FACULTY OF SEXUAL & REPRODUCTIVE HEALTHCARE

ROYAL COLLEGE OF OBSTETRICIANS & GYNAECOLOGISTS

Faculty of Sexual & Reproductive Healthcare Clinical Guidance

Progestogen-only Pills

Clinical Effectiveness Unit

November 2008

(Updated June 2009)

ISSN 1755-103X

DETAILS OF CHANGES TO ORIGINAL GUIDANCE DOCUMENT

The print version of this CEU Guidance Document (issued in November 2008) contained some inconsistencies that the CEU has corrected in this version. These corrections are to the UK Medical Eligibility Criteria for Contraceptive Use for POP use (page 1 and page 2, Table 2), advice for women who miss or are late taking POP (page 3, Figure 1) and recommendations for timing of initiation of POP (page 5, Table 3).

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

First published in 2008 (Updated June 2009)

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 (November 2008) Progestogen-only Pills

(Date of planned revision 2013)

Purpose and scope

This Guidance document provides evidence-based recommendations and good practice points for clinicians on the use of progestogen-only pills (POPs) by women of reproductive age. The POPs currently available in the UK are listed in Table 1. In this Guidance *traditional* POPs include those containing levonorgestrel, norethisterone or etynodiol diacetate. The desogestrel-only pill is one of the new generation of POPs and will be named specifically where relevant.

Readers may wish to refer to other Guidance documents that provide further information on the use of POPs in specific circumstances: young people,[1] women aged over 40 years,[2] breastfeeding,[3] inflammatory bowel disease,[4] unlicensed use[5] and drug interactions.[6]

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.

What should a clinician assess before POP use?

The *UK Medical Eligibility Criteria for Contraceptive Use* (UKMEC)[7] provides evidence-based recommendations to allow couples to select the most appropriate method of contraception without imposing unnecessary restrictions. Definitions of the UKMEC categories are summarised in Table 2 and relevant medical conditions are listed under each category.

For the majority of women a POP is a safe method of contraception (Table 2). A clinical history should identify any conditions that fall within UKMEC Categories 3 or 4 for use of a POP. In summary:

UKMEC 4 *Poses an unacceptable health risk and a POP should not be used.*

- Current breast cancer.

Table 1 Progestogen-only pills currently available in the UK

Brand name	Type of progestogen	Dose (µg)
Cerazette®	Desogestrel	75
Femulen®	Etynodiol diacetate	500
Micronor®	Norethisterone	350
Norgeston®	Levonorgestrel	30
Noriday®	Norethisterone	350

UKMEC 3 *The risks may outweigh the advantages but use of a POP may be considered. A decision about use requires clinical judgement and/or referral to a specialist contraceptive provider.*

The *initiation* of a POP in women with:

- A history of breast cancer (*no evidence of disease in the last 5 years*)
- Gestational trophoblastic neoplasia (*abnormal serum hCG*)
- Active viral hepatitis
- Severe decompensated cirrhosis
- Liver tumours (*benign and malignant*)
- Use of liver enzyme-inducing medication.

The *continuation* of a POP by women with:

- The occurrence of *new symptoms* or having a *new diagnosis* of ischaemic heart disease, stroke, or migraine with aura.

Notably, women may initiate POPs if they have or have had an ectopic pregnancy, ovarian cyst, VTE, stroke, ischaemic heart disease or migraine *with aura* (UKMEC 2: benefits outweigh risks).

Other information gathered as part of a standard consultation should be documented (Box 1). The consultation may provide an opportunity for a general health check including: an individual assessment of the

Box 1 Appropriate information to document when prescribing progestogen-only pills (adapted from *Service Standards for Record Keeping*)[8]

DOCUMENTATION WHEN ISSUING A PROGESTOGEN-ONLY PILL

Medical history and clinical assessment

- Age
- Previous contraception used and problem encountered including emergency contraception
- Menstrual history including start date of last menstrual period (LMP)
- Medical and gynaecological history
- Obstetric history including ectopic pregnancy
- Coital history
- Medication – prescribed/non-prescribed/complementary
- Allergies

Information, advice and counselling

- Contraceptive choices discussed/preparation chosen
- Risks/benefits/uncertainties discussed
- Mode of action and efficacy
- Side effects including bleeding patterns
- Teaching about use of method
- Leaflets given – including manufacturer's leaflet
- Follow-up arrangements
- Record prescription and quantity issued
- Special instructions if any (e.g. additional contraception)
- Any change in personal history or medication since the last attendance should be recorded
- Any problems encountered, if any, and actions given

Table 2 *UK Medical Eligibility Criteria for Contraceptive Use* for progestogen-only pill use[7]

