FSRH clinical guidance; Problematic Bleeding with Hormonal Contraception CEU July 2015

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Expected Bleeding Patterns

Table 1 Expected bleeding patterns after commencing hormonal contraception and in the longer term

Contraceptive method	Bleeding patterns in women in the first 3 months	Bleeding patterns in women in the longer term
Combined hormonal contraception (pill, patch or ring)	Up to 20% of COC users have irregular bleeding	Irregular bleeding usually settles[8] No significant differences in bleeding between pill and patch use[9,10] The combined vaginal ring may afford better cycle control (less unscheduled bleeding) when compared to the pill[9] Users of estradiol COC have reported shorter, lighter bleeds and a higher rate of absent withdrawal bleeds than women using an EE-containing COC[11]
Progestogen-only pill	Bleeding is unpredictable With traditional POPs, one-third of women have a change in bleeding[12] A comparative study of DSG LNG POP reported that frequent bleeding, prolonged bleeding and infrequent bleeding were more common in DSG users than LNG users in the first reference period of 90 days[13]	Bleeding may not settle with time Traditional POP users can be advised that frequent and irregular bleeding are common, while prolonged bleeding and amenorrhoea are less likely[14] As a guide, women considering DSG-only POP can be advised that after 12 months of use, over a 3-month period approximately:[13,14] ● 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) ● 2 in 10 women will experience bleeding/spotting episodes lasting for more than 14 days (prolonged bleeding)

Expected Bleeding Pattern

Progestogen-only injectable (IM and SC)	Bleeding disturbances (spotting, light, heavy or prolonged bleeding) are common.[15-18] Around 1 in 10 women may be amenorrhoeic in the first 3 months of use[16]	Rates of amenorrhoea increase with duration of use and are similar for IM and SC DMPA. Around 50% or more are amenorrhoeic at 12 months[16,18,19]
Progestogen-only implant	Bleeding disturbances are common. The bleeding pattern in the first 3 months is broadly predictive of future bleeding patterns for many women[20,21]	As a guide, around: ● 2 in 10 women are amenorrhoeic ● 3 in 10 women have infrequent bleeding ● Fewer than 1 in 10 women have frequent bleeding ● 2 in 10 women have prolonged bleeding[20,21] In 75% of reference periods bleeding-spotting days are fewer than or comparable to those observed during the natural cycle, but they occur at unpredictable intervals[20]
Levonorgestrel-releasing intrauterine system (LNG-IUS) 52 mg (Mirena®)	Frequent bleeding/spotting is common in the first few months after insertion[22]	There is a decrease over time in the number of bleeding and spotting days with all doses of LNG-IUS[22] A 90% reduction in menstrual blood loss has been demonstrated over 12 months of 52 mg LNG-IUS use[23] At 1 year, infrequent bleeding is usual with the LNG-IUS and some women will be amenorrhoeic[24]. 24% of 52 mg LNG-IUS users are amenorrhoeic at 3 years[22]
LNG-IUS 13.5 mg (Jaydess®)	Frequent bleeding/spotting is common in the first few months after insertion[22]	There is a decrease over time in the number of bleeding and spotting days with all doses of LNG-IUS[22] Users of the 13.5 mg LNG-IUS report more spotting days than bleeding days over the duration of licensed use[22] Fewer women (13% at 3 years) will experience amenorrhoea with this dose of LNG-IUS compared to the 52 mg LNG-IUS[22]

The health professional making an assessment of women using hormonal contraception with problematic bleeding should:

Take a clinical history
Exclude sexually transmitted infections (STIs)
Check cervical screening history
Consider the need for a pregnancy test
Exclude underlying pathology.

History

Box 2 Points to cover in the clinical history from a woman using hormonal contraception who presents with problematic bleeding

Clinical history taking should include an assessment of a woman's:

- Own concerns
- Current method of contraception and duration of use[a]
- Compliance with the current contraceptive method[b]
- Use of any medications (including over-the-counter preparations) which may interact with the contraceptive method
- Illness/condition that may affect absorption of orally administered hormones
- Cervical screening history[c]
- Risk of sexually transmitted infections (i.e. those aged <25 years, or at any age with a new partner, or more than one partner in the last year)
- Bleeding pattern before starting hormonal contraception, since starting and currently
- Other symptoms suggestive of an underlying cause (e.g. abdominal or pelvic pain, postcoital bleeding, dyspareunia, heavy menstrual bleeding)
- Possibility of pregnancy

[a]Progestogen-only methods are more likely to result in problematic bleeding than combined hormonal methods.
[b]For example, missed pills.
[c]A woman presenting with abnormal bleeding who is participating in a National Cervical Screening Programme does not require a cervical screen unless one is due.

