FACULTY OF SEXUAL & REPRODUCTIVE HEALTHCARE

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Faculty of Sexual & Reproductive Healthcare Clinical Guidance

Progestogen-only Pills

Clinical Effectiveness Unit

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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

DETAILS OF CHANGES TO ORIGINAL GUIDANCE DOCUMENT

Since this set of guideline was first published, the following changes have been made:
January 2016 - On page 18, the words "a traditional" have been added to the third auditable outcome.
February 2019 - Table 2 and 3. CPD Question 8.
April 2019 - Section 10.1 and CPD Question 6 has been updated to reflect updates to other FSRH guidance

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NICE has accredited the process used by the Faculty of Sexual & Reproductive Healthcare to produce its Progestogen-only Pills guidance. Accreditation is valid for 5 years from May 2011. More information on accreditation can be viewed at www.nice.org.uk/accreditation.

For full details on our accreditation visit:
www.nice.org.uk/accreditation.

ABBREVIATIONS USED

BMI	body mass index
CEU	Clinical Effectiveness Unit
CHC	combined hormonal contraceptive/contraception
CI	confidence interval
COC	combined oral contraceptive/contraception
Cu-IUD	copper intrauterine device
DSG	desogestrel
EC	emergency contraception
EE	ethinylestradiol
FSH	follicle-stimulating hormone
FSRH	Faculty of Sexual & Reproductive Healthcare
HIV	human immunodeficiency virus
HRT	hormone replacement therapy
IM	intramuscular
IU	international unit
LAM	lactational amenorrhoea method
LNG	levonorgestrel
LNG-IUS	levonorgestrel intrauterine system
NET	norethisterone
NET-EN	norethisterone enantate
POP	progestogen-only pill
RCT	randomised controlled trial
SC	subcutaneous
SPC	Summary of Product Characteristics
STI	sexually transmitted infection
UKMEC	*UK Medical Eligibility Criteria for Contraceptive Use*
UPA	ulipristal acetate
UPSI	unprotected sexual intercourse
USMEC	*US Medical Eligibility Criteria for Contraceptive Use*
VTE	venous thromboembolism
WHOMEC	*World Health Organization Medical Eligibility Criteria for Contraceptive Use*

SUMMARY OF KEY RECOMMENDATIONS

Factors affecting efficacy

C If used consistently and correctly, progestogen-only pills (POPs) are more than 99% effective.

C POP users taking enzyme-inducing drugs should be advised to switch to the progestogen-only injectable or intrauterine contraception. For short durations of enzyme-inducing treatment (<2 months) women can continue the POP providing they use additional precautions during treatment and for 28 days afterwards. Women wishing to start the POP after stopping enzyme-inducing drugs should be advised to use condoms until 28 days after the last dose of enzyme-inducing drug.

✓ Desogestrel (DSG) pills may have potential benefits over traditional POPs because ovulation is inhibited in up to 97% of cycles and they have a 12-hour window for missed pills.

✓ Women should be advised that regular pill taking is required for efficacy and to take the pill at a time of day that will best suit them to promote adherence.

C Available evidence has not shown an increased risk of pregnancy in POP users with a heavier body weight or a higher body mass index. There is insufficient evidence to support a dose of more than one pill per day for women who are heavy or overweight.

C If a woman vomits within 2 hours of pill taking, another pill should be taken as soon as possible. If the subsequent pill is missed, additional precautions are required until 48 hours after pill taking has been resumed.

Eligibility

✓ Few medical conditions restrict the use of the POP. Health professionals should be familiar with the most up-to-date *UK Medical Eligibility Criteria for Contraceptive Use* (UKMEC).

Health benefits and concerns

C The DSG pill may offer some benefits in the management of dysmenorrhoea.

B The limited available evidence does not support an association between cardiovascular disease and use of a POP.

C The available evidence does not support an association between breast cancer and use of a POP. However, due to the limited available evidence, an increased risk cannot be completely excluded. Any increased risk is likely to be small and to reduce with time after stopping.

Health benefits and concerns

C Mood changes have been reported in women using the POP but there is no evidence of a causal association between use and mood changes or depression.

B While the overall risk of pregnancy is reduced with use of traditional POPs, around 1 in 10 pregnancies that do occur may be ectopic.

B There is no evidence suggesting a delay in return of fertility following discontinuation of a POP; therefore if pregnancy is not desired, other contraceptive methods should be used immediately following discontinuation of the POP.

Side effects

C Changes in bleeding patterns associated with the POP are common and women should be informed about such changes.

C Studies investigating the effects of POP on libido are lacking and therefore a possible effect cannot be excluded; however, no association has yet been demonstrated.

C Evidence does not support a causal association between POP use and weight change.

Follow-up and ongoing use

✓ Women may be given up to a 12-month supply of POPs 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.

✓ The POP can be used until the age of 55 years when natural loss of fertility can be assumed for most women. Alternatively, if they are aged over 50 years and amenorrhoeic they can continue using a POP and have FSH concentrations tested on two occasions 6 weeks apart. If both FSH measurements are >30 IU/l this is suggestive of ovarian failure and they should continue with a POP or barrier method for one further year.