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 **Parity** *nulliparous and parous* **Breastfeeding** **Postpartum** *(in non-breastfeeding women)* **Post-abortion** **Past ectopic pregnancy** **History of pelvic surgery** **Smoking** **Obesity** **Hypertension** *adequately controlled hypertension; consistently elevated blood pressure levels (properly taken measurements)* **History of high blood pressure during pregnancy** *(where current blood pressure in normal)* **Venous thromboembolism (VTE)** *family history of VTE in first-degree relative of any age; major surgery without prolonged immobilisation; minor surgery without immobilisation; immobility (unrelated to surgery) (e.g. wheelchair use, debilitating illness)* **Superficial venous thrombosis** **Valvular and congenital heart disease** **Headaches** *non-migrainous (mild or severe) [Initiation and Continuation]. Migraine without aura at any age [Initiation only]* **Epilepsy** **Depressive disorders** **Endometriosis** **Benign ovarian tumours** *(including cysts)* **Severe dysmenorrhoea** **Gestational trophobalstic neoplasia (GTN)** *(includes hydatidiform mole, invasive mole, placental site trophoblastic tumour) hCG normal* **Cervical ectropion** **Cervical intraepithelial neoplasia (CIN)** **Cervical cancer** *(awaiting treatment)* **Breast disease** *benign breast disease; family history of breast cancer* **Endometrial cancer** **Ovarian cancer** **Uterine fibroids** **Pelvic inflammatory disease (PID)** **Sexually transmitted infections (STIs)** **High risk of HIV** **HIV infected** *not using anti-retroviral therapy* **Schistosomiasis** **Tuberculosis** **Malaria** **Diabetes** *history of gestational disease* **Thyroid disorders** **Cholestasis** *pregnancy related* **Viral hepatitis** *carrier* **Thalassaemia** **Sickle cell disease** **Iron deficiency anaemia** **Raynaud's disease** *primary; secondary without lupus anticoagulant* **Non-liver enzyme-inducing antibiotics**	**Significant multiple risk factors for arterial cardiovascular disease** *(such as older age, smoking, diabetes and hypertension)* **Hypertension** *complicated by vascular disease* **Venous thromboembolism (VTE)** *history of VTE; current VTE (on anticoagulants); major surgery with prolonged immobilisation* **Known thromobogenic mutations** *(e.g. factor V Leiden; prothrombin mutation; protein S, protein C and antithrombin deficiencies)* **History of ischaemic heart disease** *[Initiation only]* **Stroke** *(history of cerebrovascular accident) [Initiation only]* **Known hyperlipidaemias** **Migraine** *without aura at any age [Continuation only]; with aura at any age [Initiation only]; past history of migraine with aura at any age* **Vaginal bleeding patterns** **Unexplained vaginal bleeding** *(suspicious for serious underlying condition) before evaluation* **Breast disease** *undiagnosed mass; carriers of known genetic mutations associated with breast cancer (e.g. BRCA1)* **HIV infected** *using interacting anti-retroviral therapy* **AIDS and using HAART** **Diabetes** *non-vascular disease; nephropathy/retinopathy/neuropathy; other vascular disease or diabetes of >20 years' duration* **Gall bladder disease** **History of cholestasis** *past COC-related* **Cirrhosis** *mild (compensated)* **Inflammatory bowel disease** **Raynaud's disease** *with lupus anticoagulant* **Highly active antiretroviral therapy (HAART)**
UKMEC 3 (A condition where the *theoretical or proven risks usually outweigh the advantages* of using the method)[a]	
Current ischaemic heart disease *[Continuation]* **Stroke** *(history of cerebrovascular accident) [Continuation only]* **Headaches** *migraine with aura, at any age [Continuation]* **Gestational trophoblastic neoplasia (GTN)** *(includes hydatidiform mole, invasive mole, placental site trophoblastic tumour) hCG abnormal* **Breast cancer** *past and no evidence of current disease for 5 years* **Viral hepatitis** *active* **Cirrhosis** *severe (decompensated)* **Liver tumours** **Drugs that affect liver enzymes**	
UKMEC 4 (A condition which represents an *unacceptable health risk* **if the contraceptive is used)**	
Breast cancer *current (within the last 5 years)*	

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.*
[a]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.

risk of sexually transmitted infections (STIs); check cervical screen history; measurement of blood pressure; smoking status and an assessment of weight.

The WHO and UK *Selected Practice Recommendations for Contraceptive Use*[9,10] suggest documenting blood pressure prior to starting a POP.[9,10] Blood pressure can be documented as part of a routine health check but will not necessarily influence POP use. Blood pressure can be assessed at follow-up as part of a wider health check but is not mandatory.

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

2 A clinical history should be taken to identify conditions given a UKMEC Category 3 or 4 for progestogen-only pill use. (Good Practice Point)

3 Blood pressure and an assessment of weight can be documented before starting a progestogen-only pill but this should be seen as part of a more general health check. (Good Practice Point)

What information should be given to women considering a POP?

All women considering a POP should be given oral and written information, such as the appropriate fpa leaflet, as part of routine counselling.[11] The clinician should discuss mode of action, efficacy (missed pills, vomiting, drug interactions), side effects (bleeding and progestogenic effects) and return of fertility.

Mode of action

All POPs alter cervical mucus to prevent sperm

penetration into the upper reproductive tract.[12,13] In addition, *traditional* POPs inhibit ovulation but this can be variable. Up to 60% of cycles in women using a levonorgestrel-only pill are anovulatory.[12]

In women using the desogestrel-only pill up to 97% of cycles are anovulatory and inhibition of ovulation is the primary mode of action of these pills.[12,14]

4 Women may be advised that *traditional* progestogen-only pills work by altering cervical mucus to prevent sperm penetration and for some women ovulation is also inhibited. (Grade C)

5 Women may be advised that the primary mode of action of the desogestrel-only pill is inhibition of ovulation. (Grade C)

Contraceptive efficacy

Daily pill taking of POPs will maintain contraceptive efficacy.[15–20] Ideally a pill should be taken at or around the same time *every day* and there should be *no pill-free interval*. If taken consistently and correctly POPs are more than 99% effective in preventing pregnancy.[11,13] Failure rates for *traditional* POPs vary (0.3 and 8.0 per 100 woman-years)[21] but are lower for women aged over 40 years (0.3 per 100 woman-years) compared to younger women.[22] Increasing parity is associated with an increase in efficacy but this may be linked to age.[22]

In the only comparative trial (desogestrel vs levonorgestrel-only pills) the overall failure rate for the desogestrel-only pill was 0.41 per 100 woman-years (95% CI 0.085–1.204) and for the traditional levonorgestrel-containing pill was 1.55 per 100 woman-years (95% CI 0.422–3.96).[23] Although the desogestrel-only pill is more effective at inhibiting ovulation than a *traditional* POP this study was not powered to detect differences in efficacy and the failure rates of the two POPs are not significantly different.[23]

