussion Points for Progestogen-only Implants

The following discussion points have been developed by the FSRH Education Committee.

Discussion Points

1 Discuss and consider how you would promote the uptake of long-acting reversible contraception in your surgery/service.

2 Discuss how you would counsel a woman considering Implanon as her method of contraception.

3 The main side effect of Implanon is menstrual disturbance. Discuss how you would manage this in the clinical situation.

Questions for Progestogen-only Implants

The following questions and answers have been developed by the FSRH Education Committee.

Indicate your answer by ticking the appropriate box for each question	***True***	***False***
1 Implanon is a contraceptive implant releasing levonorgestrel and is licensed for 3 years' use.	☐	☐
2 Some 30% of women discontinue Implanon due to non-bleeding side effects.	☐	☐
3 Liver enzyme-inducing drugs reduce the efficacy of Implanon.	☐	☐
4 Implanon may be used without restriction (UKMEC 1) in breastfeeding women.	☐	☐
5 Prophylactic use of antibiotics is recommended prior to Implanon fitting in women with complicated congenital heart disease or valve replacement.	☐	☐
6 Combined oral contraception may be beneficial in managing problematic bleeding in women using Implanon.	☐	☐
7 Following mid-trimester abortion, Implanon insertion should be delayed until Days 21–28.	☐	☐
8 Past history of deep vein thrombosis is an absolute contraindication (UKMEC 4) for Implanon use.	☐	☐
9 Long-term Implanon use is associated with a clinically significant reduction in bone mineral density.	☐	☐
10 Implanon can be inserted up to 5 days after a first- or second-trimester abortion without the need for additional protection.	☐	☐

Answers

1 False, 2 False, 3 True, 4 True, 5 False, 6 True, 7 False, 8 False, 9 False, 10 True

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STEPS INVOLVED IN THE DEVELOPMENT OF CEU GUIDANCE

STEP	TIME TAKEN
Formulation of **key clinical questions** by the Clinical Effectiveness Unit (CEU). **Systematic literature review** involving searching electronic, bibliographic databases by CEU researchers. **Obtaining and reviewing** copies of the full papers of all relevant publications identified through the searches. **Formal, critical appraisal** of key papers and development of short evidence tables.	This process must be completed in a maximum of 8 weeks.
Draft One Guidance document is written, providing recommendations and good practice points based on the literature review.	The CEU has overall responsibility for writing the Guidance document. The Multidisciplinary Group and other peer reviewers should highlight inconsistencies and errors or where the text is incomprehensible.
Multidisciplinary Group Meeting comprising stakeholders and including service user representation, representation from the Faculty of Sexual and Reproductive Healthcare (FSRH) Education Committee and, where possible, representation from the FSRH Clinical Effectiveness Committee (CEC) and FSRH Council.	A one-day meeting held in Aberdeen with the Multidisciplinary Group to discuss the Draft One Guidance document.
. **Preparation of Draft Two Guidance document** based on discussion at the Multidisciplinary Group.	The Multidisciplinary Group meeting is held at least 2 months before the Guidance deadline to allow time for development of further drafts.
Peer Review of Draft Two Guidance document by the Multidisciplinary Group and the FSRH CEC.	
All **written feedback on the Draft Two Guidance document** is tabulated and the CEU response to these comments outlined.	
Draft Three Guidance document is prepared based on written feedback and is sent to the Multidisciplinary Group and the FSRH CEC. In addition, two independent peer reviewers are identified by the CEC to provide feedback at this stage.	Only minor comments can be accepted at this stage.
The Final Guidance document is published by the FSRH.	Proofreading of the Guidance document is then performed by three members of the CEU team independently and comments collated and sent back by the Unit Director. A pdf version of the Guidance is available on the FSRH website.

COMMENTS AND FEEDBACK ON PUBLISHED GUIDANCE

All comments on published Guidance can be sent directly to the Clinical Effectiveness Unit (CEU) via e-mail (**ceu.guidance@abdn.ac.uk**).

You will receive an automated acknowledgment on receipt of your comments. If you do not receive this automated response please contact the CEU by telephone [+44 (0) 1224 553623] or e-mail (**ffp.ceu@abdn.ac.uk**).

The CEU is unable to respond individually to all feedback. However, the CEU will review all comments and provide an anonymised summary of comments and responses which, after review by the Clinical Effectiveness Committee, will be posted on the Faculty website (**www.fsrh.org**).