✓ There is no evidence that changing the type and dose of POPs will improve bleeding but it may help some individuals.

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 (March 2015, updated April 2019)

Progestogen-only Pills

(Revision due by March 2020)

1 Purpose and Scope

This guidance provides evidence-based recommendations and good practice points on use of the progestogen-only pill (POP). It is intended for any health professional or service providing contraception or contraceptive advice in the UK. The document updates and replaces Faculty of Sexual & Reproductive Healthcare (FSRH) clinical guidance *Progestogen-only Pills* published in 2009.[1] The main changes from the previous guidance include:

- Some eligibility criteria have changed since *UK Medical Eligibility Criteria for Contraceptive Use* (UKMEC) was updated in 2009[2]
- Changes to advice on switching between contraceptive methods
- Ethynodiol diacetate (Femulen®) POP has been discontinued
- Several generic bioequivalent desogestrel (DSG) pill products are now available (see section 2).

POPs containing levonorgestrel (LNG) or norethisterone (NET) will be referred to in this guidance as *traditional* POPs. DSG pills will be named specifically where relevant.

The recommendations included in this document should be used to guide clinical practice; however, 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

POPs are taken daily with no pill-free interval. For effectiveness, the POP should be taken at or around the same time each day (see section 4.2). POPs currently available in the UK contain either NET 350 µg (Micronor®, Noriday®), LNG 30 µg (Norgeston®) or DSG 75 µg (Cerazette® and other branded generic products).

3 What is the Mode of Action of POPs?

The POP has several independent modes of action that contribute to its contraceptive effect.[3] POPs increase the volume and viscosity of cervical mucus preventing sperm penetration into the upper reproductive tract.[3] This change occurs soon after starting a POP and it is advised that 2 days of pill taking is sufficient to achieve this element of contraceptive protection. However, the contraceptive effect provided by changes to cervical mucus is also short-lived,

unless maintained by regular pill taking.[3] It has been estimated that full protection conferred via cervical mucus may last for less than 24 hours.[3]

POPs can also act to suppress ovulation.[3] The extent to which this occurs is variable; for example, up to 60% of cycles in women using an LNG pill are anovulatory, whereas ovulation is suppressed in up to 97% of cycles in women using the DSG pill.[4,5]

Other modes of action include endometrial changes that hinder implantation, and reduction in cilia activity in the fallopian tube that slows the passage of an ovum.[3]

4 How Effective are POPs and What Factors Might Affect Efficacy?

A comparative trial of the DSG versus LNG-only pill reported an overall failure rate for the LNG pill of 1.55 per 100 woman-years [95% confidence interval (CI) 0.422–3.963] and for the DSG pill 0.41 per 100 woman-years (95% CI 0.085–1.204). The failure rates were not found to be significantly different[6] but the study was not powered to detect differences in efficacy and around one-third of women were breastfeeding at the time of initiation.[6] After excluding those women who were breastfeeding, the reported Pearl indices [for those who were switching from a combined oral contraceptive (COC) or starters (not breastfeeding or switching)] were 1.41 (95% CI 0.290–4.116) and 0.17 (95% CI 0.004–0.928) for the LNG and DSG pills, respectively.[6]

A Cochrane Review[7] of six trials concluded that there were inadequate data from randomised controlled trials (RCTs) to compare POPs with one another or with combined hormonal contraceptives (CHCs). The review also indicated that because of low fertility during breastfeeding, any potential improved efficacy associated with the DSG pill might be confined to non-breastfeeding women.

Theoretically the DSG pill may be expected to be more effective than traditional POPs, especially with typical use, because ovulation is suppressed more consistently and it has a longer missed pill window (see section 4.3).

C If used consistently and correctly, POPs are more than 99% effective.

4.1 Drug interactions

Drugs that induce cytochrome P450 enzymes have the potential to decrease the efficacy of POPs by increasing the metabolism of progestogens. FSRH guidance on *Drug Interactions with Hormonal Contraception*[8] advises that ideally women using enzyme-inducing drugs should be advised to switch to a method for which the contraceptive efficacy is unaffected by such drugs (i.e. the progestogen-only injectable or intrauterine contraception). Women using enzyme-inducing drugs for durations of 2 months or less can be given the option of continuing with their method in addition to using condoms during treatment and for 28 days afterwards.[8] If a woman has recently stopped these medications and wishes to start the POP, she should be advised to use condoms until 28 days after the last dose of enzyme-inducing drugs.[8]

C POP users taking enzyme-inducing drugs should be advised to switch to the progestogen-only injectable or intrauterine contraception. For short durations of enzyme-inducing treatment (<2 months) women can continue the POP providing they use additional precautions during treatment and for 28 days afterwards. Women wishing to start the POP after stopping enzyme-inducing drugs should be advised to use condoms until 28 days after the last dose of enzyme-inducing drug.

4.2 Timing of pill taking

It is important that the POP is taken at the same time each day to ensure maximal efficacy. Advice regarding the timing of pill taking should be individualised to suit a woman's lifestyle and facilitate adherence.