Weight and efficacy

It has been suggested that the efficacy of *traditional* POPs may be reduced in women weighing >70 kg. It has been practice for some clinicians in the UK to advise women weighing >70 kg to take two *traditional* POPs per day instead of the licensed regimen of one pill per day. Direct evidence to support this practice is limited. Moreover, a large observational study found no association between body weight and accidental pregnancy in POP users.[24] Indirect evidence from studies in women using a levonorgestrel implant or combined hormonal vaginal ring suggest that efficacy is reduced with increasing body weight.[25–28] As ovulation is sporadic in levonorgestrel-only implant users data have been extrapolated to *traditional* POPs, which are also less reliable at ovulation inhibition. Current evidence does not support the unlicensed use of two *traditional* POPs per day for women weighing >70 kg. The efficacy of the desogestrel-only pill is not influenced by weight.[12]

6 **Women may be advised that if used consistently and correctly all progestogen-only pills are more than 99% effective. (Grade C)**

7 Women should be advised to take one progestogen-only pill at or around the same time every day and without a pill-free interval. (Grade C)

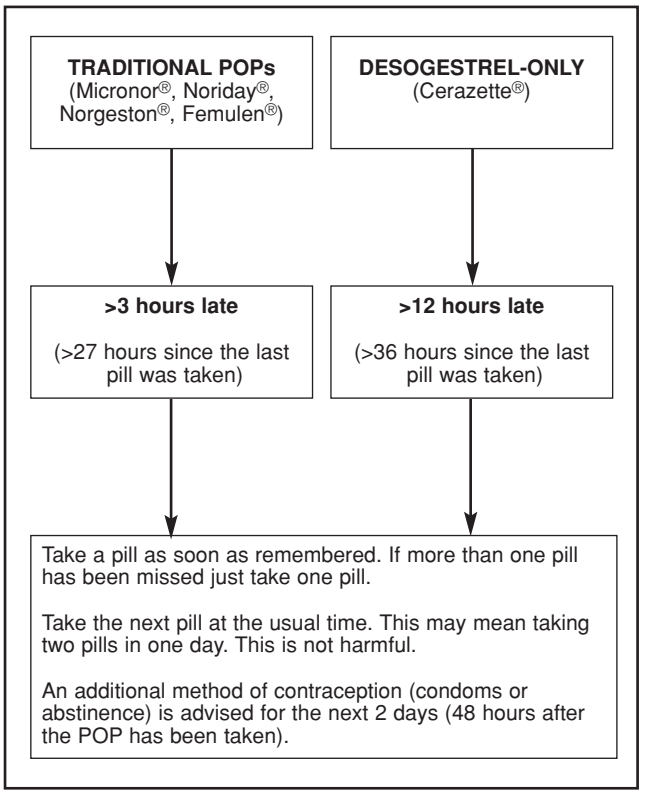

Figure 1 Advice for women who miss or are late taking the progestogen-only pill (POP)

8 Women may be advised that there are no data to suggest that some progestogen-only pills are better at preventing pregnancy than others. (Grade B)

9 There is no evidence that the efficacy of progestogen-only pills (*traditional* or desogestrel-only) is reduced in women weighing >70 kg and therefore the licensed use of one pill per day is recommended. (Grade B)

Missed pills and efficacy

Figure 1 outlines advice for women when a POP is late or missed. POPs should be taken at the same time every day (every 24 hours). If more than 27 hours have elapsed since the last *traditional* POP was taken (or more than 36 hours after a desogestrel-only pill) then the missed pill rules should be followed (Figure 1).[11]

Sex occurring before a missed or late pill is protected because the effect on cervical mucus aims to prevent sperm penetration into the upper reproductive tract.

After a missed or late pill a woman should be advised to abstain or use additional contraception such as condoms for the next 2 days (48 hours after the pill has been taken) until the effect on cervical mucus has been restored. Emergency contraception may be indicated if unprotected sex occurs during this 48-hour period.

The short time frame (3 hours) when taking a *traditional* POP may be too short for some women to allow good daily pill taking. Although the desogestrel-only pill and a levonorgestrel-only pill are comparable in clinical trials, the 12-hour window with desogestrel-only pills may facilitate timely pill taking which may improve efficacy.

10 Women may be advised that if a *traditional* progestogen-only pill is more than 3 hours late or a desogestrel-only pill is more than 12 hours late they should:
- **take the late or missed pill now**
- **continue pill taking as usual (this may mean taking two pills at the same time)**
- **use condoms or abstain from sex for 48 hours after the pill is taken. (Grade C)**

11 Some women may consider that the desogestrel-only pill, with the 12-hour window, will improve pill taking and they should be supported in this choice. (Good Practice Point)

Vomiting (or severe diarrhoea) and efficacy

If a woman vomits within 2 hours of taking a POP then she should be advised to take another pill as soon as possible. If she is now >3 hours (or >12 hours for a desogestrel-only pill) late, continues to vomit or has very severe (*cholera-like*) diarrhoea she will need to follow the missed pill rules if she is sexually active (Figure 1).[9,10]

12 If a woman vomits within 2 hours of pill taking another pill should be taken as soon as possible. (Grade C)

Drug interactions and efficacy

Little evidence was identified which specifically investigated any interaction between POPs and liver enzyme-inducing drugs.[13,29] Nevertheless, liver enzyme-inducing drugs increase the metabolism of progestogen, thus potentially decreasing the contraceptive efficacy of POPs.[30] The use of a POP with a liver enzyme-inducer is not recommended as the correct dose of progestogen to provide contraceptive protection cannot be determined.[7,15,16,31] After stopping a liver enzyme-inducing drug it can take up to 4 weeks for liver enzymes to return to normal, therefore if a POP is started during this time condoms or abstinence is advised.

