

Faculty of Sexual & Reproductive Healthcare Clinical Guidance



Contraception for Women Aged Over 40 Years

Clinical Effectiveness Unit

July 2010

ABBREVIATIONS USED

BASHH	British Association for Sexual Health and HIV
BMD	bone mineral density
BMI	body mass index
CEU	Clinical Effectiveness Unit
CHC	combined hormonal contraception
COC	combined oral contraception
Cu-IUD	copper-bearing intrauterine device
CVR	combined vaginal ring
DMPA	depot medroxyprogesterone acetate
EC	emergency contraception
EE	ethinylestradiol
FSH	follicle-stimulating hormone
FSRH	Faculty of Sexual and Reproductive Healthcare
HIV	human immunodeficiency virus
HRT	hormone replacement therapy
LARC	long-acting reversible contraception
LH	luteinising hormone
LNG-IUS	levonorgestrel-releasing intrauterine system
MI	myocardial infarction
NET-EN	norethisterone enantate
NICE	National Institute for Health and Clinical Excellence
POC	progestogen-only contraception
POEC	progestogen-only emergency contraception
POP	progestogen-only pill
RCOG	Royal College of Obstetricians and Gynaecologists
STI	sexually transmitted infection
UKMEC	<i>UK Medical Eligibility for Contraceptive Use</i>
UPSI	unprotected sexual intercourse
VTE	venous thromboembolism

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 multidisciplinary group

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

First published in 2010

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SUMMARY OF KEY RECOMMENDATIONS

Sexual and Reproductive Health Issues

- B** Women should be informed that although a natural decline in fertility occurs from their mid-30s, effective contraception is required to prevent an unintended pregnancy.
- B** Women should be informed that the risks of chromosomal abnormalities, miscarriage, pregnancy complications and of maternal morbidity and mortality increase for women aged over 40 years.

Medical Eligibility Criteria

- C** Women aged over 40 years can be advised that no contraceptive method is contraindicated by age alone.
- ✓** When prescribing contraception for women aged over 40 years, health professionals should be guided by the *UK Medical Eligibility Criteria for Contraceptive Use (UKMEC)*. Clinical judgement is also required, particularly when prescribing for women with multiple medical and social factors.

Long-acting Reversible Contraception

- C** Women and their partners should be advised that very long-acting reversible contraception can be as effective as sterilisation.
- C** Women should be advised that return of fertility can be delayed for up to 1 year after discontinuation of progestogen-only injectable contraception.

Combined Hormonal Contraception

- B** Women can be advised that combined hormonal contraception (CHC) use in the perimenopause may help to maintain bone mineral density.
- C** Use of CHC may help to reduce menstrual pain and bleeding.
- C** Women can be advised that in clinical practice CHC may reduce menopausal symptoms.
- ✓** Women experiencing menopausal symptoms while using CHC may wish to try an extended regimen.
- B** CHC use provides a protective effect against ovarian and endometrial cancer that continues for 15 years or more after stopping CHC.
- B** Women can be advised that there may be a reduction in the incidence of benign breast disease with CHC use.
- B** Women can be advised that there is a reduction in the risk of colorectal cancer with CHC use.
- B** Women can be advised that there may be a small additional risk of breast cancer with CHC use, which reduces to no risk 10 years after stopping CHC use.
- B** Women who are aged 35 years or over and smoke should be advised that the risks of using CHC usually outweigh the benefits.
- B** Clinicians should be aware that there may be a very small increased risk of ischaemic stroke with CHC use.

SUMMARY OF KEY RECOMMENDATIONS

Combined Hormonal Contraception (continued)

- C** Women with cardiovascular disease, stroke or migraine with aura should be advised against the use of CHC.
- ✓** Practitioners who are prescribing CHC to women aged over 40 years may wish to consider a pill with <math><30\ \mu\text{g}</math> ethinylestradiol as a suitable first choice.
- B** Hypertension may increase the risk of stroke and myocardial infarction (MI) in those using COC.
- C** Blood pressure should be checked before and at least 6 months after initiating a woman aged over 40 years on CHC and monitored at least annually thereafter.

Progestogen-only Contraception

- B** Women can be informed that there is no conclusive evidence of a link between progestogen-only methods and breast cancer.
- C** Progestogen-only methods may help to alleviate dysmenorrhoea.
- ✓** Women should be advised that altered bleeding patterns are common with use of progestogen-only contraception (POC).
- B** Women should be advised that the levonorgestrel-releasing intrauterine system (LNG-IUS) can be used for the treatment of heavy menstrual bleeding once pathology has been excluded.
- B** Women should be informed that the progestogen-only injectable is associated with a small loss of BMD, which usually recovers after discontinuation.
- ✓** Women who wish to continue using depot medroxyprogesterone acetate (DMPA) should be reviewed every 2 years to assess the benefits and potential risks. Users of DMPA should be supported in their choice of whether or not to continue using DMPA up to a maximum recommended age of 50 years.
- B** Women can be advised that although the data are limited, POC does not appear to increase the risk of stroke or MI, and there is little or no increase in venous thromboembolism risk.
- C** Caution is required when prescribing DMPA to women with cardiovascular risk factors due to the effects of progestogens on lipids.

Non-hormonal Methods of Contraception

- C** Women should be informed that spotting, heavier or prolonged bleeding and pain are common in the first 3–6 months of copper-bearing intrauterine device (Cu-IUD) use.
- C** Men and women can be advised that when used consistently and correctly, male condoms and female condoms are, respectively, up to 98% and 95% effective at preventing pregnancy.
- C** Women can be advised that when used consistently and correctly with spermicide, diaphragm and caps are, respectively, estimated to be between 92% and 96% effective at preventing pregnancy.
- B** When using lubricant with latex condoms a non-oil-based preparation is recommended.