4.3 Missed pills

Traditional POPs only suppress ovulation in approximately 50% of cycles. Therefore if more than 27 hours have elapsed between pills there is a risk that the contraceptive effect of the cervical mucus will be lost and additional precautions will be required to avoid pregnancy. However, ovulation suppression is maintained in DSG pill users who take their pills up to 12 hours late.[9] Figure 1 outlines advice for women when a POP is late or missed.

During regular POP use cervical mucus changes prevent sperm penetration into the upper genital tract and sperm in the lower genital tract do not survive for more than a few hours. Therefore sex that occurs before a missed pill does not present a risk of pregnancy and emergency contraception (EC) would not be required.

✓ DSG pills may have potential benefits over traditional POPs because ovulation is inhibited in up to 97% of cycles and they have a 12-hour window for missed pills.

✓ Women should be advised that regular pill taking is required for efficacy and to take the pill at a time of day that will best suit them to promote adherence.

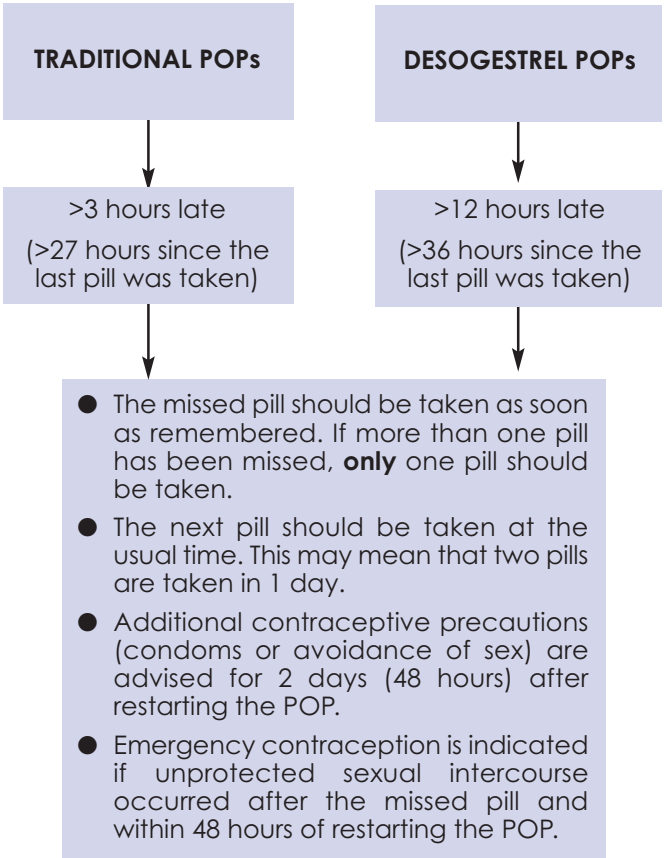

Figure 1 Faculty of Sexual & Reproductive Healthcare advice for women when a progestogen-only pill (POP) is late or missed

4.4 Weight

There is a lack of available data on POP efficacy and body weight. Studies of other contraceptive methods[10–12] have shown lower contraceptive serum levels with increasing body weight and body mass index (BMI), although no reduction in efficacy has yet been demonstrated.

Data from a small preliminary *in vitro* study of 16 women[13] found that a single tablet of LNG 30 µg (*n*=8) or NET 350 µg (*n*=8) prevented sperm migration in cervical mucus about 12 hours after ingestion. Three women, all of whom weighed over 75 kg and had a BMI >35 kg/m^2, showed no significant changes to their cervical mucus; two following LNG and one following NET.[13] As the study[13] only examined the impact of a single dose, further evidence is required before conclusions can be drawn about the impact of weight or BMI on the cervical mucus effect.

An observational study found no association between body weight and accidental pregnancy in traditional POP users.[14] However, the authors acknowledged that the study was underpowered to detect a relationship. The CEU is not aware of any studies that have examined the effectiveness of the DSG pill in women of differing weights or BMIs.

A comparative study examining inhibition of ovulation with use of the DSG pill compared to a LNG pill reported that ovulation was suppressed in all but 1/59 cycles. The weight range of the women in the DSG group was 46–78 kg,[4] suggesting that the DSG pill is effective in women up to this weight. Some 16/57 LNG cycles were ovulatory, and women in this group weighed between 50 and 91 kg. No analysis was carried out by weight.

The Summary of Product Characteristics (SPC) for POPs[15–17] does not advise dose adjustments based on weight. Therefore, in the absence of any evidence to suggest otherwise, the CEU would advise the licensed use of one pill per day, even in women with a BMI >30 kg/m^2.

There is currently no UK guidance on the use of oral contraceptives in women who have undergone bariatric surgery for obesity. *US Medical Eligibility Criteria for Contraceptive Use* (USMEC) guidelines suggest that restrictive procedures that decrease the storage capacity of the stomach (e.g. vertical banded gastroplasty, laparoscopic adjustable gastric band or laparoscopic sleeve gastrectomy) are conditions for which there is no restriction of the use of oral contraceptives such as the POP (USMEC 1).[18] However for procedures that decrease the absorption of nutrients and calories by shortening the functional length of the small intestine (e.g. Roux-en-Y gastric bypass or biliopancreatic diversion), the theoretical or proven risks usually outweigh the advantages of using the method (USMEC 3).[18]

C Available evidence has not shown an increased risk of pregnancy in POP users with a heavier body weight or a higher BMI. There is insufficient evidence to support a dose of more than one pill per day in women who are heavy or overweight.