Progestogens do not undergo secondary reabsorption in the gut after breakdown by gut flora, therefore the efficacy of a POP is *not reduced* by concurrent use of non-liver enzyme-inducing antibiotics.[6]

13 Women using liver enzyme-inducing medications short term should be advised to use condoms in addition to progestogen-only pills and for at least 4 weeks after the liver enzyme-inducer is stopped. (Grade C)

14 Women using liver enzyme-inducing medications *long term* should be advised that the efficacy of progestogen-only pills is reduced and an alternative contraceptive method should be considered. (Grade C)

15 Women may be advised that the efficacy of progestogen-only pills is not reduced by use of non-liver enzyme-inducing antibiotics and additional contraceptive protection is not required. (Grade C)

Return of fertility

Observational studies have reported no delay in return of fertility after stopping a *traditional* POP.[22,32,33] A randomised control trial found that after stopping the desogestrel-only pill the average number of days to first ovulation was 17.2 and the minimum time to first ovulation was 7 days.[34] If a woman does not wish to conceive when considering stopping a POP then another method of contraception is required immediately and advice on use of additional contraception or abstinence may be appropriate.

16 Women may be advised that there is no delay in return of fertility following discontinuation of a progestogen-only pill and therefore if pregnancy is not desired then another effective method of contraception should be used. (Grade C)

Side effects and discontinuation

Bleeding patterns

Altered bleeding patterns is the most common reason given by women for stopping POPs. Indeed almost half of POP users experience prolonged bleeding and up to 70% report breakthrough bleeding or spotting in one or more cycles.[35] Bleeding patterns associated with POPs may depend upon the progestogen used, the dose at which it is given and the circulating endogenous estradiol concentrations.[36] Ovulation and subsequent endogenous progestogen concentrations may also influence bleeding patterns. Women should be advised about the likelihood and types of bleeding patterns expected with POP use. As a general guide:
- 20% of women will be amenorrhoeic
- 40% will bleed regularly
- 40% will have erratic bleeding.

Between 10% and 25% of women using a POP will discontinue this method within 1 year as a result of these bleeding patterns. Discontinuation rates depend on the type or changes in bleeding patterns and the willingness of women to adapt and tolerate these changes. Effective counselling about the likelihood of changes to bleeding changes can help reduce discontinuation rates.[13]

Several non-menstrual side effects have been cited as possible reasons for discontinuation of POPs. However, inconsistencies in data collection mean that direct casual relationships cannot be confirmed. However, discontinuation rates for combined oral contraceptive users and POP users are not significantly different.[13]

17 Women should be advised that changes in bleeding patterns with progestogen-only pill use are common: 2 in 10 women have no bleeding, 4 in 10 women have regular bleeding and 4 in 10 women have irregular bleeding. (Grade C)

Weight change

Weight change (an increase or decrease) has been documented with POP use.[13] Nevertheless, there is no good evidence of a causal association between POP use and weight change.

18 Women may be advised that there is no evidence of a causal association between progestogen-only pill use and weight change. (Grade C)

Table 3 Recommendations for timing of initiation of progestogen-only pills

Circumstance	Recommendations for timing of initiation	Additional contraception advised
General initiation	Progestogen-only pills (POPs) can be started up to and including Day 5 after the start of the menstrual cycle.	NO
	POPs can also be started at any other time if the clinician is reasonably certain that the woman is not pregnant and there has been no risk of conception.	YES, for 48 hours
	If the woman is amenorrhoeic, the clinician must be reasonably certain that the woman is not pregnant and there is no risk of conception.	YES, for 48 hours
Postpartum	POPs initiated up to Day 21 postpartum.	NO
	POPs initiated after Day 21 postpartum.	YES, for 48 hours
Following miscarriage or abortion	POPs initiated on the day of surgical abortion or second part of medical abortion or immediately following miscarriage.	NO
	POPs initiated >5 days after surgical abortion or second part of medical abortion or miscarriage.	YES, for 48 hours
Switching from another method of contraception		
Combined hormonal contraception (CHC)	Can be initiated 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 has been no risk of conception.	NO
Progestogen-only pill (POP)	Can be initiated 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 has been no risk of conception.	NO
Progestogen-only implant	Can be initiated immediately if the implant has been used consistently and correctly or if the clinician is reasonably certain that the woman is not pregnant and that there has been no risk of conception.	NO
Progestogen-only injectable	If the woman's previous method was an injectable she should start POPs when the repeat injection would have been given or before.	NO
Levonorgestrel-releasing intrauterine system (LNG-IUS) or copper-bearing intrauterine device (IUD)	POP initiation at time of IUD removal (avoid intercourse or use condoms in addition for 7 days before the removal of an IUD).	YES, for 48 hours
	POP initiation at least 2 days before the removal of an IUD.	NO
	POP initiation at time of LNG-IUS removal.	NO
Barrier method (male condom, female condom, cap or diaphragm)	Can be initiated 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.	YES, for 48 hours unless POP initiated on Days 1–5 of menstrual cycle

Depression and mood change

The Summary of Product Characteristics (SPC) for POPs suggests that depression and mood change may be associated with POP use.[15–20,31] The Clinical Effectiveness Unit (CEU) could find no direct evidence to suggest that symptoms of depression increase with POP use. No data were found in relation to POP use in women with bipolar disease or postnatal depression. Women with depressive disorders may use POPs without restriction (UKMEC 1).[7]

19 Women should be advised that mood change can occur with progestogen-only pill use but there is no evidence of a causal association for depression. (Grade C)

Headache

No good evidence was identified that investigated POP use and incidence of headaches or migraine. For women of any age who develop migraine *with aura* while using a POP the risks of *continuing* POP use may outweigh the benefits (UKMEC 3).[7] Use may be considered with clinical judgement and/or referral to a specialist contraceptive provider. Investigation of headache may be indicated. Women with pre-existing migraine *with aura* may initiate use of a POP (UKMEC 2).

