FACULTY OF SEXUAL & REPRODUCTIVE HEALTHCARE

ROYAL COLLEGE OF OBSTETRICIANS & GYNAECOLOGISTS

Faculty of Sexual & Reproductive Healthcare Clinical Guidance



Progestogen-only Implants

Clinical Effectiveness Unit

February 2014

ISSN 1755-103X

ABBREVIATIONS USED

BMD	bone mineral density
BMI	body mass index
CEU	Clinical Effectiveness Unit
CHC	combined hormonal contraception
COC	combined oral contraception
Cu-IUD	copper-bearing intrauterine device
DMPA	depot medroxyprogesterone acetate
EC	emergency contraception
EE	ethinylestradiol
ENG	etonogestrel
FSRH	Faculty of Sexual & Reproductive Healthcare
HIV	human immunodeficiency virus
LARC	long-acting reversible contraception
LNG	levonorgestrel
LNG-IUS	levonorgestrel-releasing intrauterine system
LoC SDI	Letter of Competence in Subdermal Contraceptive Implant Techniques
MHRA	Medicines and Healthcare Products Regulatory Agency
MRI	magnetic resonance imaging
NICE	National Institute for Health and Care Excellence
POP	progestogen-only pill
SPC	Summary of Product Characteristics
STI	sexually transmitted infection
UKMEC	UK Medical Eligibility Criteria for Contraceptive Use
UPSI	unprotected sexual intercourse
VTE	venous thromboembolism
WHO	World Health Organization
WHOMEC	World Health Organization Medical Eligibility Criteria for Contraceptive Use

GRADING 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 guideline group

Published by the Faculty of Sexual & Reproductive Healthcare
Registered in England No. 2804213 and Registered Charity No. 1019969

First published in 2014

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SUMMARY OF KEY RECOMMENDATIONS

Eligibility

✓ Health professionals should be familiar with the most up to date UK Medical Eligibility Criteria for the progestogen-only implant.

Timing of repeat insertions

C If an implant is replaced immediately, and after no longer than 3 years since insertion, there is no need for additional contraceptive precautions after replacement.

Health benefits and risks

C The progestogen-only implant may help to alleviate dysmenorrhoea.

C There is little or no increased risk of venous thromboembolism, stroke or myocardial infarction associated with the use of the progestogen-only implant.

B There is no evidence of a clinically significant adverse effect on bone mineral density with use of a progestogen-only implant.

C Fewer than one-quarter of women using the progestogen-only implant will have regular bleeds. Infrequent bleeding is the most common pattern (approximately one-third); around one-fifth of women experience no bleeding; and approximately one-quarter have prolonged or frequent bleeding. Altered bleeding patterns are likely to remain irregular.

C Although some women do report changes in weight, mood and libido when using the progestogen-only implant, there is no evidence of a causal association.

C Women may experience improvement, worsening or new onset of acne during use of a progestogen-only implant.

C Although some women report headache with use of the progestogen-only implant, there is no evidence of a causal association.

Insertion, removal and replacement

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

✓ Appropriate local anaesthesia should be administered prior to insertion and removal of a progestogen-only implant.

C There is no need for additional precautions or abstinence prior to removal of a progestogen-only implant, providing the removal occurs no later than 3 years after insertion.

B After removal of a progestogen-only implant, effective contraception is required immediately if pregnancy is not desired.

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Follow-up

✓ Women using progestogen-only implants should be advised that no routine follow-up is required, but that they can return at any time to discuss problems or to change their contraceptive method.

✓ 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 skin changes or pain around the site of the implant; they become pregnant; or they develop any condition that may contraindicate continuation of the method.

Factors affecting efficacy

C Concomitant use of enzyme-inducing drugs may reduce the efficacy of the progestogen-only implant. Women should be advised to switch to a method unaffected by enzyme-inducing drugs or to use additional contraception until 28 days after stopping the treatment.

C Obesity (BMI>30 kg/m^2) is a condition for which there is no restriction on the use of the progestogen-only implant (UKMEC 1).

C No increased risk of pregnancy has been demonstrated in women weighing up to 149 kg. However, because of the inverse relationship between weight and serum etonogestrel levels, a reduction in the duration of contraceptive efficacy cannot be completely excluded.

✓ Women using the progestogen-only implant should be informed, where relevant, that the manufacturer states that earlier replacement can be considered in 'heavier' women but that there is no direct evidence to support earlier replacement.

Other things to consider

B The consistent and correct use of condoms is the most efficient means of protecting against HIV and other sexually transmitted infections.

✓ A woman with an impalpable implant should be advised to use additional precautions or avoid intercourse until the presence of an implant is confirmed.

✓ The location of an impalpable or deep implant should be identified before exploratory surgery. Referral to an expert implant removal centre is recommended.

✓ After exclusion of other causes, women who experience troublesome bleeding while using the progestogen-only implant, and who are eligible to use combined hormonal contraception, may be offered combined oral contraception (COC) cyclically or continuously for 3 months (outside the product licence). Longer-term use of the implant and COC has not been studied and is a matter of clinical judgement.

C The progestogen-only implant is not known to be harmful in pregnancy but women with a continuing pregnancy should be advised to have the implant removed. Women may retain the implant if they wish to continue the method after a non-continuing pregnancy.

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Faculty of Sexual & Reproductive Healthcare Clinical Effectiveness Unit

A unit funded by the FSRH and supported by NHS Greater Glasgow & Clyde to provide guidance on evidence-based practice

FSRH Guidance (February 2014)
Progestogen-only Implants

(Revision due by February 2019)

1 Purpose and Scope

This Guidance provides evidence-based recommendations and good practice points on use of the progestogen-only implant. It is intended for any health professional or service providing contraception or contraceptive advice in the UK. The document supersedes previous Faculty of Sexual & Reproductive Healthcare (FSRH) guidance on progestogen-only implants.[1] The main changes from the previous guidance are:

- Information on Nexplanon®, the implant that has replaced Implanon®
- Updated UK Medical Eligibility Criteria for Contraceptive Use (UKMEC)[2]
- Changes to advice on switching from combined hormonal methods, the progestogen-only pill (POP) or levonorgestrel-releasing intrauterine system (LNG-IUS) to the implant
- Modified recommendations in relation to body weight and timing of implant replacement
- More detailed information on insertion and removal procedures
- Updated advice on management of impalpable, deep, bent or fractured implants.

From 1999 until 2010 the only progestogen-only implant available in the UK was the Implanon etonogestrel (ENG) implant.[3] Implanon has now been replaced by a bioequivalent implant known as Nexplanon.[4] Other contraceptive implants are available outside the UK. This guidance will not cover these methods in detail but some information is provided on page 16.

Recommendations are based primarily on evidence directly relating to both forms of the ENG implant (referred to as the progestogen-only implant) and consensus opinion of experts. Where there is limited evidence, extrapolation of data from other progestogen-only implants (Norplant® and Jadelle®) has been used. As Nexplanon and Implanon are bioequivalent,[4] recommendations other than those relating to insertion and localisation apply equally to both products.

The recommendations should be used to guide clinical practice but they are not intended to serve alone as a standard of medical care or to replace clinical judgement in the management of individual cases. A key to the Grading of Recommendations, based on levels of evidence, is provided on the inside front cover of this document. Details of the methods used by the Clinical Effectiveness Unit (CEU) in developing this guidance are outlined in Appendix 1 and in the CEU section of the FSRH website (www.fsrh.org).

2 Background

The progestogen-only implant is a single, non-biodegradable, subdermal rod licensed for up to 3 years of use.[3,4] Each implant contains 68 mg ENG.[3,4] The release rate decreases with time from approximately 60–70 µg/day in Weeks 5–6 to approximately 25–30 µg/day at the end of the third year.[3,4]

The main difference between Nexplanon and Implanon is that barium sulphate has been added to Nexplanon to enable detection by X-ray (see page 13). The applicator has also been modified to reduce the risk of deep insertion and to facilitate one-handed insertion.

Implanon is no longer available to order. Existing stocks can be used if the implant is still within its expiry date and the health professional has been trained in Implanon insertion.

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3 Mode of Action and Efficacy

The progestogen-only implant is a long-acting reversible method of contraception (LARC). The primary mode of action is to prevent ovulation.[5,6] Implants also prevent sperm penetration by altering the cervical mucus[5] and possibly prevent implantation by thinning the endometrium.

A small clinical trial showed that serum levels of ENG over 90 pg/ml will inhibit ovulation in 97% of women, but that lower concentrations may result in ovulation in up to 52% of women.[7] Serum levels of above 90 pg/ml have been demonstrated within 8 hours of implant insertion.[6,8] Serum concentrations decrease with time from a maximum of between 472 and 1270 pg/ml (1–13 days after insertion) to a mean concentration of around 200 pg/ml at the end of the first year of use. By the end of Year 3 the mean concentration of ENG is 156 (range 111–202) pg/ml. Varying body weight is thought to be partly responsible for the wide range of serum levels observed.[4] In clinical trials, ovulation was not observed in the first 2 years, and only rarely in the third year of use.[6,8–10]

The implant is a highly effective contraceptive.[11] The overall pregnancy rate reported in the National Institute of Health and Care Excellence (NICE) guideline on *Long-acting Reversible Contraception*[12] is <1 in 1000 over 3 years. A review of contraceptive failure in the USA[11] has estimated that the percentage of women in the USA experiencing an unintended pregnancy within the first year of using the progestogen-only implant is 0.05%.[11] For women who have undergone female sterilisation, the percentage of women experiencing pregnancy in the first year of use is 0.5%; for men undergoing male sterilisation the corresponding figure is 0.15%.