4.5 Vomiting or severe diarrhoea

Women who vomit within 2 hours of taking a POP should be advised to take another pill as soon as possible.[19] If this means that the subsequent pill is taken more than 3 hours late (12 hours for a DSG pill) then the missed pill rules for POP should be followed. This would also apply if a woman were to continue to vomit or have very severe watery diarrhoea.

C If a woman vomits within 2 hours of pill taking, another pill should be taken as soon as possible. If the subsequent pill is missed, additional precautions are required until 48 hours after pill taking has been resumed.

5 Who is Eligible to Use the POP?

Few medical conditions restrict the use of the POP. UKMEC[2] provides evidence-based recommendations for the use of contraceptive methods in the presence of a range of medical conditions and social factors. Health professionals should refer to UKMEC (http://www.fsrh.org/pages/clinical_guidance.asp) when assessing an individual's eligibility for any contraceptive, including the POP. Unless specifically stated, UKMEC does not consider multiple conditions. Assessing an individual's eligibility in the presence of multiple medical and social factors requires clinical judgement based on the evidence available. Table 1 outlines the UKMEC categories and definitions.

✓ Few medical conditions restrict the use of the POP. Health professionals should be familiar with the most up-to-date *UK Medical Eligibility Criteria for Contraceptive Use* (UKMEC).

6 When Can Women Start or Switch to a POP?

The CEU supports starting the POP at any time during a woman's menstrual cycle providing a woman is not pregnant or at risk of pregnancy. Where pregnancy cannot be excluded, for example, following use of EC, the CEU supports starting the POP in certain circumstances, for example, if the woman is likely to continue to be at risk of pregnancy or unlikely to return. More detailed guidance is available in the FSRH guidance on *Quick Starting Contraception*.[20]

Women can start the POP up to Day 5 of the menstrual cycle without the need for additional contraceptive precautions; thereafter 48 hours of additional precautions are required. When quick starting POP following a risk of pregnancy, a pregnancy test is advised no sooner than 3 weeks after the most recent episode of unprotected sexual intercourse (UPSI). When starting after either Day 5 of the menstrual cycle, Day 5 post-abortion, or Day 21 postpartum, consideration of EC and a pregnancy test ≥3 weeks after the most recent episode of UPSI may be required if there has been a risk of pregnancy.

There are no studies examining the maintenance of the contraceptive effect when switching from other methods of contraception to POPs. To ensure consistency with other FSRH recommendations, for example, starting advice, and other method-specific guidelines, the CEU recommends the advice outlined in Table 2 (advice may differ from the SPC for individual POPs).

Table 1: Summary of *UK Medical Eligibility Criteria for Contraceptive Use* (UKMEC) categories

UKMEC Category	Definition
1	A condition for which there is no restriction for the use of the contraceptive method.
2	A condition for which the advantages of using the method generally outweigh the theoretical or proven risks.
3	A condition for which the theoretical or proven risks usually outweigh the advantages of using the method. The provision of a method requires expert clinical judgement and/or referral to a specialist contraceptive provider, since use of the method is not usually recommended unless other more appropriate methods are not available or not acceptable.
4	A condition which represents an unacceptable health risk if the method is used.

Table 2: Faculty of Sexual & Reproductive Healthcare advice on starting the progestogen-only pill

Circumstance	Timing of initiation	Need for additional precautions	Clarification
Women with menstrual cycles	Day 1–5 of the menstrual cycle	**No**	It is advisable to check that the woman's menstrual period is typical of the woman's usual bleeding pattern in terms of duration, heaviness and timing
	After Day 5 of the menstrual cycle	**Yes** (48 hours)	If there has been a risk of pregnancy consider PT, EC and quick starting (see below)[b]
Women who are amenorrhoeic	At any time	**Yes** (48 hours)	PT prior to starting. If PT is negative but UPSI in the last 21 days, consider EC, quick start POP and repeat PT at 3 3 weeks.
Postpartum (breastfeeding and non-breastfeeding)	Up to Day 21 postpartum	**No**	POP can be started at any time after childbirth, including immediately after delivery.
	After Day 21 postpartum	**Yes** (48 hours) unless using LAM	If there has been a risk of pregnancy consider PT, EC and quick starting (see below)[b]
Post first- or second-trimester abortion	Day 1–5[a]	**No**	POP can be initiated after the first part of a medical abortion[21] (please see FSRH guideline Contraception After Pregnancy)
	At any other time	**Yes** (48 hours)	If there has been a risk of pregnancy consider PT, EC and quick starting (see below)[b]
Quick starting after oral EC[b]	Immediately after LNG EC OR 5 days after UPA EC	**Yes** (until 48 hours after starting POP)	Advise a pregnancy test no sooner than 3 weeks from last UPSI

[a]The FSRH advises that women should ideally start on the day or day after a first- or second-trimester abortion.
[b]See FSRH guidance *Quick Starting Contraception*[20]
EC, emergency contraception; LAM, lactational amenorrhoea; LNG, levonorgestrel; POP, progestogen-only pill; PT, pregnancy test; UKMEC, UK Medical Eligibility Criteria for Contraceptive Use; UPA, ulipristal acetate; UPSI, unprotected sexual intercourse.