SUMMARY OF KEY RECOMMENDATIONS

Emergency Contraception and Sexually Transmitted Infections

- ✓ Women should be made aware of the different types of emergency contraception available including when they can be used and how they can be accessed.
- C Men and women should be advised that the use of condoms can reduce the risk of acquiring and transmitting sexually transmitted infections.

Stopping Contraception

- ✓ Women using non-hormonal methods of contraception can be advised to stop contraception after 1 year of amenorrhoea if aged over 50 years, 2 years if the woman is aged under 50 years.
- C After counselling (about declining fertility, risks associated with insertion, and contraceptive efficacy), women who have a Cu-IUD containing ≥ 300 mm² copper, inserted at or over the age of 40 years, can retain the device until the menopause or until contraception is no longer required.
- ✓ Women who continue to use their IUD until contraception is no longer required should be advised to return to have the device removed.
- ✓ Women using exogenous hormones should be advised that amenorrhoea is not a reliable indicator of ovarian failure.
- ✓ In women using contraceptive hormones, follicle-stimulating hormone (FSH) levels may be used to help diagnose the menopause, but should be restricted to women over the age of 50 years and to those using progestogen-only methods.
- ✓ FSH is not a reliable indicator of ovarian failure in women using combined hormones, even if measured during the hormone-free interval.
- ✓ Women over the age of 50 years who are amenorrhoeic and wish to stop POC can have their FSH levels checked. If the level is ≥ 30 IU/L the FSH should be repeated after 6 weeks. If the second FSH level is ≥ 30 IU/L contraception can be stopped after 1 year.
- ✓ Women who have their LNG-IUS inserted for contraception at the age of 45 years or over can use the device for 7 years (off licence) or if amenorrhoeic until the menopause, after which the device should be removed.

Hormone Replacement Therapy and Contraception

- C Women using hormone replacement therapy (HRT) should be advised not to rely on this as contraception.
- ✓ Women can be advised that a progestogen-only pill can be used with HRT to provide effective contraception but the HRT must include progestogen in addition to estrogen.
- A Women using estrogen replacement therapy may use the LNG-IUS to provide endometrial protection. When used as the progestogen component of HRT, the LNG-IUS should be changed no later than 5 years after insertion (the licence states 4 years), irrespective of age at insertion.



Faculty of Sexual and 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 (July 2010) Contraception for Women Aged Over 40 Years

(Update due by July 2015)

1 Background

Contraceptive choice for women aged over 40 years may be influenced by many factors: frequency of intercourse, natural decline in fertility, sexual problems, the wish for non-contraceptive benefits, menstrual dysfunction and concurrent medical conditions.

This guidance provides evidence-based recommendations to guide clinicians, women and couples in making decisions about contraceptive choices, including stopping contraception. It is beyond the scope of this guidance to make recommendations on management of the perimenopause and use of hormone replacement therapy (HRT), except in the context of contraceptive use.

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

2 Sexual and Reproductive Health in Women Aged Over 40 Years

2.1 Fertility

As age increases, fertility declines for women and to a much lesser degree for men.¹ The natural decline in fertility is related to many factors but the quality and quantity of oocytes is important. Although there is a decline in fertility from the mid-30s onwards, sexually active women require contraception if they do not wish to become pregnant.

B Women should be informed that although a natural decline in fertility occurs from their mid-30s, effective contraception is required to prevent an unintended pregnancy.

2.2 Pregnancy

There is an increasing trend within the UK for women to have children later in life.^{2,3} The live birth rate for all age groups in England and Wales has increased since 2007, with the greatest increase seen in women aged 40 years and over (live birth rate was 12.0/1000 women in 2007 and 12.6/1000 in 2008), with the number of live births to mothers aged 40 and over nearly doubling from 13 555 in 1998 to 26 419 in 2008.^{2,4} Women in their 40s also experience unintended pregnancies and some opt for an abortion. In Scotland in 2008, the rate of

abortion in women aged over 40 was 2.2 per 1000;⁵ in England and Wales amongst those aged 40–44 years it was 4 per 1000 ($n = 7663$), which was almost equivalent to the rates for young women under the age of 16 ($n = 4113$).

Although more individuals are delaying starting a family until later in life, later childbirth is associated with worsening reproductive outcomes: more infertility and medical co-morbidity, and an increase in maternal and fetal morbidity and mortality. The maternal mortality rate in the UK is highest in the 40 years and over age group, with a rate of 29.4 per 100 000 maternities in 2003–2005 compared with a rate of 14.0 per 100 000 for all ages.⁶

In addition, the risk of pregnancy affected by trisomy 21 (Down syndrome) rises from 1 in 1600 in mothers aged <23 years to 1 in 40 for mothers aged 43 years.⁷ A prospective multicentre study of singleton pregnancies found that maternal age was associated with an increased risk of miscarriage, gestational diabetes, placental praevia and Caesarean section.⁸ In the same study, maternal age greater than 40 years was associated with placental abruption, preterm delivery, low birth weight and increased perinatal mortality.⁸

The evidence for increased risk of non-chromosomal congenital abnormality in the older maternal age group is mixed. However, a recent review of data from the EUROCAT congenital anomaly register is reassuring. Increasing age alone does not appear to be a risk factor for non-chromosomal abnormality but reproductive, social, ethnic, environmental and lifestyle factors together with maternal age may have an effect.⁹

B Women should be informed that the risks of chromosomal abnormalities, miscarriage, pregnancy complications and of maternal morbidity and mortality increase for women aged over 40 years.