4 Who is Eligible to Use Progestogen-only Implants?

The UK Medical Eligibility Criteria for Contraceptive Use (UKMEC)[2] provide evidence-based recommendations on the use of contraceptive methods in the presence of a range of medical conditions and social factors. The most recent UKMEC (available from www.fsrh.org) should be referred to when assessing a woman's eligibility for any contraceptive method including the progestogen-only implant. Unless specifically stated, UKMEC does not take account of multiple conditions. There are no defined rules for assessing multiple UKMEC categories. Assessing a person's eligibility in the presence of multiple medical and social factors requires clinical judgement based on the available evidence.

There is no upper age limit for the use of the progestogen-only implant.[2,13] FSRH guidance is available on the use of contraceptives in women aged over 40 years.[13]

✓ Health professionals should be familiar with the most up to date UK Medical Eligibility Criteria for the progestogen-only implant.

5 When can a Progestogen-only Implant be Safely Inserted?

FSRH guidance advises that a woman may start the progestogen-only implant up to and including Day 5 of the menstrual cycle without the need for additional contraceptive protection (Table 1). This is in line with the Summary of Product Characteristics (SPC).[14] The CEU recommends that a woman may start the progestogen-only implant at any other time if it is reasonably certain that she is not pregnant (Box 1) or the other criteria for quick starting contraception are met (page 3).[15]

When enquiring about a woman's last menstrual period, health professionals should check that the last menstrual period was typical of her normal bleeding pattern in terms of duration, heaviness and timing. Bleeding during or soon after stopping hormonal contraception is not the same as a natural period, and even regular withdrawal bleeds on combined hormonal contraception (CHC) may not be a reliable indicator that a woman is not pregnant. If there is uncertainty about a woman's menstrual history a pregnancy test should be performed before implant insertion and again no sooner than 3 weeks after the last episode of unprotected sexual intercourse (UPSI). Women having an implant inserted at the beginning of a period should be advised to have a pregnancy test if the period is subsequently found to be lighter or shorter than usual.

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Table 1 Faculty of Sexual & Reproductive Healthcare (FSRH) advice on starting the progestogen-only implant

Situation	Starting implant	Requirements for additional contraception
Women having menstrual cycles	Day 1–5 of menstrual cycle	Not required
	Any other time; consider pregnancy	7 days
Women who are amenorrhoeic	At any time if it is reasonably certain she is not pregnant	7 days
Postpartum (includes any delivery from 24 weeks' gestation)	On or before Day 21 postpartum[a]	Not required
	After Day 21 postpartum	7 days (unless menstruation recommenced and Days 1–5)
Post first- or second-trimester abortion	Up to and including Day 5 post-abortion[b]	Not required
	At any other time if it is reasonably certain she is not pregnant or at risk of pregnancy	7 days
Following oral emergency contraception	Immediately following administration[c]	7 days after levonorgestrel, 14 days after ulipristal acetate
Other situations in which pregnancy cannot be excluded	Consider quick starting implant or bridging method[C]	7 days

[a]The Summary of Product Characteristics advises insertion between Days 21 and 28. Ovulations have been noted around Day 30.[16] FSRH advises Day 21 for postpartum contraceptive starting in line with the World Health Organization as highly unlikely women will have ovulated by Day 21 and to ensure contraceptive effect is established before ovulation.
[b]The Clinical Effectiveness Unit advises that women ideally start on the day or day after a first- or second-trimester abortion.
[c]A pregnancy test is advised no sooner than 3 weeks after unprotected sexual intercourse.

Box 1 Criteria for excluding pregnancy (adapted from *UK Selected Practice Recommendations for Contraceptive Use*[17])

Health professionals can be 'reasonably certain' that a woman is **not currently pregnant** if any one or more of the following criteria are met and there are no symptoms or signs of pregnancy:

- She has not had intercourse since last normal menses
- She has been correctly and consistently using a reliable method of contraception (see text above)
- She is within the first 7 days of the onset of a normal menstrual period
- She is within 4 weeks postpartum for non-lactating women
- She is within the first 7 days post-abortion or miscarriage
- She is fully or nearly fully breastfeeding, amenorrhoeic, and less than 6 months postpartum.

A pregnancy test, if available, adds weight to the exclusion of pregnancy, **but only if performed at least 3 weeks since the last episode of unprotected sexual intercourse (UPSI).**

NB. Health professionals should also consider if a woman is **at risk of becoming pregnant** as a result of UPSI within the last 7 days.

For the purposes of excluding pregnancy, the CEU consider that hormonal, intrauterine and barrier methods can be deemed reliable providing they have been used consistently and correctly on every incidence of intercourse.[15] This should be assessed on an individual basis.

Although ovulation-suppressing levels of ENG are reached within 1 day of implant insertion, the time to onset of reliable ovulation suppression is unknown. Therefore, when starting the implant after Day 5, women should use additional precautions or avoid sex for the next 7 days.

In certain circumstances, the CEU also supports starting the progestogen-only implant when pregnancy cannot be excluded.[15] More detailed guidance is available in the FSRH guidance on *Quick Starting Contraception*.[15] Alternatively, a short-acting method can be quick started as a 'bridging method' until the woman returns for implant insertion.

FSRH guidance advises that women being quick started should have a pregnancy test no sooner than 3 weeks after the last episode of UPSI, irrespective of subsequent bleeding patterns.[15]

Pregnancy testing is also advised if women do not adhere to advice on additional contraceptive precautions and intercourse has occurred. For details on what to do if pregnancy occurs see page 15.

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6 What Advice Should be Given When Switching from Hormonal Methods of Contraception to the Progestogen-only Implant?

6.1 FSRH advice on switching from other contraceptive methods

No studies were identified that assessed the maintenance of the contraceptive effect when switching from other methods of contraception to the progestogen-only implant. To ensure recommendations are consistent with other FSRH guidance, the CEU recommends following the advice outlined in Table 2. This is in some instances more cautious than the advice in the SPC for Nexplanon (see page 5).

Table 2 Faculty of Sexual & Reproductive Healthcare (FSRH) advice on switching to the progestogen-only implant

Situation	Implant inserted	Advice regarding additional contraceptive precautions and emergency contraception	Rationale
Switching from CHC	Immediately after the last day of active hormone use (i.e. Day 1 of the hormone-free interval)	No additional precautions required	In theory the implant could be started up to Day 3 of the hormone-free interval without the need for additional precautions as ovulation would not be expected until Day 10 (following two missed pills),[18] allowing 7 days for the implant to work
	Week 1 following the hormone-free interval	7 days of additional precautions required. If UPSI has occurred after Day 3 of the hormone-free interval advise restarting the CHC method for at least 7 days	When switching after a 7-day hormone-free interval there are no data to confirm that suppression of ovulation is maintained
	Week 2–3 of pill/ring/patch	No additional precautions required providing the CHC method has been used consistently and correctly for seven consecutive days before switching	There is evidence to suggest that taking hormonally active pills for seven consecutive days prevents ovulation.[19] Therefore as long as seven pills have been taken, theoretically up to seven pills can be missed without any effect on contraceptive efficacy
Switching from an injectable	Any time within 14 weeks of last injection	No additional precautions required	Ovulation would not be expected to return until at least 7 days after the method has stopped being effective during which time the new method will be effective
	14 weeks + 1 day or more since last injection	7 days of additional precautions required EC would be required if UPSI occurred any time after 14 weeks	
Switching from a POP or LNG-IUS	Any time	7 days of additional precautions required or continue to use the existing method for a further 7 days	As POP and LNG-IUS do not necessarily suppress ovulation, it may take up to 7 days for the implant to suppress ovulation. While a cervical mucus effect may be maintained, there is no evidence to support this
Switching from a non-hormonal method	Days 1–5 of cycle	No additional precautions required	
	Outside Days 1–5 or if amenorrhoeic	7 days of additional precautions required. Cu-IUD should be retained for 7 days if UPSI occurred in the 7 days before implant insertion	

CHC, combined hormonal contraception; Cu-IUD, copper-bearing intrauterine device; EC, emergency contraception; LNG-IUS, levonorgestrel-releasing intrauterine system; POP, progestogen-only pill; UPSI, unprotected sexual intercourse.

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6.2 SPC advice on switching from a combined hormonal method

The implant should ideally be inserted on the day after the last day of active pill, ring or patch use but at the latest can be inserted up to the day following the usual hormone-free interval. In this instance no additional precautions are required. Thereafter 7 days of additional precautions would be required.

6.3 SPC advice on switching from other progestogen-only methods

No additional precautions are required when the implant is inserted on the day the progestogen-only injectable is due, within 24 hours of the last POP being taken and on the same day that the previous implant or LNG-IUS is removed.

7 Timing of Repeat Insertions

The licensed duration of the implant is 3 years.[4] Although some studies.[20,21] have included a small number of women who have used the implant beyond 3 years, the CEU does not recommend extended use of the implant beyond 3 years, irrespective of the woman's age. Ovulation within the first week of implant removal is rare. Therefore, women who return on schedule (no more than 3 years since date of insertion) for implant replacement do not need to: abstain from sexual intercourse prior to removal, use additional contraceptive protection, or use emergency contraception (EC) if sexual intercourse has occurred. After 3 years of use there is a potential risk of pregnancy and additional contraceptive precautions should be advised. If UPSI has occurred after the licensed duration of the implant, the need for pregnancy testing and EC should be considered. Women requesting replacement should either return when pregnancy can be excluded (no sooner than 3 weeks after UPSI) or may have immediate replacement if quick starting is appropriate (refer to FSRH guidance on *Quick Starting Contraception*).[15]

C If an implant is replaced immediately, and after no longer than 3 years since insertion, there is no need for additional contraceptive precautions after replacement.