20 Women should be advised that there is no evidence of a causal association between the use of a progestogen-only pill and headache. (Good Practice Point)

21 Women of any age with a history of migraine (*with or without aura*) may safely use progestogen-only pills (UKMEC 1 or 2). (Grade C)

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

Cardiovascular disease and breast cancer

Few studies have been large enough to evaluate the risk of *cardiovascular disease* associated with POP use. Although limited by the small numbers of women using progestogen-only contraceptives, data from a World Health Organization study suggest there is little or no increase in risk of VTE, stroke or acute myocardial infarction (MI) associated with

use of a POP (or injectable).[37] A retrospective case-control study found no significant increase in cardiovascular disease with POP use.[38] The study using the General Practice Research Database showed a non-significant association between exposure to progestogens alone and VTE (relative risk 2.4, 95% CI 0.8–6.5). However, when progestogens were used for contraception and not in higher doses for the treatment of gynaecological disorders there was no effect on risk of VTE.[39]

There does not appear to be a causal association between POP use and *breast cancer*.[13]

23 There is no causal association between progestogen-only pill use and cardiovascular disease (MI, VTE and stroke) or breast cancer. (Grade B)

When can POPs be safely started?

POPs can be started up to and including Day 5 of the menstrual cycle without the need for additional contraceptive protection (Table 3). If started at other times, additional contraception or abstinence is advised for 48 hours. The initiation of POPs in other circumstances is summarised below.

Postpartum (breast or bottle feeding)

Women who are postpartum (vaginal or operative delivery) may choose to use a POP without restriction regardless of how they are feeding their baby (UKMEC 1).[7] A systematic review found no evidence to suggest that POPs have a detrimental effect on breast milk or infant growth.[40] Women who are breastfeeding may use POPs (UKMEC 1).[3,7] If started up to and including Day 21 contraceptive protection is immediate. If starting after Day 21 condoms or abstinence are advised for 48 hours. This is based on the earliest date of ovulation of postnatal women.

24 Progestogen-only pills can be started up to and including Day 5 of the normal menstrual cycle to provide immediate contraceptive protection. If started after this time condoms or abstinence are advised for 48 hours. (Grade C)

25 Progestogen-only pills can be started up to and including Day 21 postpartum (*no additional contraceptive protection is required*). If started after this time condoms or abstinence are advised for 48 hours. (Grade C)

Following abortion or miscarriage

The use of POPs is unrestricted in women following abortion (UKMEC 1)[7,41] or miscarriage (<24 weeks gestation). The *UK Selected Practice Recommendations for Contraceptive Use* suggest that if a POP is started more than 7 days after abortion or miscarriage then additional contraception or abstinence is advised for 48 hours.[9,10] However, in keeping with advice on use of POPs during normal menstrual cycles[10] the CEU recommends that if a POP is started more than 5 days after abortion or miscarriage then condoms or abstinence are required for the next 48 hours.

26 Progestogen-only pills can be started at the time of abortion or miscarriage (<24 weeks' gestation) or within *5 days*. If started after this time condoms are required for the next 48 hours. (Grade C)

Ongoing use of POPs and follow up

A woman may be offered up to 12 months' supply of POPs at her first and subsequent visits.[9,10] Follow up should be tailored to an individual woman and return appointments can be made at any time if there are problems. A review should identify any problems with pill taking; bleeding patterns; and change in medical, drug, family and sexual history, as well as providing an opportunity for reassessment of weight/body mass index and blood pressure.

A woman can continue to use a POP until the age of 55 years when natural loss of fertility can be assumed. Alternatively she can continue using a POP and have follicle-stimulating hormone (FSH) concentrations assessed on two occasions at least 1 month apart. If both FSH measurements are >30 IU/l this is highly suggestive of ovarian failure. In this case she may continue with a POP or a barrier method for a further period of 1 year (or 2 years if she is aged <50 years).

27 In the absence of special problems, women may be given up to 12 months' supply of progestogen-only pills at their first and follow-up visits. Follow up should be tailored to the individual woman, who should be advised to return at any time if problems arise. (Grade C)

28 Women may be advised that a progestogen-only pill can be continued until the age of 55 years when natural loss of fertility can be assumed. Alternatively they can continue using a POP and have FSH concentrations checked on two occasions 1–2 months apart. If both FSH measurements are >30 IU/l this is suggestive of ovarian failure and they may continue with a progestogen-only pill or barrier contraception for one further year (or 2 years if aged <50 years). (Good Practice Point)

Managing bleeding problems in women using a POP

Bleeding is a common problem for POP users. Although bleeding may settle with time there is no evidence to indicate which women may become amenorrhoeic or have a change in bleeding pattern and which women may experience irregular bleeding or for how long. Other causes of bleeding should be considered in POP users who have continued bleeding or a change in their usual bleeding pattern. STIs (in particular *Chlamydia trachomatis*), poor pill taking, drug interactions or pregnancy should be considered. Women should be investigated for gynaecological pathology if this is clinically indicated.[9,10]

There is a lack of evidence on effective treatment of bleeding in women using POPs.[42] Studies have investigated the use of an estrogen[43] or an anti-progestogen[44] versus placebo for the treatment of bleeding associated with POP use. Results do not support routine clinical use as a treatment for problematic women in women using a POP.[42] There is no evidence that one POP is associated with less bleeding than another POP or that taking two pills per day improves bleeding. Although bleeding may settle with time there is no definitive time frame within which one can expect bleeding to stop.

29 Women who have a change in bleeding pattern when using a progestogen-only pill need to be assessed and the risk of STIs, pregnancy or gynaecological pathology considered. (Good Practice Point)

30 There is no evidence that changing the type and dose of progestogen will improve bleeding but this may help some individuals. If, after exclusion of other causes, bleeding patterns are still unacceptable then an alternative contraceptive method may need to be considered. (Good Practice Point)