STI

A single vaginal swab can be sent for combined *C. trachomatis* and *Neisseria gonorrhoea* testing by nucleic acid amplification testing.

Vaginal swabs can be self-taken if preferred.

Urine testing is no longer recommended for STI screening in women.

Cervical screening
A cervical screening test is not a diagnostic test for cancer. Can be taken if it is due or overdue. No evidence was identified in the scientific literature to support cervical screening if not due.

Pregnancy Test
A pregnancy test should be undertaken
no evidence which suggested that problematic bleeding in a woman who has been using hormonal methods consistently and correctly is associated with an increased risk of pregnancy.

Clinical Examination

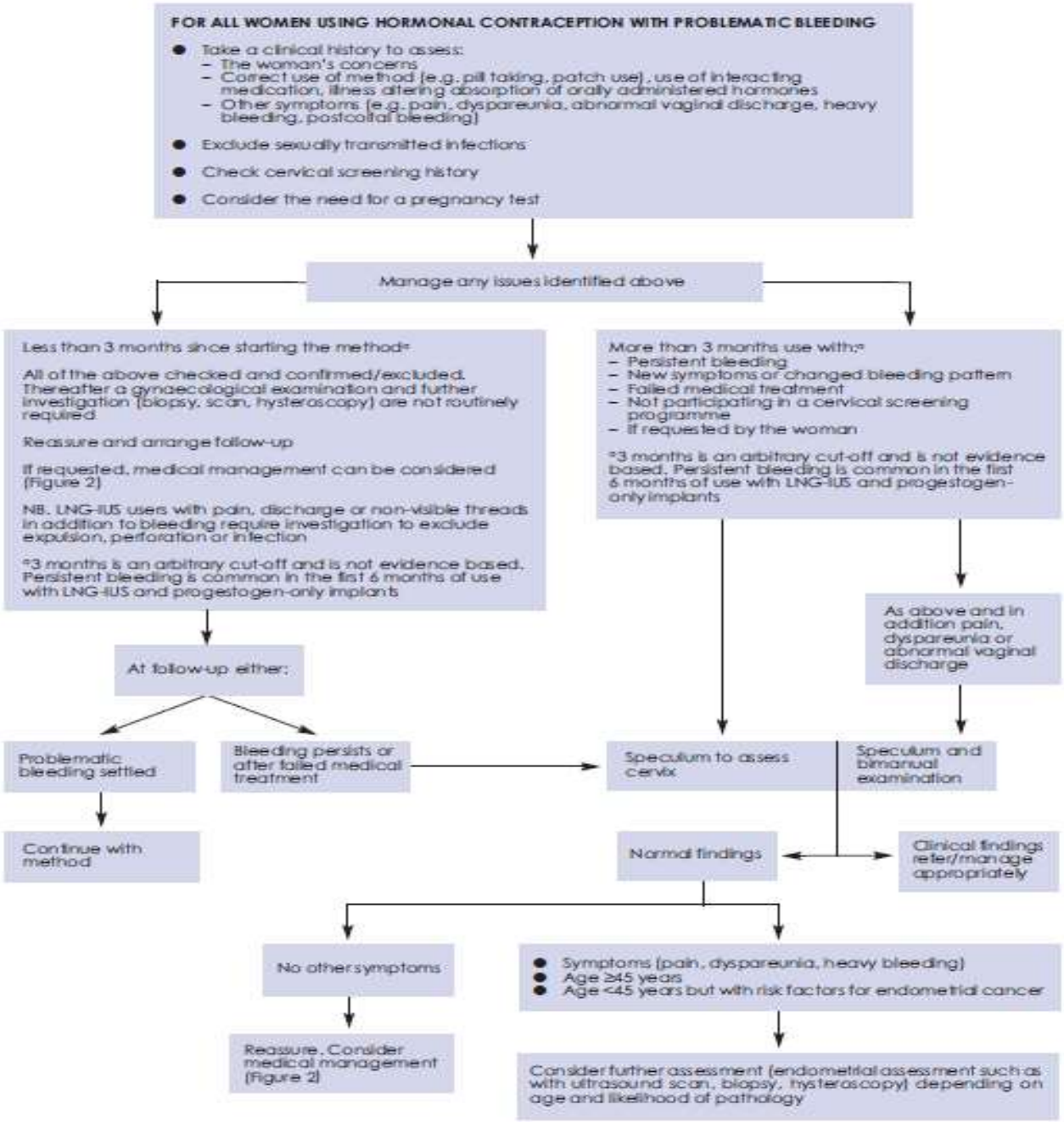
- may not be required if no risk factors for STIs,
- no symptoms suggestive of underlying causes, up to date with smears and have had no more than 3 months of problematic bleeding.