7 What are the Non-contraceptive Benefits, Health Concerns and Side Effects Associated with Use of POPs?

7.1 Non-contraceptive benefits

7.1.1 Dysmenorrhoea

Suppression of ovulation via hormonal contraceptives, such as the DSG pill, may help to alleviate dysmenorrhoea and mid-cycle ovulatory pain. An observational study[24] found self-reported improvements in primary dysmenorrhoea amongst women who used the DSG pill for 12 weeks. There is limited evidence of improvement in pelvic pain and dysmenorrhoea in women with endometriosis who had surgery followed by 6 months of the DSG pill.[25]

C The DSG pill may offer some benefits in the management of dysmenorrhoea.

7.2 Health concerns

7.2.1 Cardiovascular health

Few studies have been large enough to evaluate the risk of venous thromboembolism (VTE) associated with use of progestogen-only contraceptives. However, the available evidence does not demonstrate an increased risk associated with the POP.[26–28]

Theoretically there is a risk that some NET products could increase a woman's risk of VTE because of partial metabolism of NET and norethisterone acetate (NET-EN) to ethinylestradiol (EE).[29,30] However, conversion to EE has only been demonstrated at NET doses of 5 mg or more. As the NET-containing POP available in the UK contains only 350 µg, [31] any such risk is unlikely to apply.

Hypertension is a condition for which there is no restriction on the use of POPs. Even for women with vascular disease, the advantages of using a POP generally outweigh the theoretical or proven risks.[2] There is no evidence that POPs increase blood pressure.[3]

The POP is generally appropriate for women with cardiac disease, and is useful as a bridging method while specialist advice is being sought about contraceptive options.[32]

B The limited available evidence does not support an association between cardiovascular disease and use of a POP.

7.2.2 Breast cancer

The annual risk of breast cancer rises with increasing age irrespective of hormone use. Due to the small numbers of women using progestogen-only methods in studies that have investigated the association between hormonal contraceptive use and breast cancer, data are limited on the risk associated with use of progestogen-only methods.[33] Any attributable risk is likely to be small and, as with combined methods, is likely to reduce with time after stopping. Current breast cancer is a condition which represents an unacceptable health risk for use of the POP (UKMEC 4).[2]

C The available evidence does not support an association between breast cancer and use of a POP. However, due to the limited available evidence, an increased risk cannot be completely excluded. Any increased risk is likely to be small and to reduce with time after stopping.

7.2.3 Depression and mood change

As with other forms of hormonal contraception, depression and mood change have been noted as possible undesirable effects associated with POP use within the SPCs.[15,17,34] Causality cannot be determined and the CEU found no direct evidence from studies to suggest a causal association. Depressive disorders are conditions for which there is no restriction on the use of a POP (UKMEC 1).[2]

C Mood changes have been reported in women using the POP but there is no evidence of a causal association between use and mood changes or depression.

7.2.4 Ectopic pregnancy

The risk of ectopic pregnancy associated with a contraceptive method will be determined, in the first instance, by the ability of the method to prevent pregnancy, and subsequently by the

proportion of ectopic pregnancies to intrauterine pregnancies that occur. Other factors may influence a woman's risk of ectopic pregnancy including age, smoking, and previous history of ectopic pregnancy.

The incidence of ectopic pregnancy associated with the POP is difficult to determine due to the small numbers of ectopic pregnancies that occur and the inability to adequately control for the necessary factors that may influence risk. Up to 10% of pregnancies that occur in traditional POP users may be ectopic.[3] Methods that suppress ovulation are likely to be associated with a lower overall rate of ectopic pregnancy than those that do not. Women should be informed of possible signs of ectopic pregnancy (e.g. lower abdominal pain or shoulder tip pain).

A previous history of ectopic pregnancy is a condition that does not place any restrictions on the use of POPs.[2]

B While the overall risk of pregnancy is reduced with use of traditional POPs, around 1 in 10 pregnancies that do occur may be ectopic.

7.2.5 Headaches

No good evidence was identified that investigated the influence of POP use on headache incidence. There are limited data on the effects of progestogen on migraine development but the available evidence does not suggest an increased risk of migraine associated with use of POPs.[35] Data from two small non-comparative retrospective studies[36,37] and one small non-comparative diary-based pilot study[38] have suggested that the DSG pill may confer some benefits to women who experience migraine by reducing the frequency[36,38] and intensity of headaches,[37] thereby improving quality of life.[36]

Migraine is associated with an increased risk of ischaemic stroke.[39–41] However, as progestogen-only methods have not been shown to be associated with an increased risk of stroke, for women who have migraine with or without aura the advantages of using the POP generally outweigh the theoretical or proven risks (UKMEC 2).[2]

7.2.6 Ovarian cysts/persistent ovarian follicles

It is not uncommon for women using POPs to experience persistent ovarian follicles (ovarian cysts).[3] Benign ovarian tumours, including cysts, are a condition for which there is no restriction on the use of POPs (UKMEC 1).[2]

7.2.7 Return of fertility

Observational studies[42–44] have reported no delay in return of fertility after stopping a traditional POP. An RCT[9] found that after stopping the DSG pill, the average number of days to first ovulation was 17.2 (range 7–30) days. If women considering stopping a POP do not wish to conceive then another method of contraception is required immediately. Advice on switching between methods and the need for additional precautions can be found in Table 3.