8 What are the Benefits and Risks of Progestogen-only Implant Use?

8.1 Non-contraceptive benefits

Dysmenorrhoea and ovulatory pain that are not associated with any identifiable pathological condition may be alleviated by hormonal methods that inhibit ovulation, and improvements have been noted with the progestogen-only implant.[22,23]

A few small studies/case reports[24–26] suggest that the progestogen-only implant may be beneficial in the treatment of endometriosis but it is not specifically listed as a treatment option within current guidelines.[27]

C The progestogen-only implant may help to alleviate dysmenorrhoea.

8.2 Health concerns

8.2.1 Cardiovascular health

Few studies have been large enough to evaluate the risk of venous thromboembolism (VTE) associated with progestogen-only contraception.

Those studies that have looked at different progestogen-only contraceptives generally suggest that there is little or no risk of VTE,[28,29] no statistically significant increased risk of myocardial infarction[30] and no statistically significant increased risk of stroke.[31] However, more research is required in high-risk women and few studies have included the ENG implant.

Studies looking at cardiovascular risk factors (e.g. lipids and carbohydrate metabolism) in healthy, non-obese implant users have generally been reassuring.[32–35]

C There is little or no increased risk of venous thromboembolism, stroke or myocardial infarction associated with the use of the progestogen-only implant.

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8.2.2 Bone mineral density

There is limited available evidence looking at the effect of the progestogen implant on bone mineral density (BMD). A Cochrane review[36] has concluded that it is not possible to determine from the current evidence whether hormonal contraception influences fracture risk.

One comparative study investigating BMD after 2–3 years of implant use reported no changes in BMD compared with intrauterine device users,[37] while other studies reported reduced BMD in the forearm bones compared to pre-insertion measurements[38] or non-user controls.[39] Although differences in BMD were statistically significant, it is not known if they are clinically significant.

B There is no evidence of a clinically significant adverse effect on bone mineral density with use of a progestogen-only implant.

8.2.3 Breast cancer

There are insufficient data to make an evidence-based recommendation concerning the effect of progestogen-only implants on breast cancer risk.[40] The limited data on progestogen-only methods suggest that any attributable risk is likely to be small and is likely to reduce with time after stopping.

8.2.4 Ectopic pregnancy

Progestogen-only implants are such effective contraceptives that the absolute risk of pregnancy (either intrauterine or ectopic) while using these methods is very low. Past ectopic pregnancy is a condition for which there is no restriction on the use of the progestogen-only implant (UKMEC 1).[2]

8.2.5 Gynaecological cancers

There are few epidemiological data on use of the progestogen-only implant and gynaecological cancers. Histological and cytological monitoring of implant users over 2 years showed a reduction in endometrial thickness and no change in cervical cytology.[41] UKMEC[2] provides guidance on the use of the progestogen-only implant in women with gynaecological cancers.

8.3 Side effects

8.3.1 Changes to bleeding patterns

Unscheduled bleeding in the first 3 months after starting a new hormonal contraceptive method is common.[42] The progestogen-only implant is associated with unpredictable bleeding patterns, however the bleeding pattern in the first 3 months is broadly predictive of future bleeding patterns for many women.[43] Dissatisfaction with bleeding has been cited as a reason for implant discontinuation.[44–47] Infrequent bleeding (<2 episodes of bleeding/spotting over a 90-day period according to the World Health Organization definition) is common, with around one-third of implant users in clinical trials experiencing this scenario. Amenorrhoea (no bleeding over a 90-day period) has been cited in around 21% of users; prolonged bleeding (≥1 bleeding/spotting episode occurring on ≥10 days in a 90-day period) in around 17% of users; and around 6% of users have reported frequent bleeding (>4 episodes of bleeding/spotting in a 90-day period).[43,47]

Information on the management of problematic bleeding is given later in this guidance (page 14). Although bleeding changes are associated with the implant, it is also important to consider other factors such as sexually transmitted infections (STIs) (page 12) and gynaecological pathology (page 14).

C Fewer than one-quarter of women using the progestogen-only implant will have regular bleeds. Infrequent bleeding is the most common pattern (approximately one-third); around one-fifth of women experience no bleeding; and approximately one-quarter have prolonged or frequent bleeding. Altered bleeding patterns are likely to remain irregular.

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8.3.2 *Changes in weight, mood, libido*

There are reports of women experiencing weight gain[46–50] and mood changes[46,48–50] whilst using the progestogen-only implant. Decreased libido is listed within the SPC as a commonly (between 1 in 100 to 1 in 10) reported undesirable effect within clinical trials.[3,14] Non-comparative studies[46,48–50] have reported decreased libido in fewer than 6% of users of progestogen-only implants.

NICE guidelines[12] advise that there is not an association between use of the progestogen-only implant, weight change, mood change and reduced libido. No subsequent evidence was identified that would alter this conclusion.

C Although some women do report changes in weight, mood and libido when using the progestogen-only implant, there is no evidence of a causal association.

8.3.3 *Acne*

Progestogen-only implant use may affect acne in some women. Acne has been shown to occur, improve or worsen with the use of a progestogen-only implant.[46,50–54]

C Women may experience improvement, worsening or new onset of acne during use of a progestogen-only implant.

8.3.4 *Headache*

Headache is very commonly reported in clinical trials of the progestogen-only implant[46–50] and the SPC includes headache as a possibly related undesirable effect.[3,4] However, headaches are a common symptom in the general population and NICE[12] indicate that a causal relationship cannot be confirmed. No subsequent evidence was identified that would alter this conclusion.

There is no restriction on initiating the progestogen-only implant in women who have non-migrainous headaches or a pre-existing condition of migraine without aura (UKMEC 1).[2]

For women who develop migraine (with or without aura) whilst using the progestogen-only implant or who have a pre-existing condition of migraine with aura, the advantages of using the progestogen-only implant are generally felt to outweigh the theoretical or proven risks (UKMEC 2).[2]

C Although some women report headache with use of the progestogen-only implant, there is no evidence of a causal association.

8.3.5 *Skin atrophy*

Skin atrophy is recognised as a potential adverse effect of steroid hormone use, and there are case reports[55,56] in the literature of atrophy at the site of subdermal implants (see advice on insertion site of replacement implants on page 9).

9 Are there Any Risks Associated with the Insertion or Removal Procedure?

Non-insertion of the implant, deep insertion and nerve injury are three types of harm cited in litigation cases involving the contraceptive implant.[57] Vascular injury and rarely intravascular insertion have also been reported.[4] Estimating the frequency with which such events happen is difficult as much of the evidence comes from postmarketing surveillance and case reports.

Significant complications including pregnancy should be reported to the local clinical governance team, to the Medicines and Healthcare Products Regulatory Authority (MHRA) Yellow Card scheme and to the manufacturer.

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9.1 Non-insertion

Non-insertion of Implanon has been noted in clinical trials[47,58] and postmarketing surveillance studies.[59,60]

Nexplanon has inbuilt safety features to reduce the risk of non-insertion but it is still important to check for the presence of the implant in the applicator and to palpate the skin after insertion (page 9). The applicator should be checked immediately at the end of the insertion procedure. The needle should be fully retracted and only the purple tip of the obturator should be visible.[4]

9.2 Deep insertion

When inserted correctly the implant should be situated subdermally (subcutaneously), just under the skin.[4] Significant migration of the implant is not thought to occur when an implant has been correctly inserted;[61] therefore, deep implant insertions are more likely a result of the insertion technique. If an implant is inserted too deeply it may be difficult to remove and/or locate, and there is greater potential for neurovascular injury, infection and scar formation.[47]

9.3 Nerve or vascular injury

Incidents of nerve injury and neuropathy associated with the insertion[62] or removal of Implanon[63,64] are documented in the literature. It was previously recommended that the insertion site for Implanon should be in the groove between the bicep and the tricep muscles. The manufacturer then changed the SPC to recommend insertion 8–10 cm (3-4 inches) above the medial epicondyle of the humerus. The SPC for Nexplanon[4] states that the implant should be inserted at the inner side of the upper arm to avoid the large blood vessels and nerves that lie deeper in the connective tissue between the bicep and tricep muscles.

9.4 Other complications

Fibrosis around the implant[47] and implant breakages[46,47] (page 14) have been documented as possible complications. Through the FSRH enquiry service anecdotal reports have been received of implants being sited too superficially, causing pain and altered sensation.

10 How Should the Progestogen-only Implant be Inserted, Removed and Replaced?

The SPC for Nexplanon[4] includes instructions on insertion, removal and replacement procedures (www.medicines.org.uk). The equipment required is listed in Appendix 2.

There is little evidence to guide best practice in insertion and removal techniques. Practice is reported to vary among instructing doctors.[65] This is potentially confusing for trainees in implant techniques. Therefore, for clarification the text that follows includes practical advice based on the opinions of the guideline development group.

10.1 Training requirements

Health professionals offering the progestogen-only implant should hold the FSRH Letter of Competence in Subdermal Contraceptive Implant Techniques (LoC SDI), or have achieved equivalent recognised competencies. Skills should be maintained by recertifying according to FSRH guidelines (or equivalent) and attending regular updates. Detailed information can be found on the FSRH website (www.fsrh.org).

C Health professionals who insert and/or remove progestogen-only implants should be appropriately trained, maintain competence and attend regular updates.

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10.2 Aseptic precautions

Equipment for insertion and removal should be laid on a sterile field. The insertion/removal site should be cleaned with antiseptic solution. The guideline development group advise that non-sterile gloves can be used for implant insertion providing a no-touch technique is used (i.e. avoid touching the insertion site or parts of the sterile equipment that come in contact with the woman's arm). A no-touch technique may be difficult during some removal procedures, therefore the guideline development group advise use of sterile gloves for implant removal.