2.3 Change of partner

The average age for men and women to get divorced in England and Wales is 43.7 years and 41.2 years, respectively. Many individuals in their 40s may therefore enter new relationships after coming out of long-term monogamous relationships. Individuals in this situation may need additional support to review their contraceptive options as well as being reminded about the need to consider sexual health screening and use of condoms for the prevention of sexually transmitted infections (STIs).

2.4 Transition to menopause

The menopause is a retrospective diagnosis confirmed after 12 months of amenorrhoea. For most women, the 40s and 50s are a time when they move from normal ovulatory menstrual cycles to the cessation of ovulation and menstruation. During this time, intermittent ovulation and anovulation occur; there may be a rise in follicle-stimulating hormone (FSH) levels and women will experience shortening and/or lengthening of their menstrual cycle.

3 Contraception – Medical Eligibility Criteria

There are a wide range of contraceptive methods available, none of which are contraindicated based on age alone (Table 1).¹⁰ However, as individuals get older, age may become a more significant risk factor for developing incidental medical conditions that could impact on contraceptive choice.

A clinical history (medical, sexual, reproductive and social) will enable practitioners to assess the risk of STIs, sexual function and medical and social factors that may influence contraceptive use such as frequency of intercourse, change of partner, plans to have children, menstrual dysfunction and lifestyle factors such as smoking.

The *UK Medical Eligibility Criteria for Contraceptive Use* (UKMEC)¹⁰ provides evidence-based recommendations on the use of contraceptive methods in the presence of different medical and social factors thus ensuring women can select the most appropriate method of contraception for them (Table 2). UKMEC should be referred to when assessing a person's eligibility for a particular method. UKMEC does not, however, take account of multiple conditions, and therefore assessing a person's eligibility in the presence of multiple medical and social factors will require clinical judgement and balancing of the risks and benefits. For

Table 1 UK Medical Eligibility Criteria for Contraceptive Use (UKMEC) categories based on age¹⁰

Contraceptive method	Age range (years)	UKMEC category
Combined hormonal contraception (CHC) (combined oral contraception, transdermal patch, combined vaginal ring)	≥40	2
Progestogen-only pill (POP)	≥40	1
Progestogen-only implant	≥40	1
Depot medroxyprogesterone acetate (DMPA)	18–45	1
	>45	2
Norethisterone enantate (NET-EN)	18–45	1
	>45	2
Copper-bearing intrauterine device (Cu-IUD)	≥40	1
Levonorgestrel-releasing intrauterine system (LNG-IUS)	≥40	1
Barrier methods	≥40	1
Emergency contraception	≥40	1

Table 2 Definition of UK Medical Eligibility Criteria for Contraceptive Use (UKMEC) categories¹⁰

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

detailed information about the health risks and benefits associated with individual methods, practitioners should refer to the appropriate method-specific guidance produced by the CEU.

- C** Women aged over 40 years can be advised that no contraceptive method is contraindicated by age alone.
- ✓** When prescribing contraception for women aged over 40 years, health professionals should be guided by UKMEC. Clinical judgement is also required, particularly when prescribing for women with multiple medical and social factors.

4 Contraception Used by Women Aged Over 40 Years

In 2008/2009, data from the Office for National Statistics¹¹ indicated that of women aged 40–49 years who were surveyed and using at least one method of contraception, the four most commonly reported methods were sterilisation (either own or partner), the pill, male condoms and intrauterine methods.

5 Long-acting Reversible Methods of Contraception

The National Institute for Health and Clinical Excellence (NICE)¹² defines long-acting reversible methods of contraception (LARC) [also referred to as 'long-lasting reliable contraception'] as those methods that require administering less than once per cycle or month (i.e. the progestogen-only injection and implant, and intrauterine methods). Their typical failure rates are lower than shorter-acting methods such as the contraceptive pill¹³ and are also more cost effective at 1 year of use.¹² The very long-acting methods such as the progestogen-only implant and the intrauterine methods have failure rates comparable to female sterilisation and thus offer a reliable, reversible alternative for women who do not want to be sterilised or for whom sterilisation is not advised.

LARC methods such as the progestogen-only implant and injectable are used to a lesser extent amongst those aged over 40 years than younger women, although women over 40 are more likely to report use of intrauterine methods.¹¹ Faculty of Sexual and Reproductive Healthcare (FSRH) CEU guidance indicates that there is no delay in return of fertility with

LARCs,^{14–16} other than with the progestogen-only injectable.¹⁷ Return of fertility can be delayed for up to 1 year after discontinuation of the progestogen-only injectable,¹⁷ which may be unacceptable to those women who still wish to conceive, given the rapid decline in background fertility in this age group.

C Women and their partners should be advised that very long-acting reversible contraception can be as effective as sterilisation.

C Women should be advised that return of fertility can be delayed for up to 1 year after discontinuation of progestogen-only injectable contraception.

6 Combined Hormonal Contraception

There are currently three forms of combined hormonal contraception (CHC) available in the UK: the combined oral contraceptive pill (COC), the combined transdermal patch, and the combined vaginal ring (CVR).

Most of the available evidence regarding health benefits and risks is for COC. However, UKMEC¹⁰ assumes that the risks are similar and therefore guidelines apply to all three methods. Where there is evidence available for the CVR or transdermal patch this will be highlighted.

A new type of COC that contains estradiol valerate as opposed to ethinylestradiol (EE) is available.¹⁸ The concept of a 'natural' estrogen pill may appeal to some women but there is currently no evidence of clinically significant benefits over pills containing synthetic estrogen. Until further data emerge, the indications and contraindications to the use of estradiol valerate-containing pills must be assumed to be the same as for other combined hormonal contraceptives.¹⁹

6.1 Health benefits and risks associated with CHC use

6.1.1 Bone health

It is not possible to say, from the evidence that currently exists, whether use of steroidal contraception influences fracture risk. Studies have often failed to include women from older age groups and do not generally include the low-dose formulation COCs or other CHC methods such as the CVR and transdermal patch.