References

1 Faculty of Family Planning and Reproductive Health Care Clinical Effectiveness Unit. Contraceptive choices for young people. *J Fam Plann Reprod Health Care* 2004; **30**: 237–251.
2 Faculty of Family Planning and Reproductive Health Care Clinical Effectiveness Unit. Contraception for women aged over 40 years. *J Fam Plann Reprod Health Care* 2005; **31**: 51–64.
3 Faculty of Family Planning and Reproductive Health Care Clinical Effectiveness Unit. Contraceptive choices for breastfeeding women. *J Fam Plann Reprod Health Care* 2004; **30**: 181–189.
4 Faculty of Family Planning and Reproductive Health Care Clinical Effectiveness Unit. Contraceptive choices for women with inflammatory bowel disease. *J Fam Plann Reprod Health Care* 2003; **29**: 127–134.
5 Faculty of Family Planning and Reproductive Health Care Clinical Effectiveness Unit. The use of contraception outside the terms of the product licence. *J Fam Plann Reprod Health Care* 2005; **31**: 225–241.
6 Faculty of Family Planning and Reproductive Health Care Clinical Effectiveness Unit. Drug interactions with hormonal contraception. *J Fam Plann Reprod Health Care* 2005; **31**: 139–150.
7 Faculty of Family Planning and Reproductive Health Care Clinical Effectiveness Unit. *UK Medical Eligibility Criteria for Contraceptive Use*. 2006. http://www.fsrh.org/admin/uploads/ 298_UKMEC_200506.pdf [Accessed 4 September 2008].
8 Faculty of Family Planning and Reproductive Health Care. *Service Standards for Record Keeping*. 2007. http://www.ffprhc.org.uk/admin/uploads/ServiceStandardsRecordKeeping.pdf [Accessed 4 September 2008].
9 World Health Organization. *Selected Practice Recommendations for Contraceptive Use* (2nd edn). 2004. http://www.who.int/reproductive-health/publications/spr/spr.pdf [Accessed 4 September 2008].
10 Faculty of Family Planning and Reproductive Health Care Clinical Effectiveness Unit. *UK Selected Practice Recommendations for Contraceptive Use*. 2002. http://www.fsrh.org/admin/uploads/Final%20UK%20recommendations1.pdf [Accessed 4 September 2008].
11 fpa. *Your Guide to the Progestogen-only Pill*. 2007. http://www.fpa.org.uk/attachments/published/165/PDF%20Progestogen-only%20pill%20April%202007.pdf [Accessed 4 September 2008].
12 Rice CF, Killick SR, Dieben TOM, Coelingh Bennink H. A comparison of the inhibition of ovulation achieved by desogestrel 75 micrograms and levonorgestrel 30 micrograms daily. *Hum Reprod* 1999; **14:** 982–985.
13 McCann MF, Potter LS. Progestin-only oral contraception: a comprehensive review. *Contraception* 1994; **50**: S159–S188.
14 Rice CF, Killick SR, Hickling D, Coelingh Bennink H. Ovarian activity and vaginal bleeding patterns with a desogestrel-only preparation at three different doses. *Hum Reprod* 1996; **11**: 737–740.
15 Pharmacia Limited. Noriday Tablets. Summary of Product Characteristics (SPCs). 2003. http://www.medicines.org.uk [Accessed 4 September 2008].
16 Wyeth Pharmaceuticals. Microval 30 Microgram Tablets. Summary of Product Characteristics (SPCs). 2003. http://www.emedicine.org.uk [Accessed 4 September 2008].
17 Schering Health Care Limited. Norgeston. Summary of Product Characteristics (SPCs). 2001. http://www.medicines.org.uk [Accessed 4 September 2008].
18 Janssen-Cilag Ltd. Micronor Oral Contraceptive Tablets. Summary of Product Characteristics (SPCs). 2001. http://www.medicines.org.uk [Accessed 4 September 2008].
19 Schering Health Care Limited. Neogest 75 Microgram Tablets. Summary of Product Characteristics (SPCs). 2000. http://www.medicines.org.uk [Accessed 4 September 2008].
20 Pharmacia Limited. Femulen Tablets. Summary of Product Characteristics (SPCs). 2002. http://www.medicines.org.uk [Accessed 4 September 2008].
21 Hatcher RA, Trussell J, Nelson AL, Cates W, Stewart FH, Kowal D. Contraceptive efficacy: In: *Contraceptive Technology* (19th revised edn). New York, NY: Ardent Media, 2007.
22 Vessey MP, Lawless M, Yeats D, McPherson K. Findings in a large prospective study with special reference to effectiveness. *Br J Fam Plann* 1985; **10**: 117–121.
23 Collaborative Study Group on the Desogestrel-containing Progestogen-only Pill. A double-blind study comparing the contraceptive efficacy, acceptability and safety of two progestogen-only pills containing desogestrel 75 micrograms/day or levonorgestrel 30 micrograms/day. Collaborative Study Group on the Desogestrel-containing Progestogen-only Pill. *Eur J Contracept Reprod Health Care* 1998; **3**: 169–178.
24 Vessey M. Oral contraceptive failures and body weight: findings in a large cohort study. *J Fam Plann Reprod Health Care* 2001; **27**: 90–91.
25 Sivin I. International experience with Norplant and Norplant-2 contraception. *Stud Fam Plann* 1988; **19**: 81–94.
26 Sivin I, Campodonico I, Kiriway O. The performance of levonorgestrel rod and Norplant contraceptive implant: a 5-year randomised study. *Hum Reprod* 1998; **13**: 3371–3378.
27 Koetsawang S, Ji G, Krishna U, Cuadros A, Dhall GI, Wyss R, *et al*. World Health Organization Task Force on Long-Acting Systemic Agents for Fertility Regulation. Microdose intravaginal levonorgestrel contraception: a multicentre clinical trial. III. The relationship between pregnancy rate and body weight. *Contraception* 1990; **41**: 143–150.
28 Glasier A. Implantable contraceptives for women: effectiveness, discontinuation rates, return to fertility, and outcomes of pregnancy. *Contraception* 2002; **65**: 29–37.
29 Donley TG, Smith RF, Roy B. Reduced oral contraceptive effectiveness with concurrent antibiotic use: a protocol for prescribing antibiotics to women of childbearing age. *Compendium* 1990; **11**: 392–396.
30 *British National Formulary* (BNF 53). 2007. www.bnf.org [Accessed 4 September 2008].
31 Organon Laboratories Limited. Cerazette 75 Microgram Tablets. Summary of Product Characteristics (SPCs). 2004. http://www.medicines.org.uk [Accessed 4 September 2008].
32 Lawson JP. Experience with norethisterone 0.35 mg daily as an oral contraceptive. *Br J Fam Plann* 1982; **8**: 84–89.
33 Eckstein P, Whitby M, Fotherby K, Butler C, Mukherjee T, Burnett JBC, *et al*. Clinical and laboratory findings in a trial of norgestrel, a low-dose progestogen-only contraceptive. *BMJ* 1972; **3**(5820): 195–200.
34 Korver T, Klipping C, Heger-Mahn D, Duijkers I, van Osta G, Dieben T. Maintenance of ovulation inhibition with the 75 microg desogestrel-only contraceptive pill (Cerazette) after scheduled 12-h delays in tablet intake. *Contraception* 2005; **71**: 8–13.
35 Kovacs G. Progestogen-only pills and bleeding disturbances. Hum Reprod 1996; 11: 20–23.
36 Porter C, Rees MC. Bleeding problems and progestogen-only contraception. *J Fam Plann Reprod Health Care* 2002; **28**: 178–181.
37 World Health Organization. Cardiovascular disease and use of oral and injectable progestogen only contraceptives and combine injectable contraceptives. Results of an international, multicentre, case control study. *Contraception* 1998; **57**: 315–324.
38 Heinemann LA, Assmann A, DoMinh T, Garbe E. Oral progestogen-only contraceptives and cardiovascular risk: results from the Transnational Study on Oral Contraceptives and the Health of Young Women. *Eur J Contracept Reprod Health Care* 1999; **4**: 67–73.
39 Vasilakis C, Jick H, del Mar Melero-Montes M. Risk of idiopathic venous thromboembolism in users of progestagens alone. *Lancet* 1999; **354**: 1610–1611.
40 Truitt ST, Fraser AB, Grimes DA, Gallo MF, Schulz KF. Combined hormonal versus nonhormonal versus progestin-only contraception in lactation. *Cochrane Database Syst Rev* 2003; (2): CD003988.
41 Royal College of Obstetricians and Gynaecologists (RCOG). T*he Care of Women Requesting Induced Abortion* (Evidence-based Clinical Guideline Number 7). 2004. London, UK: RCOG Press, 2004.
42 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. http://www.mrw.interscience.wiley.com/cochrane/clsysrev/articles/CD003449/pdf_fs.html [Accessed 4 September 2008].
43 Johannisson E, Landgren BM, Diczfalusy E. Endometrial morphology and peripheral steroid levels in women with and without intermenstrual bleeding during contraception with the 300 microgram norethisterone (NET) minipill. *Contraception* 1982; **25**: 13–30.
44 Gemzell-Danielsson K, Gemzell-Danielsson K, Killick SR, Croxatto HB, Bouchard P, Cameron S, *et al*. Improving cycle control in progestogen-only contraceptive pill users by intermittent treatment with a new anti-progestogen. *Hum Reprod* 2002; **17**: 2588–2593.