10.3 Positioning

The woman should lie down with her arm externally rotated and either flexed or extended out on a support. An alternative position may be used for removal if it enables better access.

10.4 Anaesthesia

The insertion site should be anaesthetised using lidocaine 1%. Lidocaine 1% with adrenaline 1:200 000 can be used instead to avoid bleeding, for example, for deep implant removal or women with bleeding disorders (outside product licence). For women with an allergy to lidocaine, health professionals should seek guidance from a local anaesthetist as to an appropriate alternative. The point of a needle should be used to check that adequate analgesia has been provided.

✓ Appropriate local anaesthesia should be administered prior to insertion and removal of a progestogen-only implant.

10.5 Insertion

The SPC advises that the implant should be inserted 8–10 cm up the arm from the medial epicondyle. Because of natural variation in arm lengths the guideline development group agreed that 8–10 cm is not always the ideal distance, and that as a general guide the insertion site should be one-third of the way up the arm from the elbow.

Care should be taken to avoid deep insertion into muscle, nerves or blood vessels (page 8).

As a guide, two marks can be made on the arm: one indicating where the implant will be inserted and the other a few centimetres in the direction the implant is to be inserted. Use of a water-soluble marker may reduce the risk of inadvertent skin tattoo.

The implant should be checked, prepared and inserted according to the manufacturer's SPC (www.medicines.org.uk).The applicator should initially be angled at 30° to the skin and then lowered to a horizontal position as soon as the needle pierces the dermis. The manufacturer advises that inserting the implant in a seated position allows better visualisation of the angle of insertion.

Immediately after insertion the health professional should verify the presence of the implant by palpation. Both ends of the implant should be palpable. Pushing down on one end of the implant should cause the other end to pop up. Women should also be encouraged to palpate the device or observe the implant pop up to confirm that it is present. Palpation of the device should be documented.

10.6 Removal

The reasons for requesting implant removal should be discussed with each individual patient. Advice should be offered to those experiencing problems with the implant (see section on the management of problems on page 13). A woman has the right to insist on implant removal at any time after insertion. Removal should only be delayed if the woman is deemed not to have capacity to make the decision or if the resources for safe removal are not available.

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If the progestogen-only implant is removed within its licensed duration, women do not need to use additional precautions or abstain from sexual intercourse prior to removal. Future contraceptive needs should be discussed, and women who wish to avoid pregnancy should be advised that contraception is required immediately after implant removal.

The implant should be palpated before preparing equipment. (NB. Implants inserted outside the UK may consist of two or more rods.) The distal end of the implant (the end closest to the elbow) should be marked before cleaning the skin. If the distal end is not palpable, pushing on the proximal end (the end closest to the shoulder) should cause the distal end to pop up.

The skin should be flat when making the incision but the proximal end can be pushed down to stabilise the implant during removal.[14] A small longitudinal incision should be made. It may be possible to push the implant out of the incision (known as the 'pop-out technique')[58] but forceps can be used if this is not possible.

If the rod is close to the brachial artery removal should not be attempted. Similarly, removal attempts should be stopped if there is any indication of sensory disturbance.

C There is no need for additional precautions or abstinence prior to removal of a progestogen-only implant, providing the removal occurs no later than 3 years after insertion.

B After removal of a progestogen-only implant, effective contraception is required immediately if pregnancy is not desired.

10.7 Replacement

If a woman wishes to continue with the implant as her method of contraception a replacement implant may be inserted through the same incision by which the previous implant was removed.[14] To avoid insertion into thickened scar tissue the implant should be inserted subdermally along a fresh track adjacent to the previous track. If the previous implant was incorrectly sited a new site should be used. Additional contraceptive precautions are not required if the implant is replaced no later than 3 years after insertion. See page 5 for advice on replacement more than 3 years after insertion.

Because of the theoretical risk of skin atrophy, the guideline development group advises that consideration may be given to switching arms after two consecutive implants. Eligible women can use implants throughout their reproductive years and there is no maximum number of implants a woman can have.

10.8 Aftercare

Women should be informed that mild discomfort and bruising can be expected after insertion or removal of an implant. The guideline development group recommends applying paper sutures to the wound after removal or replacement of an implant (optional after insertion). A sterile dressing should be applied for at least 24 hours after the procedure. A pressure bandage may also be applied. Paper sutures should be left until wound edges are adherent. Women should be advised to seek medical advice if they develop signs of wound infection, haematoma or other complications.

10.9 Resuscitation

As with all procedures there is a risk of collapse due to a vasovagal reaction or anaphylaxis. The FSRH *Service Standards for Sexual and Reproductive Healthcare*[66] provide recommendations on essential drugs and equipment for resuscitation.

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10.10 Documentation

Recommendations for record keeping specific to the progestogen-only implant can be found in the FSRH *Service Standards for Sexual and Reproductive Healthcare*.[66]

11 What Information Should be Given to Implant Users About Continuation and Follow-up?

There is no need for routine follow-up of women who have a progestogen-only implant inserted. Women who are quick started with the progestogen-only implant following administration of EC should be advised to undergo a pregnancy test no sooner than 3 weeks after UPSI.[15]

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 changes to the shape of the implant; it appears to have broken (page 14); or there are any changes to the skin (such as a rash) or pain around the site of the implant. If a woman develops any medical problems or starts any medication that may affect their implant, the use of the method should be reviewed.

✓ Women using progestogen-only implants should be advised that no routine follow-up is required, but that they can return at any time to discuss problems or change their contraceptive method.

✓ Women using a progestogen-only implant should be advised to return if: they cannot feel their implant or if it appears to have changed shape; they notice any skin changes or pain around the site of the implant; they become pregnant; or they develop any condition that may contraindicate continuation of the method.

12 What Factors Might Reduce the Efficacy of the Progestogen-only Implant?

12.1 Drug interactions

The contraceptive efficacy of the progestogen-only implant may be reduced by enzyme-inducing drugs. There are case reports of progestogen-only implant failure when used in conjunction with enzyme-inducing antiepileptic drugs[60] and enzyme-inducing antibiotics such as rifampicin[67] and antiretroviral therapy.[68–70] Additional precautions are advised while using enzyme-inducing drugs and for 28 days after cessation.[71] The CEU has produced guidance on *Drug Interactions with Hormonal Contraception* that should be referred to for more detailed information.[71]

C Concomitant use of enzyme-inducing drugs may reduce the efficacy of the progestogen-only implant. Women should be advised to switch to a method unaffected by enzyme-inducing drugs or to use additional contraception until 28 days after stopping the treatment.

12.2 Weight

The progestogen-only implant is a highly effective method of contraception, and 'true' failures are rare.

Pharmacokinetic studies of progestogen-only implants have shown an inverse relationship between body weight and ENG serum levels.[21,72] There are therefore concerns about the duration for which the method is effective in 'heavier' women. In one study[72] of the ENG implant over 6 months, consistently lower serum concentrations of ENG were observed amongst those women with a body mass index (BMI) of over 30, compared with those with a BMI of less than 25, although the difference was not statistically significant. In the group with a BMI of over 30 (weight range 90–164 kg), projected serum levels at 1, 2 and 3 years were estimated to be 133, 102, and 98 pg/ml, respectively.[72] A case series[73] of three morbidly obese young women (weight range 130–176 kg) who had the progestogen-only implant inserted prior to gastric band surgery included one subject whose ENG concentrations at 5 and 8 months post-insertion were only

134 and 125 pg/ml, respectively. While these serum levels are consistent with a contraceptive effect, they correspond to the lower range of ENG concentrations observed after 3 years of use in normal-weight women.[21]

Only one study was identified in which the primary outcome was to establish contraceptive failures in overweight and obese women weighing up to 149 kg (personal communication with authors).[75-76] One failure was identified in an obese woman; however, this occurred within the first month of insertion and was therefore unlikely to be related to weight. Other studies[47,74–76] that have included women weighing over 70 kg have similarly not reported any pregnancies in this weight range, although none of these studies were designed specifically to compare women of differing weights. Findings are limited by the small number of women included in such studies weighing over 100 kg, and the limited data in women weighing over 70 kg for up to 3 years of use. Reported failures in 'heavier' groups may also be low because of reduced fertility in some obese women.[77] Due to the rarity of such events, it may be difficult for any study to be adequately powered to detect differences in efficacy in 'heavy' women versus those of 'normal' weight.

The SPC for the progestogen-only implant[3,4] advises that the clinical experience in heavier women in the third year of use is limited. It therefore states that it cannot be excluded that the contraceptive effect may be lower than for women of normal weight. It advises that health professionals may therefore consider earlier replacement of the implant in 'heavier' women. The SPC[3,4] does not specify after what duration of use replacement may need to be considered. In the UK, based on average height and a BMI of 25 (overweight), 70 kg might be an arbitrary indicator of being 'heavier'. In the context of serum levels being inversely associated with weight, 70 kg may be a better proxy of 'heavier women' than BMI.

The FSRH advises that women are made aware of the manufacturer's advice, but that there is currently no direct evidence to support a need for earlier implant replacement. It has been postulated that even if ovulation suppression cannot be assured for up to 3 years post-insertion, other contraceptive mechanisms may continue to provide protection. Women should be supported to have an earlier replacement if requested. Bleeding patterns and previous fertility may help guide decisions about when to replace an implant in heavier women.

The progestogen-only implant can be used by overweight or obese women and is regarded as a 'safe' method for such women (UKMEC 1).

C Obesity (BMI>30kg/m^2) is a condition for which there is no restriction on the use of the progestogen-only implant (UKMEC 1).