A Cochrane review²⁰ that examined findings for all women collectively has recently stated that CHC does not appear to affect bone health. Other systematic reviews^{21,22} suggest that there might be a positive effect of CHC use on bone mineral density (BMD) in perimenopausal women, but it is not clear how changes in BMD before the menopause will affect fracture risk following the menopause.

B Women can be advised that CHC use in the perimenopause may help to maintain BMD.

6.1.2 Dysmenorrhoea and cycle control

Whilst Cochrane reviews have stated that there is limited evidence from randomised controlled trials to suggest that COC use can improve primary dysmenorrhoea or reduce menstrual blood loss compared with other treatment,^{23,24} data from observational studies suggest that COC use does have a beneficial effect.^{25–28} NICE guidance indicates that COC can be used for the treatment of heavy menstrual bleeding²⁹ and a placebo-controlled, double-blind, randomised trial has also suggested that low-dose COC could possibly be used to treat pain associated with endometriosis.³⁰

For perimenopausal women over the age of 40 years, CHC methods can provide cycle regularity. Unscheduled bleeding is more common with a 20 µg compared with a 30 µg EE pill.^{31,32} The CVR has been shown to provide good cycle control;³³ and following the initial two cycles, breakthrough bleeding with the transdermal patch is no more common than when using COC.³⁴

C Use of CHC may help to reduce menstrual pain and bleeding.

6.1.3 Menopausal symptoms

There is a small amount of data that suggests CHC may help to improve some of the symptoms associated with menopause.^{35,36} There may be some theoretical benefit from an

extended regimen such as taking three pill packets continuously (tricycling), although such use is outside the product licence.

C Women can be advised that in clinical practice CHC may reduce menopausal symptoms.

✓ Women experiencing menopausal symptoms while using CHC may wish to try an extended regimen.

6.1.4 Ovarian and endometrial cancer

The risk of developing or dying from ovarian or endometrial cancer is reduced with use of COC.^{37–50} The risk reduces with increasing duration of COC use; and whilst the protective effect reduces over time, it may last for 15 years or more after use.^{38,42,44,47,50} A case control study has suggested that this protective effect is more strongly associated with premenopausal than postmenopausal disease.⁵¹ Data also suggest a reduction in the incidence of ovarian cysts and benign ovarian tumours amongst women using COCs.^{52–55}

B CHC use provides a protective effect against ovarian and endometrial cancer that continues for 15 years or more after stopping CHC.

6.1.5 Benign breast disease

A decreased risk of benign breast disease and decreased risk of hospitalisation for fibroadenoma and chronic cystic disease have been noted with use of COC,^{56–58} although in all studies confounding and bias cannot be excluded.

B Women can be advised that there may be a reduction in the incidence of benign breast disease with CHC use.

6.1.6 Colorectal cancer

Studies on the risk of colorectal cancer with COC use are reassuring, with epidemiological data consistently indicating a decreased risk with use of COCs.^{59–65} The protective effect appears to be associated with current or recent use and there is currently no evidence of a duration-risk relation.

B Women can be advised that there may be a reduction in the risk of colorectal cancer with CHC use.

6.1.7 Breast cancer

The annual risk of breast cancer increases with increasing age irrespective of hormone use. Overall there is no clear evidence as to the risk of breast cancer with use of CHC. A collaborative re-analysis of early case-control studies showed an increased risk of breast cancer while using COCs,⁶⁶ with a subsequent meta-analysis showing an increased risk of premenopausal breast cancer.⁶⁷ However, other well-conducted observational studies have found no increased risk or a very small increased incidence of breast cancer or breast cancer *in situ*.^{37,41,68–70} Any increased risk associated with use has been shown to decrease with time since stopping, reducing to no significant risk 10 years after cessation.⁶⁶ CHC methods represent an unacceptable health risk for women with current breast cancer (UKMEC 4).¹⁰

A systematic review has concluded that, based on recent evidence, women who have a family history of breast cancer do not increase their risk of breast cancer by using COC.⁷¹ A family history of breast cancer is a condition for which the use of CHC methods is unrestricted (UKMEC 1).¹⁰

The evidence is mixed on whether women who are carriers of BRCA1 or BRCA2 mutations have an increased risk of breast cancer with COC use.^{72–78} Current guidance is that having a genetic mutation associated with breast cancer is a condition for which the theoretical or proven risks of using CHC generally outweigh the benefits. In these circumstances, provision 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 (UKMEC 3).¹⁰

B Women can be advised that there may be a small additional risk of breast cancer with CHC use, which reduces to no risk 10 years after stopping CHC.

6.1.8 Cervical cancer

There is a small increased risk of cervical cancer (invasive and *in situ*)^{37,41,79–82} with increasing duration of COC use. Long-term users can be reassured that the benefits of use generally outweigh the risks. The risk of invasive cancer has been shown to decline after use ceases and by 10 years or more return to that of never users.⁸⁰ Women should be informed about the link between human papillomavirus (HPV) and cervical cancer, and be advised that the risk of cervical cancer can be reduced through condom use and regular cervical screening.

6.1.9 Cardiovascular and cerebrovascular disease

Amongst women of reproductive age, morbidity and mortality from venous thromboembolism (VTE), myocardial infarction (MI) or stroke are rare but the risk increases with increasing age. Whilst use of CHC methods may be associated with small increases in cardiovascular and cerebrovascular risk, overall the absolute risks are still small and current evidence suggests that women who have used oral contraceptives have no higher risk of mortality than those who have never used them.⁸³ Table 3 outlines the UKMEC categories for use of CHC with cardiovascular and cerebrovascular disease.