- *When is examination required?*
- speculum examination:
- For persistent bleeding beyond the first 3 months of use
- For new symptoms or a change in bleeding after at least 3 months of use
- If a woman has not participated in cervical screening
- If requested by a woman
- After a failed trial of the limited medical management available (Figure 2)
- If there are other symptoms such as pain, dyspareunia, or postcoital bleeding. NB. These
- symptoms would also warrant bimanual examination.

Guidance from NICE on the management of heavy menstrual bleeding recommends a speculum and bimanual examination if there are additional symptoms such as IMB or PCB, pelvic pain or pressure symptoms suggestive of a structural or histological abnormality. This advice is also appropriate for women with problematic bleeding using hormonal contraception

endometrial biopsy should be considered in women aged ≥45 years who present with persistent problematic bleeding or a change in bleeding pattern
Endometrial biopsy may also be indicated if a woman aged <45 years has severe or persistent symptoms and/or risk factors for endometrial cancer (e.g. obesity, type 2 diabetes mellitus or polycystic ovarian syndrome

The role of endometrial polyps, fibroids or ovarian cysts as a cause of problematic bleeding is uncertain. But if such a structural abnormality is suspected a TVUSS and/or hysteroscopy may be indicated.



Treatment Options: COCs

- It is not generally recommended that a COC be changed within the first 3 months of use as bleeding disturbances often settle in this time.
- For women using a COC the lowest dose of EE to provide good cycle control should be used. However, the dose of EE can be increased to a maximum of 35 µg to provide good cycle control.
- Cycle control probably no better with patch, maybe better with ring.
- A Cochrane Review has concluded that there is insufficient evidence to recommend the use of a biphasic or triphasic COC to improve bleeding patterns.

Treatment Options; Progesterone only methods

- No evidence was identified to suggest that bleeding patterns with one progestogen-only method will predict the likely bleeding patterns with another progestogen-only method.

POPs

- Women may experience different bleeding patterns with the traditional POP and the DSG POP and could try switching to the other if bleeding is problematic.
- Traditional POP users can be advised that frequent and irregular bleeding are common, while prolonged bleeding and amenorrhoea are less likely

Injectables

- CEU would support the use of COC as a first-line option in women using progestogen-only injectable contraception who have problematic bleeding if there are no contraindications to use of estrogen. COC can be used for 3 months while continuing with DMPA.
- Continuing beyond 3 months is a matter of individual clinical judgement as little evidence regarding this.

mefenamic acid (500 mg twice or three times daily for 5 days) or Tranexamic acid 1 g four times daily is an alternative.

There is no evidence that this approach has an effect on bleeding patterns in the longer-term.

IUS

- Bleeding is very common in the first 3 months of LNG-IUS use. It may be prolonged and may take 6 months or longer to settle. Therefore, good provision of information about expected bleeding patterns likely to be experienced is an important part of management.

- In the absence of evidence, the FSRH guidance on *Intrauterine Contraception* (2015) suggests that COC could be used for 3 months for problematic bleeding with the IUS if a woman has no contraindications.

Combined hormonal contraception users	Progestogen-only pill users	Progestogen-only implants, injectable or intrauterine system
In general, continue with the same pill for at least 3 months as bleeding may settle in this time. Use a COC with a dose of EE to provide the best cycle control. Could consider increasing the EE dose up to a maximum of 35 µg. Could try a different COC but no evidence one better than any other in terms of cycle control. No evidence changing progestogen dose or type improves cycle control but may help on an individual basis. CVR may offer better cycle control than COC. There are no data on managing bleeding associated with the patch. Continue for at least 3 months as bleeding may settle in this time.	Could try a different POP. Women may experience different bleeding patterns with the traditional POP and the DSG POP. No evidence to support the use of two POPs per day to improve bleeding. Although regimens such as estrogen supplementation or tranexamic acid may help to reduce bleeding induced by progestogen-only contraceptives in the short term, evidence does not support routine use of such regimens particularly for a long-term effect.	A first-line COC (30–35 µg EE with LNG or norethisterone) can be considered for up to 3 months continuously or in the usual cyclical regimen (unlicensed). No evidence that reducing injection interval for DMPA improves bleeding. However, DMPA may be given after a 10-week interval. To reduce the duration of bleeding episodes in DMPA users, mefenamic acid 500 mg twice (or as licensed use up to three times) daily or tranexamic acid 1 g four times daily for 5 days may be effective in the short term, but confers no long-term benefit.