C No increased risk of pregnancy has been demonstrated in women weighing up to 149 kg. However, because of the inverse relationship between weight and serum etonogestrel levels, a reduction in the duration of contraceptive efficacy cannot be completely excluded.

✓ Women using the progestogen-only implant should be informed, where relevant, that the manufacturer states that earlier replacement can be considered in 'heavier' women but that there is no direct evidence to support earlier replacement.

13 What Other Issues Should Women be Advised to Consider?

13.1 Sexually transmitted infections and testing

Progestogen-only implants do not provide protection against STIs. Women requesting the progestogen-only implant should be informed about safer sex and that the consistent and correct use of condoms provides an effective means of protecting against STIs including the human immunodeficiency virus (HIV).

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While bleeding patterns can be irregular with progestogen-only methods, STIs represent a common cause of problematic bleeding in women of reproductive age. Women with postcoital or unscheduled bleeding while using the progestogen-only implant, or with concerns about STI, should be assessed to identify their individual risk of STI. The minimum tests that in combination constitute an STI check (often called an STI screen) are those for chlamydia, gonorrhoea, syphilis and HIV.[79,80]

B The consistent and correct use of condoms is the most efficient means of protecting against HIV and other sexually transmitted infections.

13.2 Emergency contraception

EC may need to be considered if a woman does not follow the relevant advice in relation to additional precautions when starting the progestogen-only implant or when taking enzyme-inducing drugs. Additionally EC may be required if the woman uses the implant for longer than its licensed duration (3 years). Readers are referred to FSRH guidance on *Emergency Contraception*[80] for further information.

14 Managing Problems Associated with Progestogen-only Implant Use

14.1 Impalpable implant

An impalpable implant should not be assumed to be a deep implant. Any woman with an impalpable implant should be advised to use additional precautions or avoid intercourse until further investigation can be undertaken and the presence of an implant confirmed. The need for EC and a pregnancy test should be considered if there has been a potential risk.

Where an implant is not palpable, both arms should be examined for insertion site scars. Clues may also be found in the clinical record or the woman's account of the insertion procedure, including the position of the arm during insertion and any problems during or after the procedure.[81]

Exploratory surgery without knowledge of the exact location of the implant is strongly discouraged.[4] High-frequency linear array ultrasound remains the recommended imaging technique for locating non-palpable or deep implants. Barium sulphate has been added to Nexplanon to make it radio-opaque. This means that it can also be seen on X-ray and computed tomography scan in addition to ultrasound and magnetic resonance imaging (MRI). X-ray can therefore be used to confirm the presence of an impalpable Nexplanon. However, if the implant is to be removed, additional imaging is recommended for more precise localisation. Removal should not be attempted without the appropriate skills. There are a number of UK specialists trained in deep implant removals. Sexual and reproductive health services should be able to provide information on the nearest specialist and local referral pathways.

If an implant remains undetectable despite imaging, the manufacturer can arrange for a blood sample to be sent to The Netherlands for ENG assay as this cannot currently be done in the UK. All requests must be discussed in advance with the manufacturer's medical department. If ENG is identified in the sample, health professionals may consider MRI. If no ENG is detected when the implant is within 3 years of insertion, it can be assumed that there is no implant present in the body.

✓ A woman with an impalpable implant should be advised to use additional precautions or avoid intercourse until the presence of an implant is confirmed.

✓ The location of an impalpable or deep implant should be identified before exploratory surgery. Referral to an expert implant removal centre is recommended. The location of an impalpable or deep implant should be identified before exploratory surgery. Referral to an expert implant removal centre is recommended.

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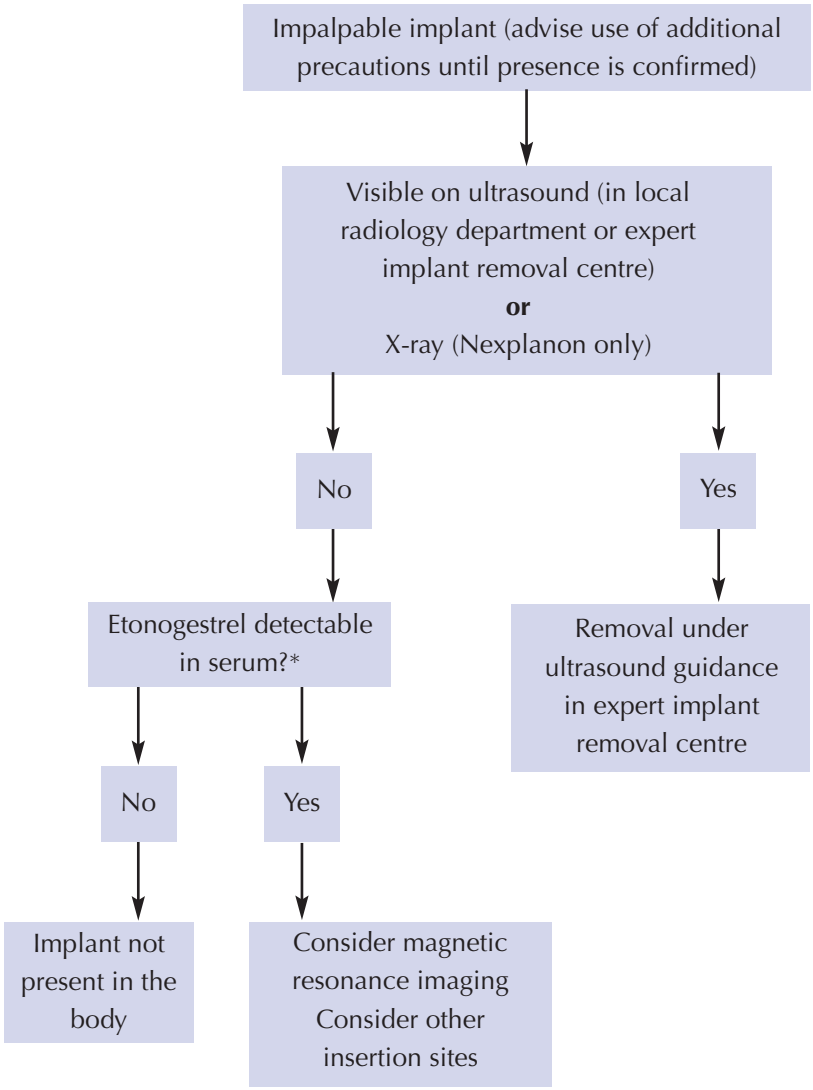
Figure 1 Management of impalpable implant (adapted with permission from Mansour *et al*.[81])



*Contact manufacturer to arrange assay. Additional hormonal medication may cross react with the assay. If in any doubt contact the manufacturer for advice.

14.2 Bent or fractured implants

Correspondence[82] from the Global Director of Scientific Affairs for MSD has suggested that the *in vitro* release rate of damaged implants is only slightly increased compared with undamaged implants and that contraceptive efficacy will not be affected.

The decision to replace a broken or bent implant is a matter of clinical judgement and the personal preference of the woman.

If a device is damaged it is recommended that the problem is reported to the manufacturer and the MHRA Yellow Card scheme. When the implant is removed, the length of the excised implant/fragments should be checked to ensure that the entire device has been removed.

14.3 Problematic bleeding

In addition to consideration of STIs (page 12) gynaecological pathology should be excluded in women with persistent problematic bleeding (or with bleeding after a spell of amenorrhoea).[42] Cervical cytology is appropriate if the woman's history and national screening guidelines indicate that the test is due or overdue.[42]

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Various treatments have been investigated for the management of bleeding problems in progestogen-only implant users.[12] Mefenamic acid and ethinylestradiol (EE) [either alone or as combined oral contraception (COC)] have been shown to reduce bleeding in Norplant users. Among ENG implant users, mifepristone in combination with EE or doxycycline has been shown to be significantly more effective than placebo, or doxycycline alone or in combination with EE at stopping an episode of uterine bleeding.[83] However, it has not been shown to have an improved effect on subsequent bleeding patterns.[83] Mifepristone is not licensed for this indication and is not available in the UK at the doses used in unscheduled bleeding studies. In theory there is potential for mifepristone to reduce the implant's efficacy, given that it is a progesterone receptor modulator and that an unexplained rise in estrogen levels has been observed with concomitant use of mifepristone and the ENG implant.[83,84] A Cochrane review[85] has concluded that evidence does not support routine use of the regimens included in their review, particularly for a long-term effect. None of the agents studied had any effect on bleeding after cessation of treatment.

Current FSRH advice on the management of unscheduled bleeding while using the progestogen-only implant is that, if medically eligible, a COC may be used for 3 months either in the usual cyclic manner or continuously without a pill-free interval.[42] Such use is outside the product licence. There is no evidence looking at the benefits/risks of longer-term COC use in conjunction with the implant. The decision to prescribe COC longer than 3 months is a matter of clinical judgement. For women who are not eligible to use COC, alternative strategies such as addition of oral progestogen are outside the product licence and are a matter of clinical judgement. If unacceptable bleeding occurs toward the end of the implant's licensed duration, early replacement of the implant may be considered as an alternative to the above strategies (outside the product licence, except for women who are overweight/heavy).

✓ After exclusion of other causes, women who experience troublesome bleeding while using the progestogen-only implant, and who are eligible to use combined hormonal contraception, may be offered combined oral contraception (COC) cyclically or continuously for 3 months (outside product licence). Longer-term use of the implant and COC has not been studied and is a matter of clinical judgement.