B There is no evidence suggesting a delay in return of fertility following discontinuation of a POP; therefore if pregnancy is not desired, other contraceptive methods should be used immediately following discontinuation of the POP.

Table 3: Faculty of Sexual & Reproductive Healthcare advice on switching from another method of contraception to a progestogen-only pill

Switching from	Timing of initiation	Need for additional precautions after starting	Additional information
CHC (if taken correctly)	Day 1–2 of HFI	**No**	Day 1 is the optimal time to switch.
	Day 3-7 of HFI OR week 1 following HFI	**Yes** (48 hours). If UPSI has occurred after Day 3 of HFI advise continuing the CHC method for at least 7 days	If CHC cannot be continued, switch to POP immediately and consider the need for EC and PT
	Week 2–3 of CHC use	**No**, providing the method has been used consistently and correctly (i.e. at least 7 consecutive pills taken or 7 days of patch or ring use prior to switching)	There is evidence to suggest that taking hormonally active pills for 7 consecutive days prevents ovulation in the subsequent 7 days[23]
Another POP	At any time	**No**	
Progestogen-only implant	Up to 3 years post-insertion	**No**	
	More than 3 years post-insertion	**Yes** (48 hours)	Consider need for EC and PT if pregnancy cannot be excluded
Progestogen-only injectable	≤14 weeks post IM or SC DMPA injection	**No**	
	>14 weeks since last IM or SC DMPA injection	**Yes** (48 hours)	Consider need for EC and PT if pregnancy cannot be excluded
LNG-IUS	No UPSI in last 7 days	**No** if (in date) IUS continued for 2 days **Yes** (48 hours) if IUS removed or out of date	
	UPSI in last 7 days	**Yes**, retain IUS for 7 days	UPSI should be avoided for 7 days prior to removal of IUS. Consider need for EC and PT if pregnancy cannot be excluded
Cu-IUD	Day 1-5 of cycle	**No**	
	After Day 5 of cycle (no UPSI in last 7 days)	**No** if (in date) IUD continued for 2 days **Yes** (48 hours) if IUD removed or out of date	
	After Day 5 of cycle (UPSI in last 7 days)	**Yes**, retain IUD for 7 days	UPSI should be avoided for 7 days prior to removal of an IUD. Consider need for EC and PT if pregnancy cannot be excluded
Barrier methods	Day 1–5 of cycle	**No**	
	After Day 5 of cycle	**Yes** (48 hours)	Consider need for EC and PT if pregnancy cannot be excluded

CHC, combined hormonal contraception; Cu-IUD, copper intrauterine device; DMPA, depot medroxyprogesterone acetate; EC, emergency contraception; HFI, hormone free interval; IM, intramuscular; LNG-IUS, levonorgestrel intrauterine system; POP, progestogen-only pill; PT, pregnancy test; SC, subcutaneous; UPSI, unprotected sexual intercourse.

7.3 Side effects

7.3.1 Bleeding

Altered bleeding patterns are a common reason given by women for stopping POPs.[6,45–47] Indeed almost half of POP users experience prolonged bleeding and up to 70% report breakthrough bleeding or spotting in one or more cycles.[47] Bleeding patterns associated with POPs may depend upon the progestogen used, the dose at which it is given, the circulating endogenous estradiol concentrations, and ovulation. A comparative study[6] of DSG and LNG POPs reported that a variable pattern of bleeding was almost twice as common in DSG users than LNG users in the first reference period of 90 days. Bleeding problems decreased with increasing duration of use, and by the fourth reference period (1 year) almost 50% of DSG users had infrequent bleeding (1–2 bleeding/spotting episodes) or amenorrhoea, compared to 10% of the LNG users. The incidence of prolonged bleeding (a bleeding/spotting episode lasting for more than 14 days) and frequent bleeding amongst DSG users (>6 bleeding/spotting episodes) also decreased with increasing duration of use.[6]

As a guide, women considering DSG-only contraception can be advised that after 12 months of use, over a 3-month period[6] approximately:

- 5 in 10 women can expect to be amenorrhoeic or have infrequent bleeding
- 4 in 10 women can expect to have 3–5 bleeding spotting/episodes (regular)
- 1 in 10 women can expect >6 bleeding/spotting episodes (frequent bleeding).

In addition:

- 2 in 10 women will experience bleeding/spotting episode lasting >14 days (prolonged bleeding).

Traditional POP users can be advised that frequent and irregular bleeding are common, while prolonged bleeding and amenorrhea are less likely.