All sexually active women presenting with problematic bleeding when using hormonal contraceptives
should be:

a. Assessed for sexually transmitted infections (STIs)

b. Given a speculum and bimanual examination

c. Advised to change their method

d. Offered cervical screening

A 25-year-old woman presents, 2 months after starting her 20 µg combined oral contraceptive pill (COC),
complaining of spotting. She wants to know if she should try another method. She has no change in
sexual history. What is the most single most appropriate management in the first instance?

a. Advise she continue with her current pill as it will settle down
b. Advise that 50% of users experience irregular bleeding and suggest stopping
c. Suggest waiting a further month and then consider a 30 µg COC
d. Switch her to another 20 µg COC with a different progestogen immediately

A 25-year-old woman who has been using the progestogen-only implant presents complaining of irregular bleeding since starting 7 months ago and would like treatment or for it to be removed. She has no significant medical history. After consideration and exclusion of other factors, what is the single most appropriate treatment to offer her?

a. COC

b. Doxycline

c. Mefenamic acid

d. Mifepristone and ethinylestradiol

A 25-year-old woman who has been using the progestogen-only injectable presents complaining of frequent bleeding since her second injection 6 weeks ago. She experiences migraine with aura. After consideration and exclusion of other factors, what is the single most appropriate treatment to offer her in the first instance?

a. A COC used cyclically or continuously for 3 months

b. Another injection of depot medroxyprogesterone acetate

c. Mefenamic acid

d. The desogestrel (DSG) progestogen-only pill (POP) once daily

A 34-year-old woman who has been using the POP presents complaining of erratic bleeding. She has been using her levonorgestrel (LNG) pill for 4 months. She is not happy and wants to know if there is any solution. She has already tried a norethisterone pill. After consideration and exclusion of other factors, what is the single most appropriate advice to offer her?

a. Advise she can try the DSG POP to see if the pattern is more acceptable

b. Advise that her bleeding will settle by 6 months of use

c. Advise that her bleeding pattern is likely to be like this with all progestogen-only methods

d. Use a COC in addition to the POP for 3 months

A 51-year-old woman who has been using the POP for the past 10 years with regular bleeds presents complaining that these are becoming erratic and more frequent. She has had no change in partner and has not missed any pills. What is the single most appropriate management of this woman?

a. Advise she is likely menopausal and that contraception can be stopped

b. Advise she should take two POP a day to regulate her bleeding

c. Examine the patient and exclude pregnancy and pathology before changing her contraception

d. Switch her onto a combined hormonal contraceptive to regulate her bleeding

An 18-year-old woman presents complaining of irregular bleeding with the progestogen-only implant. She has had the implant for 8 months. She indicates that her bleeding has become frequent in the last 6 weeks. She has a new partner of 2 months and takes no additional medication. What is the single most appropriate test to offer this woman in the first instance?

a. Cervical screening
b. Urine test for STIs
c. Pregnancy test
d. Self-taken lower vaginal swab

A 26-year-old woman presents with persistent bleeding since starting the progestogen-only implant 4 months ago. She is up to date with cervical screening and has not been sexually active in the last 4 weeks because of the bleeding and associated pelvic pain. What is the most appropriate course of action in the first instance?

a. Advise bleeding can remain irregular and suggest changing method

b. Advise bleeding usually settles with time, offer COC

c. Advise needs a speculum and bimanual examination

d. Advise needs a speculum examination

A 37-year-old woman who has had the levonorgestrel-releasing intrauterine system (LNG-IUS) for 9 months complains about the irregular spotting she has always experienced with this method. She wishes to control the bleeding while on holiday. She has no contraindications to hormonal contraceptives. What is the single most appropriate treatment to offer in the first instance to control her bleeding pattern?

a. A 20 µg COC
b. A 30–35 µg COC
c. A DSG POP
d. A LNG POP

A 40-year-old woman presents complaining about her bleeding patterns since having the LNG-IUS inserted 4 months ago. She says she was misled and that she had been told she would have no bleeding. What is the single most appropriate advice to give her regarding bleeding patterns associated with the LNG-IUS?

a. Irregular, light or heavy bleeding is common in the first 6 months. By 3 years, one quarter of women will have no bleeding

b. Irregular, light or heavy bleeding is common in the first 6 months. Thereafter women have regular monthly bleeds

c. Most women have no bleeding after 3 months of use. However, a small number of women will continue to bleed until 6 months

d. Most women have no bleeding after 6 months of use. However, a small number of women will continue to bleed until 12 months

Answers to questions.

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