(i) VTE

The relative risk of VTE is increased with use of COC.^{84–88} Two recent studies have suggested that reducing the dose of estrogen from 30 µg to 20 µg may reduce the risk of VTE.^{89,90} There is continuing debate about the effects of the type of progestogen in COCs on VTE risk,^{84,86,89–96} specifically whether COCs containing desogestrel, gestodene and cyproterone are associated with a higher risk than COCs containing levonorgestrel and norethisterone.^{84,89,90} As regards the combined transdermal patch, there is uncertainty regarding the risk of VTE compared with COCs, with current evidence suggesting a similar or slightly increased risk.^{97,98} The relative risk of VTE associated with the CVR and also the estradiol-containing pill are unknown.³³ Due to the observational design of studies looking at VTE risk with CHC, bias and confounders cannot completely be excluded and therefore the precise relative risks of different combined methods remain unknown.

(ii) MI and stroke

The data are somewhat conflicting for MI and stroke. A recent population-based cohort study found that compared with never users, neither former or current users had an elevated risk of MI⁹⁹ and whilst some studies suggest that COC use may increase the risk of ischaemic stroke, others have found no association with ischaemic^{100,101} or haemorrhagic stroke.^{101,102} Risk may be influenced by factors such as smoking, hypertension and migraine with aura.

Data have previously suggested that an increased risk of MI associated with COC use was confined to smokers,^{46,103} but two subsequent meta-analyses reported a very small increase in the risk of MI with COC use in non-smokers.^{104,105} As both smoking and age are independent risk factors for cardiovascular disease, UKMEC advises greater restrictions are placed on the use of CHC methods depending on the number of cigarettes smoked and age. For women over the age of 35 years who smoke <15 cigarettes per day, use of CHC is a UKMEC 3; for those who smoke ≥15 cigarettes per day, use is a UKMEC 4.¹⁰ After smoking cessation the risk of MI associated with smoking reduces with time, and therefore for former smokers over the age of 35 years the use of CHC becomes less restrictive a year after stopping (UKMEC 2).¹⁰

Compared to hypertensive non-COC users, hypertensive individuals who use the COC have been found to be at higher risk of stroke and acute MI, but not VTE.¹⁰⁶ Even for women with adequately controlled hypertension, alternative methods are preferable to CHC (UKMEC 3).¹⁰

The risk of stroke is increased in COC users with migraine compared to COC users without migraine.^{103,107–111} A recent meta-analysis and systematic review¹¹² has indicated that the risk of stroke associated with migraine appears only to affect those individuals with migraine with aura, and that oral contraceptive use further increases the risk of ischaemic stroke.¹¹² CHC methods represent an unacceptable health risk in the presence of migraine with aura (UKMEC 4).¹⁰

Table 3 UK Medical Eligibility Criteria for Contraceptive Use (UKMEC) categories for the use of combined hormonal contraception with cardiovascular and cerebrovascular disease¹⁰

Condition	UKMEC category
Current and history of ischaemic heart disease	4
VTE	
1 Personal history of VTE	4
2 Current VTE (on anticoagulants)	4
3 Family history of VTE	
(i) First-degree relative aged <45 years	3
(ii) First-degree relative aged ≥45 years	2
Stroke (history of cerebrovascular accident including TIA)	4
Hypertension	
(a) Adequately controlled hypertension	3
(b) Consistently elevated blood pressure levels (measurements taken properly)	
(i) Systolic >140–159 mmHg or diastolic >90–94 mmHg	3
(ii) Systolic ≥160 mmHg or diastolic ≥95 mmHg	4
(c) Vascular disease	4
Multiple risk factors for cardiovascular disease (such as older age, smoking, diabetes, obesity, hypertension)	3/4

TIA, transient ischaemic attack; VTE, venous thromboembolism.

When prescribing CHC methods to women aged over 40 years, first choice of pill should be the one containing the lowest dose of EE that provides adequate cycle control.

- B** Women who are aged 35 years or over and smoke should be advised that the risks of using CHC usually outweigh the benefits.
- B** Clinicians should be aware that there may be a very small increased risk of ischaemic stroke with CHC use.
- C** Women with cardiovascular disease, stroke or migraine with aura should be advised against the use of CHC.
- Practitioners who are prescribing CHC to women aged over 40 years may wish to consider a pill with <30 µg EE as a suitable first choice.
- B** Hypertension may increase the risk of stroke and MI in those using CHC.
- C** Blood pressure should be checked before and at least 6 months after initiating a woman aged over 40 years on a CHC method and monitored at least annually thereafter.

7 Progestogen-only Contraception

There are currently four methods of progestogen-only contraception (POC) available in the UK: the progestogen-only pill (POP), injectable, implant and the levonorgestrel-releasing intrauterine system (LNG-IUS). The FSRH has produced detailed guidance on each of these methods, which should be referred to for more detailed information.^{14,15,17,113}

7.1 Health benefits and risks associated with POC

The benefits and risks associated with POC are less well studied than CHC and most of the data relate to the use of the POP and injectable methods. Studies may be liable to a degree of prescriber bias, as women who use these methods may be more likely to have underlying disease which precludes CHC use.

7.1.1 Reproductive cancers

The evidence of an association between breast cancer and progestogen-only methods is inconclusive. Of the studies examining the effects of hormonal contraception on breast cancer, only small numbers of women have used progestogen-only methods and therefore evidence is limited.¹⁵ Some studies have suggested a risk broadly similar to that of COC;⁶⁶ however, other studies have suggested no increased risk or a very small increased risk.^{37,41,68} A recent case-control study has suggested there may be an increased risk of breast cancer

associated with use of the LNG-IUS either alone [odds ratio (OR) 1.45, 95% confidence interval (CI) 1.97–1.77] or in conjunction with estrogen (OR 2.15, 95% CI 1.72–2.68) in postmenopausal women.¹¹⁴ However, this paper did not adjust for age at menopause. Overall, most evidence is reassuring with regards to progestogen-only methods and risk of breast cancer.