14.4 Pregnancy

True method failure with the progestogen-only implant is rare.[60] Possible reasons for a pregnancy whilst using the implant are: drug interactions,[60,67–69] method insertion failure,[60,75,86] or failure to use additional precautions. Unless a woman chooses to terminate her pregnancy, it is recommended that if a pregnancy occurs while using the progestogen-only implant, the implant be removed.[3,4,12] There is no evidence of harm to the woman, the course of her pregnancy, or the fetus if pregnancy occurs while using an implant.[2,15,87]

FSRH advice has been that the implant should be inserted after the second part of a medical abortion.[2] The World Health Organization[88] states that for medical abortion, hormonal contraceptives can be started by the woman after taking the first pill.

As discussed above, an interaction between mifeprisone and ENG is possible. A small study[89] has found that the efficacy of medical abortion appeared to be slightly reduced (not statistically significantly) when women having insertion of a progestogen-only implant during the first part of medical abortion were compared to those who chose an alternative method commenced after the abortion was complete. There were a number of limitations to this study and the authors acknowledged the need for further research. The SPC for Mifegyne®[90] does not suggest the need for additional precautions or comment on the initiation of contraception.

Insertion of a progestogen-only implant prior to termination of pregnancy would be a matter of clinical judgement, taking into account personal preference and the likelihood of the woman changing her mind. Such practice would be outside the terms of the product licence.

C The progestogen-only implant is not known to be harmful in pregnancy but women with a continuing pregnancy should be advised to have the implant removed. Women may retain the implant if they wish to continue the method after a non-continuing pregnancy.

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15 Cost-effectiveness

It has been advised that increasing the uptake of LARCs such as the progestogen-only implant will reduce unintended pregnancies.[12] Use of the progestogen-only implant is cost effective at 1 year of use.[12,91] The implant is more cost effective than combined oral contraception[12,92] or progestogen-only injectables.[12] 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 LNG-IUS with 3 years of use, after which the LNG-IUS becomes more cost-effective.[12]

16 Other contraceptive implants

There are two-rod LNG-containing contraceptive implants available in other countries such as New Zealand (Jadelle) and China (Sino-implant II®). The two rods are placed in the shape of a 'V' opening toward the shoulder. These implants are licensed to provide contraceptive protection for 5 and 4 years, respectively. A six-rod levonorgestrel contraceptive implant (Norplant) may also be in use in some countries, and is licensed for 5 years' use. Women can switch from a LNG-containing implant to an ENG implant without the need for additional precautions providing it is within the licensed duration of use. If there is any doubt about when the implant was inserted, pregnancy should be excluded and additional precautions advised for 7 days. Further information on such implants can be found at www.popcouncil.org.

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References

1 Faculty of Sexual & Reproductive Health Care Clinical Guidance. *Progestogen-only Implants.* 2008. http://www.fsrh.org/pdfs/CEUGuidanceProgestogenOnlyImplantsApril08.pdf [Accessed 21 October 2013].

2 Faculty of Sexual & Reproductive Health Care. *UK Medical Eligibility Criteria for Contraceptive Use (UKMEC 2009)*. 2009. http://www.fsrh.org/pdfs/UKMEC2009.pdf [Accessed 21 October 2013].

3 Organon Laboratories Limited. Implanon 68 mg implant for subdermal use. Summary of Product Characteristics (SPC). 2009. http://www.medicines.org.uk/emc/medicine/5382/SPC/Implanon+68mg+implant+for+subdermal+use/ [Accessed 21 October 2013].

4 Merck Sharp and Dohme Corporation. Nexplanon 68 mg implant for subdermal use. Summary of Product Characteristics (SPC). 2012. http://www.medicines.org.uk [Accessed 21 October 2013].

5 Davies GC, Li XF, Newton JR, *et al.* Release characteristics, ovarian activity and menstrual bleeding with a single contraceptive implant releasing 3-ketodesogestrel. Contraception 1993; **47:** 251–261.

6 Makarainen L, van Beek I, Tuomivaara L, Asplund B, Bennink HC. Ovarian function during the use of a single contraceptive implant: Implanon compared with Norplant. *Fertil Steril* 1998; **68:** 714–721.

7 Diaz S, Pavez M, Moo-Young AJ, Bardin CM, Croxatto HB. Clinical trial with 3-keto-desogestrel subdermal implants. *Contraception* 1991; **44:** 393–408.

8 Bennink HJ. The pharmacokinetics and pharmacodynamics of Implanon, a single-rod etonogestrel contraceptive implant. *Eur J Contracept Reprod Health Care* 2000; **5**(Suppl. 2): 12–20.

9 Croxatto HB. Mechanisms that explain the contraceptive action of progestin implants for women. *Contraception* 2002; **65:** 21–27.

10 Croxatto HB, Makarainen L. The pharmacodynamics and efficacy of Implanon. *Contraception* 1998; **58:** 91S–97S.

11 Trussell J. Contraceptive efficacy. In: Hatcher R, Trussell J, Nelson AL, Cates W, Kowal D, Policar M (eds), *Contraceptive Technology (20th Revised Edition)*. New York, NY: Ardent Media, 2011; 779–863.

12 National Institute for Health and Care Excellence (NICE). *Long-acting Reversible Contraception: The Effective and Appropriate Use of Long-acting Reversible Contraception.* 2005. http://guidance.nice.org.uk/CG30 [Accessed 21 October 2013].

13 Faculty of Sexual & Reproductive Healthcare Clinical Guidance. *Contraception for Women Aged Over 40 Years.* 2010. http://www.fsrh.org/pdfs/ContraceptionOver40July10.pdf [Accessed 21 October 2013].

14 Organon Laboratories Limited. Nexplanon: Summary of Product Characteristics (SPC). 2010. http://www.medicines.org.uk/EMC/ [Accessed 21 October 2013].

15 Faculty of Sexual & Reproductive Healthcare Clinincal Effectiveness Unit. *Quick Starting Contraception.* 2010. http://www.fsrh.org/pdfs/CEUGuidanceQuickStartingContraception.pdf [Accessed 21 October 2013].

16 Bolaji II, Tallon DF, Meehan FP, O'Dwyer EM, Fottrell PF. The return of postpartum fertility monitored by enzyme-immunoassay for salivary progesterone. *Gynaecol Endocrinol* 1992; **6:** 37–48.

17 Faculty of Sexual & Reproductive Health Care. *UK Selected Practice Recommendations for Contraceptive Use.* 2002. http://www.fsrh.org/pdfs/SelectedPracticeRecommendations2002.pdf [Accessed 21 October 2013].

18 Faculty of Sexual & Reproductive Health Care Clinical Effectiveness Unit Statement. *Missed Pill Recommendations.* 2011. http://www.fsrh.org/pdfs/CEUStatementMissedPills.pdf [Accessed 21 October 2013].

19 Curtis KM, Chrisman CE, Mohllajee AP, Peterson HB. Effective use of hormonal contraceptives. Part I: Combined oral contraceptive pills. *Contraception* 2006; **73:** 115–124.

20 Zheng SR, Zheng HM, Qian SZ, Sang GW, Kaper RF. A randomized multicenter study comparing the efficacy and bleeding pattern of a single-rod (Implanon) and a six-capsule (Norplant) hormonal contraceptive implant. *Contraception* 1999; **60:** 1–8.

21 Huber J, Wenzl R. Pharmacokinetics of Implanon. An integrated analysis. *Contraception* 1998; **58**(Suppl. 6): 85S–90S.

22 Affandi B. An integrated analysis of vaginal bleeding patterns in clinical trials of Implanon. *Contraception* 1998; **58:** 99S–107S.

23 Yildizbas B, Sahin GH, Kolusari A, Zeteroglu S, Kamaci M. Side effects and acceptability of Implanon: a pilot study conducted in eastern Turkey. *Eur J Contracept Reprod Health Care* 2007;**12:** 248–252.

24 Yisa SB, Okenwa AA, Husemeyer R. Treatment of pelvic endometriosis with etonogestrel subdermal implant (Implanon). *J Fam Plann Reprod Health Care* 2005; **31:** 67–70.

25 Walch K, Unfried G, Huber J, Kurz C, van Trotsenburg M, Pernicka E, *et al*. Implanon versus medroxyprogesterone acetate: effects on pain scores in patients with symptomatic endometriosis – a pilot study. *Contraception* 2009; **79:** 29–34.

26 Ponpuckdee J, Taneepanichskul S. The effects of Implanon in the symptomatic treatment of endometriosis. *J Med Assoc Thai* 2005; **88:** s7–s10.

27 European Society for Human Reproduction and Embryology. *Guideline on the Management of Women with Endometriosis.* 2013. http://www.eshre.eu/ [Accessed 21 October 2013].

28 Lidegaard O, Nielson L, Skovlund CW, Lokkegaard E. Venous thrombosis in users of non-oral hormonal contraception: follow-up study, Denmark 2001–10. *BMJ* 2012; **344:** e2990.

29 Mantha S, Karp R, Raghavan V, Terrin N, Bauer KA, Zwicker JI. Assessing the risk of venous thromboembolic events in women taking progestin-only contraception: a meta-analysis. *BMJ* 2012; **345:** e4944.

30 Chakhtoura Z, Canonico M, Gompel A, Scarabin PY, Plu-Bureau G. Progestogen-only contraceptives and the risk of acute myocardial infarction: a meta-analysis. *J Clin Endocrinol Metab* 2011; **96:** 1169–1174.

31 Lidegaard O, Lokkegaard E, Jensen A, Skovlund CW, Keiding N. Thrombotic stroke and myocardial infarction with hormonal contraception. *N Engl J Med* 2012; **366:** 2257–2266.

32 Merki-Feld GS, Rosselli M, Imthurn B, Spanaus K. No effect of Implanon on inflammatory cardiovascular parameters. *Gynecol Endocrinol* 2011; **27:** 951–955.