Discontinuation rates of POPs may be influenced by the type or changes in bleeding patterns and individual and cultural acceptability of such changes. Informing women about the likelihood of changes to bleeding changes may help reduce discontinuation rates.[3,45] Other causes of bleeding should always be considered, particularly where there is a sudden change in bleeding pattern for an established user (see section 9).

C Changes in bleeding patterns associated with the POP are common and women should be informed about such changes.

7.3.2 Libido

Decreased libido is listed in the SPCs of DSG POPs as a commonly reported (≥1/100) adverse reaction reported in clinical trials.[17,48] The SPCs for other POPs also mention libido changes (both decreased and increased).[34,49]

Establishing causation is difficult given the subjective nature of sexual interest and the multitude of factors that may influence it.

Studies looking specifically at the impact of the POP on libido are lacking. A placebo-controlled double-blind study[50] investigating the effects of steroidal contraception on well-being and libido reported no negative effects in women using a LNG POP.

C Studies investigating the effects of POP on libido are lacking and therefore a possible effect cannot be excluded; however, no association has yet been demonstrated.

7.3.3 Weight change

In women of reproductive age, minor weight fluctuation is common. Weight changes (both increases and decreases) have been reported with POP use.[3] However a Cochrane Review[51] of 16 RCTs, one of which examined a POP, reported limited evidence of weight gain amongst users of progestogen-only contraceptives; less than 2 kg over 12 months in most studies. Whilst there is a paucity of evidence relating to the POP, the available evidence does not support a causal association between POP use and weight change.[51]

C Evidence does not support a causal association between POP use and weight change.

8 Follow-up and Ongoing Use of POPs

Women can be offered up to 12 months' supply of POP at their first and subsequent visits. Follow-up can be tailored to an individual woman and return appointments can be made at any time if she experiences any problems or has any concerns. A review should seek to identify any adherence issues, bleeding patterns and any changes in medical, drug, family or sexual history. Consideration should be given to investigating any abnormal bleeding or changes in bleeding pattern.[52]

A woman can continue to use a POP until the age of 55 years when natural loss of fertility can be assumed for most women.[53]

Alternatively if an amenorrhoeic woman wishes to stop the POP before the age of 55 years, providing she is over the age of 50 years, follicle-stimulating hormone (FSH) concentrations can be assessed and if the level is ≥30 IU/l, POP can be stopped after 1 further year.[53] For further information refer to FSRH guidelines on *Contraception for Women Aged Over 40 years*.[53]

While a POP can be used concomitantly with hormone replacement therapy (HRT) to provide effective contraception, FSRH guidelines[53] do not advise that a POP can be relied on as the progestogen component of HRT. Currently the irena LNG-IUS is the only contraceptive available in the UK that is licensed for endometrial protection.

✓ Women may be given up to a 12-month supply of POPs 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.

✓ The POP can be used until the age of 55 years when natural loss of fertility can be assumed for most women. Alternatively, if they are aged over 50 years and amenorrhoeic they can continue using a POP and have FSH concentrations tested on two occasions 6 weeks apart. If both FSH measurements are >30 IU/l this is suggestive of ovarian failure and they should continue with a POP or barrier method for one further year.

9 Managing Bleeding Problems in Women Using a POP

While bleeding patterns can be irregular with progestogen-only methods, sexually transmitted infections (STIs) can also cause a change in bleeding patterns. Women with intermenstrual, postcoital or unscheduled bleeding while using hormonal contraception should be assessed to identify their individual risk of STI.[52]

In addition to consideration of STIs, gynaecological pathology and pregnancy should be excluded in women with persistent problematic bleeding (or with bleeding after a spell of amenorrhoea). Cervical cytology is appropriate if the woman's history and national screening guidelines indicate that the test is due or overdue.[52]

Although regimens such as estrogen supplementation or tranexamic acid may help to reduce bleeding induced by progestogen-only contraceptives in the short term,[54–56] evidence does not support routine use of such regimens particularly for a long-term effect.[54] Studies looking at longer-term use of such interventions are required.

Guidance on the *Management of Unscheduled Bleeding in Women Using Hormonal Contraception* is available from the FSRH.[52] There is no evidence that changing the type of POP will improve bleeding patterns in those with unscheduled bleeding, although it may help some women. There is also no published evidence to support using two pills per day to improve bleeding.

✓ There is no evidence that changing the type and dose of POPs will improve bleeding but it may help some individuals.

10 Other Considerations

10.1 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 POP, if a pill is missed or if enzyme-inducing drugs are used. An copper IUD can be inserted for EC up to 5 days after earliest UUPSII or 5 days from expected date of ovulation.[57] A copper IUD can therefore be inserted within 5 days of the first UPSII following a missed POP (so long as previous pills were taken correctly. The earliest date of ovulation after a missed POP (traditional or desogestrel) cannot be accurately estimated. See Table 2 and FSRH guideline Emergency Contraception for guidance regarding use of oral emergency contraception after missed POP.[57]

UPA is a progesterone receptor modulator and in theory could in theory affect the efficacy of other progestogen-containing contraceptives and vice versa. Limited evidence from biomedical studies suggests that UPA-EC does not reduce contraceptive effectiveness of the DSG POP,but that DSG POP started immediately after UPA-EC could potentially reduce the effectiveness of the UPA-EC. See FSRH guideline Emergency Contraception.[57]

10.2 Sexually transmitted infections and testing

STI screening should be discussed with all sexually active women attending health services for contraceptive advice or supply. A repeat STI screen should be advised if necessary after the appropriate window period (2 weeks for detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae*; 3 months for syphilis; for blood-borne viruses refer to local protocols or British Association for Sexual Health and HIV (BASHH) guidance.