A study⁸⁰ that re-analysed data from 24 epidemiological studies has indicated that there is a small increase in the risk of cervical cancer associated with long duration of progestogen-only injectable contraceptives (>5 years) [relative risk (RR) 1.22, 95% CI 1.01–1.46]. The risk is smaller than that for CHC methods and the finding is based on far fewer women.

B Women can be informed that there is no conclusive evidence of a link between progestogen-only methods and breast cancer.

7.1.2 Menopausal symptoms

There are some older studies that suggest depot medroxyprogesterone acetate (DMPA) may help to alleviate vasomotor symptoms.^{115,116}

7.1.3 Dysmenorrhoea

Dysmenorrhoea and ovulatory pain that are not associated with any identifiable pathological condition may be alleviated by hormonal methods that inhibit ovulation such as the desogestrel POP, the progestogen-only implant and injectable hormonal contraceptives.^{117,118}

Whilst there is generally a lack of data from randomised controlled trials on which to draw firm conclusions about the role of progestogens in the treatment of pain associated with endometriosis,¹¹⁹ there are some studies that suggest the LNG-IUS and DMPA may have beneficial effects.^{120–125} Both DMPA and the LNG-IUS are acknowledged as possible treatments in the Royal College of Obstetricians and Gynaecologists (RCOG) guideline on the investigation and management of endometriosis.¹²⁶

C Progestogen-only methods may help to alleviate dysmenorrhoea.

7.1.4 Bleeding patterns

Abnormal bleeding is common in women using POC and is often cited as a reason for discontinuation.^{15,17,113} However, individual response varies and for some individuals progestogen-only methods may be useful in the management of heavy menstrual bleeding and irregular bleeding because of the associated amenorrhoea.

The LNG-IUS is licensed for use in the management of idiopathic menorrhagia^{14,127} and may therefore be a very useful treatment option for heavy menstrual bleeding, which is particularly common in women aged over 40 years. A Cochrane review has shown the LNG-IUS to be more effective than cyclical norethisterone but results in a smaller mean reduction in menstrual blood loss than endometrial ablation.¹²⁸ Quality of life measures are generally similar when comparing the LNG-IUS with endometrial ablation or hysterectomy, although LNG-IUS users may experience more progestogenic side effects.¹²⁸

Women considering POC should be advised regarding possible bleeding patterns, including infrequent or no bleeding. Guidelines are available for practitioners on how to manage women experiencing unscheduled bleeding whilst using hormonal contraception.¹²⁹ Guidance on the investigation of women with heavy menstrual bleeding has been produced by NICE²⁹ but is outside the remit of this guidance. Women over the age of 45 years with excessive bleeding should undergo an endometrial assessment.

✓ Women should be advised that altered bleeding patterns are common with use of POC.

B Women should be advised that the LNG-IUS can be used for the treatment of heavy menstrual bleeding once pathology has been excluded.

7.1.5 Bone health

Most of the concern regarding BMD and progestogen-only methods relates to the long-term use of the progestogen-only injectable, DMPA. It is recognised that use of DMPA does affect BMD; however, there is a suggestion that BMD may recover upon cessation of use.^{12,130} Data on fracture risk associated with DMPA use are limited.

In terms of advising women aged over 40 years, there is some relatively reassuring evidence from small studies to support use in women approaching the menopause.^{131–133} A cohort study ($n = 496$) of DMPA users aged 40–49 years reported no significant differences in BMD between users of DMPA, NET-EN, COC and non-user controls,¹³² whilst another study that compared the BMD of women aged 43–58 years who had used DMPA or an intrauterine device (IUD) until the menopause found that no significant differences were observed at 1 and 2–3 years following the menopause.¹³³ Over the age of 45 years, use of DMPA is UKMEC Category 2 (i.e. the benefits usually outweigh the theoretical or proven risks). There is no upper age limit specified in UKMEC. The CEU supports the use of DMPA until the age of 50 years, providing clinicians adhere to utilising the following advice issued by the Department of Health Medicines and Healthcare products Regulatory Agency (MHRA):¹³⁴

- A re-evaluation of the risks and benefits of treatment for all women should be carried out every 2 years in those who wish to continue use.
- For women with significant lifestyle and/or medical risk factors for osteoporosis, other methods of contraception should be considered.

There is currently no evidence of a clinically significant effect of other progestogen-only methods on BMD.

B Women should be informed that the progestogen-only injectable is associated with a small loss of BMD, which usually recovers after discontinuation.

✓ Women who wish to continue using DMPA should be reviewed every 2 years to assess the benefits and risks. Users of DMPA should be supported in their choice of whether or not to continue using DMPA up to a maximum recommended age of 50 years.