33 Oderich C, Wender MCO, Lubianca JN, Santos LM, de Mello GC. Impact of etonogestrel-releasing implant and copper intrauterine device on carbohydrate metabolism: a comparative study. *Contraception* 2012; **85:** 173–176.

34 Dilbaz B, Ozdegirmenci O, Caliskan E, Dilbaz S, Haberal A. Effect of etonogestrel implant on serum lipids, liver function tests and hemoglobin levels. *Contraception* 2010; **81:** 510–514.

35 Inal M, Yildirim Y, Ertopcu K, Avci ME, Ozelmas I, Tinar S. Effect of the subdermal contraceptive etonogestrel implant (Implanon) on biochemical and hormonal parameters (three years follow-up). *Eur J Contracept Reprod Health Care* 2008; **13:** 238–242.

36 Lopez LM, Frimes D, Schulz KF, Curtis KM. Steroidal contraceptives: effect on bone fractures in women. *Cochrane Database Syst Rev* 2011; **7:** CD006033.

37 Beerthuizen R, van Beek A, Massai R, Makarainen L, Hout J, Bennink HC. Bone mineral density during long-term use of the progestagen contraceptive implant Implanon compared to a non-hormonal method of contraception. *Hum Reprod* 2000; **15:** 118–122.

38 Monteiro-Dantas C, Espejo-Arce X, Lui-Filho J, Fernandes A, Monteiro I, Bahamondes L. A three-year longitudinal evaluation of the forearm bone density of users of etonogestrel- and levonorgestrel-releasing contraceptive implants. *Reprod Health* 2007; **4:** doi:10.1186/1742-4755-4-11.

39 Pongsatha S, Ekmahachai M, Suntornlimsiri N, Morakote N, Chavisitsaree S. Bone mineral density in women using the subdermal contraceptive implant Implanon for at least two years. *Int J Gynaecol Obstet* 2010; **109:** 223–225.

40 Collaborative Group on Hormonal Factors in Breast Cancer. Breast cancer and hormonal contraceptives: collaborative reanalysis of individual data on 53 297 women with breast cancer and 100 239 women without breast cancer from 54 epidemiological studies. *Lancet* 1996; **347:** 1713–1727.

41 Mascarenhas L, van Beek A., Bennink H C, Newton J. A 2-year comparative study of endometrial histology and cervical cytology of contraceptive implant users in Birmingham, UK. *Hum Reprod* 1998; **13:** 3057–3060.

42 Faculty of Sexual & Reproductive Health Care in collaboration with the Royal College of Obstetricians and Gynaecologists. *Management of Unscheduled Bleeding in Women Using Hormonal Contraception*. 2009. http://www.fsrh.org/pdfs/UnscheduledBleedingMay09.pdf [Accessed 21 October 2013].

43 Mansour D, Korver T, Marintcheva-Petrova M, Fraser IS. The effects of Implanon on menstrual bleeding patterns. *Eur J Contracept Reprod Health Care* 2008; **13**(Suppl. 1): 13–28.

44 Harvey C, Seib C, Lucke J. Continuation rates and reasons for removal among Implanon users accessing two family planning clinics in Queensland, Australia. *Contraception* 2009; **80:** 527–532.

45 Lakha F, Glasier A. Continuation rates of Implanon in the UK: data from an obervational study in a clinical setting. *Contraception* 2006; **74:** 287–289.

46 Funk S, Miller MM, Mishell DR, Archer DF, Poindexter A, Schmidt J, *et al*. Safety and efficacy of Implanon, a single-rod implantable contraceptive containing etonogestrel. *Contraception* 2005; **71:** 319–326.

47 Darney P, Patel A, Rosen K, Shapiro LS, Kaunitz AM. Safety and efficacy of a single-rod etonogestrel implant (Implanon): results from 11 clinical trials. *Fertil Steril* 2009; **91:** 1646–1653.

48 Flores JB, Balderas ML, Bonilla MC, Vázquez-Estrado L. Clinical experience and acceptability of the etonogestrel subdermal contraceptive implant. *Int J Gynecol Obstet* 2005; **90:** 228–233.

49 Rai K, Gupta S, Cotter S. Experience with Implanon in a north-east London family planning clinic. *Eur J Contracept Reprod Health Care* 2004; **9:** 39–46.

 © FSRH 2014

50 Bitzer J, Tschudin S, Alder J, Swiss Implanon Study Group. Acceptability and side-effects of Implanon in Switzerland: a retrospective study by the Implanon Swiss Study Group. *Eur J Contracept Reprod Health Care* 2004; **9:** 278–284.

51 Otero Flores JB, Balderas ML, Bonilla MC, Vázquez-Estrado L. Clinical experience and acceptability of the etonogestrel subdermal contraceptive implant. *Int J Gynecol Obstet* 2005; **90:** 228–233.

52 Yildizbas B, Sahin GH, Kolusari A, Zeteroglu S, Kamaci M. Side effects and acceptability of Implanon: a pilot study conducted in eastern Turkey. *Eur J Contracept Reprod Health Care* 2007; **12:** 248–252.

53 Croxatto HB, Urbancsek J, Massai R, Coelingh Bennik H, van Beek A, the Implanon Study Group. A multicentre efficacy and safety study of the single contraceptive implant Implanon. *Hum Reprod* 1999; **14:** 976–981.

54 Urbancsek J. An integrated analysis of nonmenstrual adverse events with Implanon. *Contraception* 1998; **58:** 109S–115S.

55 Chadha-Gupta A, Moss A. Fat atrophy at the site of a subdermal contraceptive implant. *J Fam Plann Reprod Health Care* 2007; **33:** 123–124.

56 Lindsay P. Localised lipoatrophy at the site of Implanon® insertion. *J Fam Plann Reprod Health Care* 2012; **35:** 266.

57 Rowlands S. Legal aspects of contraceptive implants. *J Fam Plann Reprod Health Care* 2010; **36:** 243–248.

58 Mascarenhas L. Insertion and removal of implanon. *Contraception* 1998; **58**(Suppl. 1): 79S–83S.

59 Bensouda-Grimaldi L, Jonville-Bera AP, Beau-Salinas F, Llabres S, Autret-Leca E, Le Reseau Des Centres Regionaux De P. Insertion problems, removal problems and contraception failures with Implanon. *Gynecol Obstet Fertil* 2005; **33:** 986–990.

60 Harrison-Woolrych M, Hill R. Unintended pregnancies with the etonogestrel implant (Implanon): a case series from postmarketing experience in Australia. *Contraception* 2005; **71:** 306–308.

61 Ismail H, Mansour D, Singh M. Migration of implanon. *J Fam Plann Reprod Health Care* 2006; **32:** 157–159.

62 Brown M, Britton J. Neuropathy associated with etonogestrel implant insertion. *Contraception* 2012; **86:** 591–593.

63 Wechselberger G, Wolfram D, Pülzl P, Soelder E, Schoeller T. Nerve injury caused by removal of an implantable hormonal contraceptive. *Am J Obstet Gynecol* 2006; **195:** 323–326.

64 Gillies R, Scougall P, Nicklin S. Etonogestrel implants – case studies of median nerve injury following removal. *Aust Fam Physician* 2011; **40:** 799–800.

65 Baird A. Do UK Faculty registered trainers teach the insertion and removal of subdermal contraceptive implants in a similar fashion? *J Fam Plann Reprod Health Care* 2013; **39:** 311–312.

66 Faculty of Sexual & Reproductive Health Care Clinical Standards Committee. *Service Standards for Sexual and Reproductive Healthcare*. 2013. http://www.fsrh.org/pdfs/ServiceStandardsSexualReproductiveHealthcare.pdf [Accessed 21 October 2013].

67 Patni S, Ebden P, Kevelighan E, Bibby J. Ectopic pregnancy with Implanon. *J Fam Plann Reprod Health Care* 2006; **32:** 115.

68 Lakhi N, Govind A. Implanon failure in patients on antiretroviral medication: the importance of disclosure. *J Fam Plann Reprod Health Care* 2010; **36:** 181–182.

69 McCarty EJ, Keane H, Quinn K, Quah S. Implanon failure in an HIV-positive woman on antiretroviral therapy resulting in two ectopic pregnancies. *Int J STD AIDS* 2011; **22:** 413–414.

70 Matiluko AA, Soundararjan L, Hogston P. Early contraceptive failure of Implanon in an HIV-seropositive patient on triple antiretroviral therapy with zidovudine, lamivudine and efavirenz. *J Fam Plann Reprod Health Care* 2007; **33:** 277–278.

71 Faculty of Sexual & Reproductive Health Care Clinical Guidance. *Drug Interactions with Hormonal Contraception.* 2011. http://www.fsrh.org/pdfs/CEUGuidanceDrugInteractionsHormonal.pdf [Accessed 21 October 2013].

72 Mornar S, Lingtak-Neander C, Mistretta S, Neustadt A, Martins S, Gilliam M. Pharmacokinetics of the etonogestrel contraceptive implant in obese women. *Am J Obstet Gynecol* 2012; **207:** e1–e6.

73 Ciangura C, Corigliano N, Basdevant A, Mouly S, Decleves XS, Touraine P, *et al*. Etonogestrel concentrations in morbidly obese women following Roux-en-Y gastric bypass surgery: three case reports. *Contraception* 2012; **84:** 649–651.

74 Xu H, Wade JA, Peipert JF, Zhao Q, Madden T, Secura GM. Contraceptive failure rates of etonogestrel subdermal implants in overweight and obese women. *Obstet Gynaecol* 2012; **120:** 21–26.