APPENDIX: DEVELOPMENT OF CEU GUIDANCE

This Guidance was developed by the Clinical Effectiveness Unit (CEU): **Dr Susan Brechin** (Unit Director); **Ms Lisa Allerton** (Unit Researcher); **Dr Madhuri Thakur** (Former Unit Researcher) on behalf of the Faculty of Sexual and Reproductive Healthcare (FSRH) with a multidisciplinary group of health professionals comprising: **Mrs Doreen Bell** (Public Partner QIS Scotland/User Representative); **Dr Amanda Britton** (Lead in Contraception and Sexual Health – Hampshire Primary Care Trust (North and East)/General Training Committee Representative FRSH, CASH, Basingstoke, UK); **Dr Jagruti Doshi** (Subspeciality Trainee in Sexual and Reproductive Health/Clinical Standards Committee Representative FSRH, Margaret Pyke Centre, London, UK); **Dr Tamsin Groom** (Consultant in Sexual and Reproductive Health); **Dr Kate Guthrie** (Consultant in Sexual and Reproductive Health, Conifer House, Hull, UK); **Dr Noel Mack** (General Practitioner, Kemnay Medical Group, Kemnay, Aberdeenshire,UK); **Dr Pauline McGough** (Consultant in Sexual and Reproductive Health, Sandyford Initiative, Glasgow, UK); **Ms Shelley Mehigan** (Nurse Specialist in Contraception/Clinical Effectiveness Committee Representative FSRH, The Garden Clinic, Sexual Health Services, Upton Hospital, Slough, UK); **Dr Radhika Shah** (General Practitioner, Camden and Islington, London, UK with a special interest in reproductive health, and Clinical Medical Officer, Brook Young Persons Advisory Services/Education Committee Representative FSRH); **Mrs Anne Simpson** (Public Partner QIS Scotland/User Representative); **Dr Anne Webb** (Consultant in Sexual and Reproductive Healthcare, Abacus Clinics for Contraception and Sexual Health, Liverpool Primary Care Trust, UK). Written feedback was received from: **Dr Alyson Elliman** (Consultant in Sexual and Reproductive Health Care, Croydon Primary Care Trust, Croydon, UK); the FSRH Clinical Effectiveness Committee and two independent reviewers: **Professor Ian Fraser** (Professor of Reproductive Medicine, The Queen Elizabeth II Research Institute for Mothers and Infants, The University of Sydney, Sydney, Australia) and **Professor Pier Georgio Crosignani** (Director, Institute of Obstetrics and Gynaecology, Ospedale Maggiore Policinico, Mangiagalli e Regnia Elena, Milan, Italy). No competing interests were noted by members of the multidisciplinary group. Administrative support to the CEU is provided by **Mrs Jane Carmichael.**