7.1.6 Cardiovascular and cerebrovascular disease

The limited data available from observational studies suggest that use of POC is not associated with an increased risk of stroke¹³⁵ or MI¹³⁶ and that there is little or no increase in

Table 4 UK Medical Eligibility Criteria for Contraceptive Use (UKMEC) categories for the use of progestogen-only methods with cardiovascular and cerebrovascular disease¹⁰

Condition	UKMEC categories			
	POP	Injectable	Implant	LNG-IUS
Current and history of ischaemic heart disease	2 Initiation 3 Continuation	3	2 Initiation 3 Continuation	2 Initiation 3 Continuation
VTE ^a				
Personal history of VTE	2	2	2	2
Current VTE (on anticoagulants)	2	2	2	2
Family history of VTE				
(i) First-degree relative aged <45 years	1	1	1	1
(ii) First-degree relative aged ≥45 years	1	1	1	1
Stroke (history of cerebrovascular accident including TIA)	2 Initiation 3 Continuation	3	2 Initiation 3 Continuation	2 Initiation 3 Continuation
Hypertension				
(a) Adequately controlled hypertension	1	2	1	1
(b) Consistently elevated blood pressure levels (measurements taken properly)				
(i) Systolic >140–159 mmHg or diastolic >90–94 mmHg	1	1	1	1
(ii) Systolic ≥160 mmHg or diastolic ≥95 mmHg	1	2	1	1
(c) Vascular disease	2	3	2	2
Multiple risk factors for cardiovascular disease (such as older age, smoking, diabetes, obesity, hypertension)	2	3	2	2

^aSee UKMEC for categories relating to surgery and immobilisation. LNG-IUS, levonorgestrel-releasing intrauterine system; POP, progestogen-only pill; TIA, transient ischaemic attack; VTE, venous thromboembolism.

the risk of VTE.⁸⁹ However, because of the adverse effect of progestogens on lipid metabolism, there is a theoretical risk of vascular disease in women with additional risk factors. DMPA has a greater effect on lipid metabolism than other progestogen-only methods, hence the more restrictive categories in UKMEC.¹⁰ Table 4 outlines the UKMEC categories for use of POC with cardiovascular and cerebrovascular disease.

- B** Women can be advised that although the data are limited, POC does not appear to increase the risk of stroke or MI, and there is little or no increase in VTE risk.
- C** Caution is required when prescribing DMPA to women with cardiovascular risk factors due to the effects of progestogens on lipids.

8 Non-hormonal contraception

8.1 Copper-bearing intrauterine device

Menstrual bleeding problems are common in women aged over 40 years and also common in users of intrauterine methods. Spotting, heavier or longer periods and pain are common in the first 3–6 months following Cu-IUD insertion.¹⁴ These bleeding patterns are not harmful and usually settle with time; however, women should be advised to seek medical advice to exclude gynaecological pathology and infection if the bleeding problems persist or occur as a new event.

A sexual health history should identify women at risk of STIs. Appropriate screening for STIs should be offered to those at risk or to those who request testing prior to IUD insertion.¹⁴ Further information can be found in Faculty guidance on intrauterine methods.¹⁴

- C** Women should be informed that spotting, heavier or prolonged bleeding and pain are common in the first 3–6 months of Cu-IUD use.

8.2 Sterilisation

Individuals considering sterilisation should be advised about all methods of contraception including LARCs. Information should be given on the advantages and disadvantages of sterilisation, including the lower failure rate and lower risk of major complications associated with vasectomy compared to laparoscopic tubal occlusion.¹³⁷ Hysteroscopic sterilisation is a less invasive alternative to laparoscopic sterilisation but its availability in the UK is currently limited. The RCOG provides guidance on sterilisation.¹³⁷

8.3 Barrier contraception

There is no restriction on the use of barrier methods based on age alone and there are few conditions that would restrict their use.¹⁰

Use of spermicide with diaphragms and caps is still recommended.¹³⁸ However, condoms should not be used with the spermicidal product, nonoxinol-9 (N-9), due to the risks of HIV transmission associated with mucosal irritation caused by frequent use.¹³⁹ Oil-based lubricants can damage condoms and so lubricants used with condoms should be non-oil-based.

- C** Men and women can be advised that when used consistently and correctly, male condoms and female condoms are, respectively, up to 98% and 95% effective at preventing pregnancy.
- C** Women can be advised that when used consistently and correctly with spermicide, diaphragm and caps are, respectively, estimated to be between 92% and 96% effective at preventing pregnancy.
- B** When using lubricant with latex condoms a non-oil-based preparation is recommended.

8.4 Natural family planning

The numbers of women over the age of 40 years who rely on fertility awareness methods are unknown. When approaching the menopause, natural family planning may become more difficult due to menstrual cycle irregularity and the increase of anovulatory cycles making it difficult to interpret ovulatory mucus.

8.5 Withdrawal

Though not promoted as a method of contraception, use of withdrawal (coitus interruptus) is reported by approximately 6% of women aged 40–44 years of age and 4% of women aged 45–49 years.¹¹ A recent review has suggested that data on withdrawal use may underestimate the numbers of couples actually using this method and that more research is needed.¹⁴⁰ Withdrawal, if used correctly (i.e. withdrawal before ejaculation every time), may work for some couples, particularly as a backup to other methods. However, couples considering withdrawal should be made aware that it may be less effective than other methods of contraception.

9 Emergency Contraception

There are no restrictions on the use of emergency contraception (EC) based on age alone. EC should be mentioned when discussing contraceptive options as women aged over 40 years may not know how to access EC or how long after unprotected sexual intercourse (UPSI) it can be used.

There are now three methods of EC available in the UK: progestogen-only emergency contraception (POEC), the Cu-IUD and the progesterone-receptor modulator, ulipristal acetate. All three methods can be used up to 120 hours (5 days) after UPSI; however, POEC is only licensed for use up to 72 hours and its effectiveness decreases with time.¹⁴¹ The Cu-IUD is thought to be the most effective emergency contraceptive, preventing around 99% of expected pregnancies. It can be used up to 5 days after the earliest expected date of ovulation regardless of the number of episodes of UPSI, and can also be used for ongoing contraception.

Further information is provided in Faculty guidance on EC¹⁴¹ and the CEU's new product review of ulipristal acetate.¹⁴²

- ✓ Women should be made aware of the different types of EC available including when they can be used and how they can be accessed.