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APPENDIX 1: DEVELOPMENT OF CEU GUIDANCE

GUIDELINE DEVELOPMENT GROUP

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Declared Interests

Ms Lynn Hearton declared that the FPA has received funding to provide an enquiry service from five pharmaceutical companies.

Ms Tina Proctor received payment from HRA Pharma for participation in consensus meetings on emergency contraception.

Ms Shelley Raine has undertaken paid consultancy work for pharmaceutical companies involved in contraception, including MSD, Bayer and Pfizer.

Dr Radhika Shah has acted as a consultant to Brook Young People Limited (Brook).

Professor Edith Weisberg has provided expert opinion for MSD and Bayer Healthcare, has been supported to attend conferences by Bayer Healthcare, and has obtained research funding for investigator-initiated research from both companies.

Patient Consultation

A questionnaire on the proposed guidance content was completed by a sample of potential users.

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 specialities, 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 (1996–2014); EMBASE (1996–2014); PubMed (1996–2014); The Cochrane Library (to 2014) 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 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 (WHO) and the British Association for Sexual Health and HIV (BASHH), and reference lists of identified publication, are also searched. Similar search strategies have been used in the development of other national guidelines. Selected key publications are appraised using methodological checklists. 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 detailed on the FSRH website (www.fsrh.org). The methods used in the development of this guidance (CEU Process Manual Version 2.0) have been accredited by NHS Evidence.

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 primary mode of action of the desogestrel (DSG) pill is:
- a. Changes to the endometrium
- b. Reduction in cilia activity
- c. Suppression of ovulation
- d. Thickening of cervical mucus

2 When starting a progestogen-only pill (POP) on Day 7 of the menstrual cycle, how many days of additional precautions are advised as a minimum?
- a. 0 days
- b. 2 days
- c. 7 days
- d. 9 days

3 Which of these drugs is not expected to affect the contraceptive efficacy of the POP?
- a. Carbamezapine
- b. Eslicarbazepine
- c. Sodium valproate
- d. Phenobarbital

4 Emergency contraception may be required in which of the following situations, if a woman:
- a. Has intercourse 3 days after starting her POP
- b. Switches to a POP on Day 8 following a hormone-free interval and intercourse has occurred in the previous 3 days
- c. Takes a short course of fluconazole and has intercourse
- d. Takes her DSG pill 4 hours late and has intercourse

5 In which of these situations are additional precautions required when switching to a POP?
- a. When switching from a levonorgestrel intrauterine system
- b. When switching from another POP
- c. When switching from the implant within its licensed duration
- d. When switching from the injectable 13 weeks after the last injection

6 Following a dose of levonorgestrel 1.5mg for a missed POP, additional precautions are advised for:
- a. 0 days
- b. 2 days
- c. 7 days
- d. 9 days

7 In relation to the management of persistent bleeding whilst using the POP, which of the following statements best reflects the available evidence?
- a. Changing the type of progestogen will alleviate persistent bleeding
- b. Increasing the dose of progestogen will alleviate persistent bleeding
- c. There is little evidence to support routine use of any tested intervention long term
- d. Using 5 mg norethisterone daily will alleviate persistent bleeding

8 A woman presents requesting to stop her POP. She is aged 52 years and has been amenorrhoeic for 13 months. What is the best course of management?

a. Advise her she can stop immediately as she has been amenorrhoeic for over 1 year
b. Advise her she needs to continue for at least another 3 years before stopping
c. Offer to test her follicle-stimulating hormone (FSH) level and if it is ≥30 IU/l , advise she can stop after a further year
d. Offer to test her FSH level and if it is ≥30 IU/l , advise she can stop immediately

9 According to the *UK Medical Eligibility Criteria for Contraceptive Use*, which of these conditions might restrict use of the POP?

a. Cardiovascular disease
b. Current breast cancer
c. Depressive disorder
d. Migraine with aura

10 A missed DSG pill (all brands) is one that is:

a. 4 hours late
b. More than 12 hours late
c. Taken 24 hours after the last pill was taken
d. Taken 36 hours after the last pill was taken

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

Auditable Outcomes for Progestogen-only Pills

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

Auditable Outcomes

1 Women should be counselled how to take the progestogen-only pill (POP) correctly and what to do if they miss a pill. This should be recorded in their patient record. [Auditable standard 97%]

2 Counselling about the side effect of bleeding problems with POP should be documented in the patient record. [Auditable standard 97%]

3 There should be recorded counselling about risk of failure and that if a traditional POP fails there is a 1 in 10 risk of ectopic pregnancy. [Auditable standard 97%]

COMMENTS AND FEEDBACK ON PUBLISHED GUIDANCE

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

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

www.fsrh.org