CEU Guidance is developed in collaboration with the Clinical Effectiveness Committee (CEC) of the FSRH. The process of Guidance development uses 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 healthcare, general practice, other allied specialities, and user representation. In addition, the aim is to include a representative from the FSRH CEC, the FSRH Education Committee and FSRH Council in the multidisciplinary group. Evidence is identified using a systematic literature review and electronic searches were performed for: MEDLINE (CD Ovid version) (from 1996–2008); EMBASE (1996–2008); PubMed (1996–2008); The Cochrane Library (to 2008) 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 pills. 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 (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 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 Guideline 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.members@ggc.scot.nhs.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

SUMMARY POINTS: PROGESTOGEN-ONLY PILLS

CLINICAL ASSESSMENT

- Health professionals should be familiar with the UK Medical Eligibility Criteria for progestogen-only pills (POPs). A medical history should specifically identify conditions given a UKMEC Category 3 or 4 for starting POP use (i.e. current or previous breast cancer; liver tumours; active viral hepatitis or severe decompensated cirrhosis; gestational trophoblastic neoplasia with abnormal hCG; concurrent use of liver enzyme-inducing medication).
- Blood pressure and an assessment of weight can be documented before starting a POP but this should be seen as part of a more general health check.

INFORMATION FOR WOMEN

- *Traditional* POPs (containing norethisterone, levonorgestrel or etynodiol diacetate) work by altering cervical mucus to prevent sperm penetration and for some women ovulation is also inhibited. The desogestrel-only pill also alters cervical mucus, however its primary mode of action is inhibition of ovulation.
- If used consistently POPs are more than 99% effective at preventing pregnancy. There are no data to suggest that some POPs are better at preventing pregnancy than others.
- Ideally women should be advised to take one POP at the same time *every day* and without a pill-free interval. Some women may consider that the desogestrel-only pill, with its 12-hour window, will improve pill taking and they should be supported in this choice.
- There is no evidence that the efficacy of POPs (*traditional* or desogestrel-only) is reduced in women weighing >70 kg and therefore the licensed use of one pill per day is recommended.
- Women can be advised that if a *traditional* POP is more than 3 hours late or a desogestrel-only pill is more than 12 hours late (Figure 1) they should:
  - take the late or missed pill now
  - continue pill taking as usual (this may mean taking two pills at the same time)
  - use condoms or abstain from sex for 48 hours after the pill is taken.
- If a woman vomits within 2 hours of pill taking another pill should be taken as soon as possible.
- Women using liver enzyme-inducing medications should be advised to use condoms in addition to POPs and for at least 4 weeks after the liver enzyme-inducer is stopped.
- Women using liver enzyme-inducing medications *long term* should be advised that the efficacy of POPs is reduced and an alternative contraceptive method should be considered.
- Women can be advised that the efficacy of POPs is not reduced by use of non-liver enzyme-inducing antibiotics and additional contraceptive protection is not required.
- There is no delay in the return of fertility following discontinuation of a POP and therefore if pregnancy is not desired another effective method of contraception may be required.
- Changes in bleeding patterns with POP use are common: 2 in 10 women have no bleeding, 4 in 10 women have a regular bleeding pattern, and 4 in 10 women have irregular bleeding.
- Women can be advised that there is no evidence of a causal association between POP use and weight change, depression, headache, cardiovascular disease (myocardial infarction, venous thromboembolism and stroke) or breast cancer.

WHEN TO START

- No *additional contraceptive protection is required* if POPs are started:
  - up to and including Day 5 of the menstrual cycle
  - up to and including Day 21 postpartum
  - up to 5 days following abortion or miscarriage (<24 weeks' gestation).
- If a POP is started outside these times condoms or abstinence is advised for 48 hours.

ONGOING USE AND FOLLOW UP

- In the absence of special problems, women can be given up to 12 months' supply of POPs at their first and follow-up visits. Follow up should be tailored to the individual, and women should be advised to return at any time if problems arise.
- Women can be advised that a POP can be continued until the age of 55 years when natural loss of fertility can be assumed. Alternatively she can continue with the POP and have follicle-stimulating hormone (FSH) concentrations checked on two occasions 1–2 months apart. If both FSH measurements are >30 IU/l this is suggestive of ovarian failure. In this case she may continue with a POP or barrier contraception for a further period of 1 year (or 2 years if she is aged <50 years).

MANAGING BLEEDING

- Women who have a change in bleeding patterns when using a POP need to be investigated to exclude sexually transmitted infections, pregnancy or gynaecological pathology.
- There is no evidence that changing the type and dose of progestogen will improve bleeding but this may help some individuals. After exclusion of other causes, if bleeding patterns are still unacceptable then an alternative contraceptive may need to be considered.

Discussion Points for Progestogen-only Pills

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

Discussion Points

1 When would the desogestrel-only pill be considered a suitable method of contraception?

2 How would you advise a woman who is 48 years old and taking the progestogen-only pill about her ongoing need for contraception?

Questions for Progestogen-only Pills

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 The only UKMEC 4 category for progestogen-only pills (POPs) is current breast cancer.	☐	☐
2 A woman who has had a previous ectopic pregnancy may safely use POPs.	☐	☐
3 The primary mode of action of all POPs is to inhibit ovulation.	☐	☐
4 It is recommended that women weighing >70 kg should take two traditional POPs a day.	☐	☐
5 The desogestrel-only pill (Cerazette®) has a 12-hour window for late pill taking.	☐	☐
6 The efficacy of POPs is reduced by concurrent use of non-liver enzyme-inducing antibiotics.	☐	☐
7 Approximately 50% of women will stop using a POP in the first year due to altered bleeding patterns.	☐	☐
8 There is no causal association between POPs and cardiovascular disease.	☐	☐
9 If a POP is started immediately after a second-trimester miscarriage or abortion additional contraception is required for 48 hours.	☐	☐
10 Follicle-stimulating hormone (FSH) concentrations cannot be assessed if a woman is taking a POP.	☐	☐

Answers

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

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 Glasgow 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.members@ggc.scot.nhs.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) 141 232 8459] or e-mail (**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, after review by the Clinical Effectiveness Committee, will be posted on the Faculty website (**www.fsrh.org**).