75 Graesslin O, Korver T. The contraceptive efficacy of Implanon: a review of clinical trials and marketing experience. *Eur J Contracept Reprod Health Care* 2008; **13:** 4–12.

76 Newton J, Newton P. Implanon – the single-rod subdermal contraceptive implant. *J Drug Eval* 2003; **1:** 181–218.

77 National Institute for Health and Care Excellence (NICE). *Fertility: Assessment and Treatment for People with Fertility Problems* (Clinical Guideline 156). 2013. http://guidance.nice.org.uk/CG156 [Accessed 21 October 2013].

© FSRH 2014

78 Medical Foundation for AIDS and Sexual Health (MedFASH), British Association for Sexual Health and HIV (BASHH). *Standards for the Management of Sexually Transmitted Infections (STIs)*. 2010. http://www.bashh.org/documents/2513.pdf [Accessed 21 October 2013].

79 British Association for Sexual Health and HIV (BASHH) Clinical Effectiveness Group. *Sexually Transmitted Infections: UK National Testing and Screening Guidelines.* 2006. http://www.bashh.org/documents/59/59.pdf [Accessed 21 October 2013].

80 Faculty of Sexual & Reproductive Health Care Clinical Guidance. *Emergency Contraception.* 2011. http://www.fsrh.org/pdfs/CEUguidanceEmergencyContraception11.pdf [Accessed 21 October 2013].

81 Mansour D, Fraser IS, Walling M, Glenn D, Graesslin O, Egarter C. Methods of accurate localisation of non-palpable subdermal contraceptive implants. *J Fam Plann Reprod Health Care* 2008; **34:** 9–12.

82 Rekers H. Removal of a fractured Nexplanon: MSD response. *J Fam Plann Reprod Health Care* 2013; **39:** 67.

83 Weisberg E, Hickey M, Palmer D, O'Connor V, Salamonsen LA, Findlay JK, *et al*. A randomized controlled trial of treatment options for troublesome uterine bleeding in Implanon users. *Hum Reprod* 2009; **24:** 1852–1861.

84 Weisberg E, Croxatto HB, Findlay JK, Burger HG, Fraser IS. A randomized study of the effect of mifepristone alone or in combination with ethinyl estradiol on ovarian function in women using the etonogestrel-releasing subdermal implant, Implanon. *Contraception* 2011; **84:** 600–608.

85 Abdel-Aleem H, D'Arcangues C, Vogelsong K, Gulmezoglu AM. Treatment of vaginal bleeding irregularities induced by progestin only contraceptives. *Cochrane Database Syst Rev* 2007; **2:** CD003449.

86 Singh M, Mansour D, Richardson D. Location and non-palpable Implanon implants with the aid of ultrasound guidance. *J Fam Plann Reprod Health Care* 2006; **32:** 153–156.

87 Cooling H, Pauli H. Full term pregnancy with Implanon *in situ*. *J Fam Plann Reprod Health Care* 2006; **32:** 204.

88 World Health Organization. *Safe Abortion: Technical and Policy Guidance for Health Systems (2nd edn)*. Geneva, Switzerland: World Health Organization, 2012.

89 Church E, Sengupta S, Chia KV. The contraceptive implant for long acting reversible contraception in patients undergoing first trimester medical termination of pregnancy. *Sex Reprod Healthc* 2010; **1:** 105–109.

90 Nordic Pharma Ltd. Mifegyne: Summary of Product Characteristics (SPC). 2012. http://www.medicines.org.uk [Accessed 21 October 2013].

91 Mavranezouli I. The cost-effectiveness of long-acting reversible contraceptive methods in the UK: analysis based on a decision-analytic model developed for a NICE clinical practice guideline. *Hum Reprod* 2008; **23:** 1338–1345.

92 Liptez C, Phillips CJ, Fleming CF. The cost effectiveness of a long-acting reversible contraceptive (Implanon®) relative to oral contraception in a community setting. *Contraception* 2009; **79:** 304–309.

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APPENDIX 1: DEVELOPMENT OF CEU GUIDANCE

GUIDELINE DEVELOPMENT GROUP

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Declared Interests
No relevant interests were declared.

Clinical Effectiveness Unit (CEU) Guidance is developed in collaboration with the Clinical Effectiveness Committee (CEC) of the Faculty of Sexual & Reproductive Healthcare (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 specialties, and user representation. In addition, the aim is to include a representative from the FSRH CEC, the FSRH Meetings 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) (1996–2013); EMBASE (1996–2013); PubMed (1996–2013); The Cochrane Library (to 2013) 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 relevant 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 (WHO) and the British Association for Sexual Health and HIV (BASHH), 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 Care 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 on the inside front cover of this document 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. The process for the development of CEU guidance is given in the table on the inside back cover of this document and is detailed on the FSRH website (www.fsrh.org). The methods used in the development of this guidance have been accredited by NHS Evidence.

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APPENDIX 2: EQUIPMENT RECOMMENDED FOR INSERTION OR REMOVAL OF A PROGESTOGEN-ONLY IMPLANT

INSERTION PROCEDURE

- Implant
- Sterile dressing pack with gauze
- Sterile gloves (or non-sterile gloves if using no-touch technique)
- Local anaesthetic
- Syringe
- Needles
- Adhesive dressing, or gauze dressing, bandage and medical tape
- Paper suture strips optional

REMOVAL PROCEDURE

As for insertion except:

- Implant required only if being replaced
- Sterile gloves essential
- Disposable or reusable removal forceps should be available but may not be required
- Scalpel (small blade)
- Paper suture strips essential

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Questions for Continuing Professional Development

The following questions 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), which is accessible to all Diplomates, Members, Associate Members and Fellows of the FSRH.

1 The main mode of action of the etonogestrel implant is by:

a. Inhibiting ovulation
b. Thickening the cervical mucus
c. Thinning the endometrium
d. Preventing implantation.

2 Inhibition of ovulation is achieved in the majority of women when serum etonogestrel levels are at least:

a. 90 pg/ml
b. 200 pg/ml
c. 472 pg/ml
d. 1200 pg/ml.

3 Serum levels of etonogestrel sufficient to inhibit ovulation have been demonstrated as early as:

a. 4 hours after insertion
b. 8 hours after insertion
c. 24 hours after insertion
d. 72 hours after insertion.

4 Emergency contraception may need to be considered in which of the following situations:

a. If a woman has had sex in the 7 days prior to switching from her progestogen-only injectable (12 weeks after last injection) to the progestogen-only implant
b. If a woman has switched from the implant after 2 years of use to a non-hormonal method and has had sex in the 7 days prior to implant removal
c. If a woman has had had her implant in for more than 3 years and has had sex in the last 3 days
d. If a woman has had a course of broad-spectrum antibiotics and not used condoms.

5 In which of the following situations would it be necessary to advise a woman to use additional precautions to ensure contraceptive protection?

a. When the progestogen-only implant has been inserted after Day 5 of the woman's menstrual cycle
b. When the implant has been inserted on Day 3 of the woman's pill-free interval
c. When the implant has been inserted 7 days prior to a woman having her intrauterine device removed
d. When the implant has been inserted 13 weeks after last depot medroxyprogesterone acetate injectable contraception.

6 Which of the following drugs has the potential to affect the contraceptive efficacy of the progestogen-only implant?

a. Sodium valporate
b. Lamotrigine
c. Levetiracetam
d. Efavirenz.

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7 Eight months after her implant was inserted, a woman presents at clinic concerned about persistent bleeding. After excluding risks of STIs, other pathology and pregnancy, which of the following best describes how this woman should be managed?

a. The woman should be advised that after 7 months of use her bleeding patterns are likely to remain as they are and the clinician should remove the implant
b. The woman should be advised that bleeding patterns can remain irregular with use of the progestogen-only implant and she can be offered a combined hormonal contraceptive method
c. The woman should be advised that bleeding patterns can remain irregular with use of the progestogen-only implant and as she was advised of this before insertion no action should be taken
d. The woman should be advised that the bleeding patterns will settle down over time and that no action should be taken.

8 Which of the following best describes how a woman who has an impalpable Nexplanon (12 months after insertion), not located on ultrasound or X-ray, should be managed?

a. She should be advised that it is likely that there is no implant present, be offered a pregnancy test and another implant fitted
b. She should be referred to the nearest regional centre for the management of impalpable implants where she will undergo further testing
c. If there is evidence from the woman's notes that the implant was palpable at the time of insertion, removal should be attempted to try to retrieve the device
d. If there is evidence from the woman's records that the implant was palpable at the time of insertion, then it can be assumed that the device is present and no further action is required.

9 Starting the progestogen-only implant in a woman with migraine with aura would be classified as a:

a. UKMEC 1
b. UKMEC 2
c. UKMEC 3
d. UKMEC 4.

10 Women who have an implant should be followed up at:

a. 6 months
b. 12 months
c. 24 months
d. None required.

What learning needs did this guidance address and how will it change your practice? (Please write below)

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Auditable Outcomes for Progestogen-only Implants

The following auditable outcomes have been suggested by the FSRH Clinical Standards Committee.

Auditable Outcomes

1 What is the proportion of women with an implant who have documented evidence of a palpable implant at the time of insertion? [Target 100%]

2 What is the proportion of women with an impalpable implant who are managed as per current guidance including discussion about additional precautions and imaging? [Target 100%]

3 What is the proportion of eligible women experiencing unscheduled bleeding who are offered the combined oral contraceptive pill? [Target 90%]

COMMENTS AND FEEDBACK ON PUBLISHED GUIDANCE

All comments on published guidance can be sent directly to the Clinical Effectiveness Unit (CEU) at **ceu.members@ggc.scot.nhs.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 are reviewed by the Clinical Effectiveness Committee and any necessary amendments made.