10 Sexually Transmitted Infections

Practitioners should not assume that sexual risk taking is confined to younger individuals. Whilst young people under 25 years are most at risk of STIs, there has been a rise in the number of STI diagnoses in over-40-year-olds.^{143,144} Men and women aged over 40 years should be reminded about the use of condoms for protection against STIs (including HIV) even after contraception is no longer required, and the importance of STI testing with a change of sexual partner.

- c Men and women should be advised that the use of condoms can reduce the risk of acquiring and transmitting STIs.

11 Diagnosing the Menopause

The menopause is usually diagnosed clinically and in retrospect after 1 year of amenorrhoea. In terms of diagnosing the menopause, there is no single independent biological marker of the perimenopause. Serum levels of FSH, and estrogen and progesterone fluctuate around the menopause^{145–148} whilst levels of luteinising hormone (LH) remain within the normal range. An increase in FSH stimulates ovarian folliculogenesis, which occurs at an accelerated rate up until the menopause when all follicles are depleted.^{149–151} Increased folliculogenesis results in increased estrogen production, which may contribute to irregular bleeding and symptoms such as bloating and breast tenderness. An elevated serum FSH level indicates a degree of ovarian failure but it is not predictive of when final sterility has been reached. A woman's age and menstrual cycle/bleeding patterns may be the most useful factors in determining the likelihood of the approaching menopause, unless menstrual bleeding patterns are altered by hormonal contraception.

12 Stopping Contraception

Women may need advice on stopping contraception around the menopause (Table 5). In general the CEU advises that contraception may be stopped at the age of 55 years; however, this advice may need to be tailored to the individual woman. Women who are not using hormonal contraception and who continue to have regular menstrual bleeding at the age of 55 years should continue with some form of contraception. Whilst UKMEC does not give an upper age limit for the use of CHC or the progestogen-only injectable, the CEU does not recommend use of these methods beyond the age of 50 years.^{17,152} Ideally women over 50 years should be advised to switch to an alternative method such as the POP, implant, LNG-IUS or barrier method until the age of 55 years or until the menopause can be confirmed. Women who have been diagnosed with premature ovarian failure may occasionally have spontaneous return of ovarian activity and should be referred to a specialist for contraceptive guidance.

12.1 Non-hormonal methods

Whilst there is very little evidence to inform how and when methods of contraception can be stopped, traditional clinical practice has been that non-hormonal contraception can be stopped 1 year after the last menstrual period in those aged over 50 years, and 2 years after the last menstrual period in those under 50. The probability of menstruation (and possibly ovulation) after a year of amenorrhoea for women aged over 45 years has been estimated by WHO to be 2–10%.¹⁵³

All Cu-IUDs are licensed for at least 5 years of use or longer.¹⁴ Although outside the manufacturer's recommended duration of use, Faculty guidance states that if inserted at or after the age of 40 years, a Cu-IUD with ≥ 300 mm² copper can be used until menopause has been diagnosed.¹⁴

- ✓ Women using non-hormonal methods of contraception can be advised to stop contraception after 1 year of amenorrhoea if aged over 50 years, or 2 years if the woman is aged under 50 years.
- C** After counselling (about declining fertility, risks associated with insertion, and contraceptive efficacy), women who have a Cu-IUD containing ≥ 300 mm² copper, inserted at or over the age of 40 years, can retain the device until the menopause or until contraception is no longer required.
- ✓ Women who continue to use their IUD until contraception is no longer required should be advised to return to have the device removed.

12.2 Hormonal methods

As hormonal contraception can affect bleeding patterns, laboratory testing may have some value in determining when contraception can be stopped.

Studies have shown that it is possible to measure FSH levels whilst using progestogen-only methods of contraception.^{154,155} However testing may be best restricted to women over the age of 50 years, as they are more likely to be menopausal.

- ✓ Women using exogenous hormones should be advised that amenorrhoea is not a reliable indicator of ovarian failure.
- ✓ In women using contraceptive hormones, FSH levels may be used to help diagnose the menopause, but should be restricted to women over the age of 50 years and to those using progestogen-only methods.
- ✓ FSH is not a reliable indicator of ovarian failure in women using combined hormones, even if measured during the hormone-free interval.
- ✓ Women over the age of 50 years who are amenorrhoeic and wish to stop POC can have their FSH levels checked. If the level is ≥ 30 IU/L the FSH should be repeated after 6 weeks. If the second FSH level is ≥ 30 IU/L contraception can be stopped after 1 year.

Table 5 Advice for women on stopping contraception

Contraceptive method	Advice on stopping contraception	
	Age <50 years	Age ≥50 years
Non-hormonal	Stop contraception after 2 years of amenorrhoea	Stop contraception after 1 year of amenorrhoea
CHC	Can be continued up to age 50 years ^a	Stop CHC at age 50 years and switch to a non-hormonal or progestogen-only method, then follow appropriate advice
DMPA	Can be continued up to age 50 years ^a	Stop DMPA at age 50 years and choose from options below: Switch to a non-hormonal method and stop after 2 years of amenorrhoea OR Switch to the POP, implant or LNG-IUS and follow advice below
Implant POP LNG-IUS	Can be continued to age 50 years or longer ^a	Continue method If amenorrhoeic either check FSH levels and stop method after 1 year if serum FSH is ≥30 IU/L on two occasions 6 weeks apart OR Stop at age 55 years when natural loss of fertility can be assumed for most women If not amenorrhoeic, consider investigating any abnormal bleeding or changes in bleeding pattern, and continue contraception beyond age 55 years until amenorrhoeic for 1 year

^aIf a woman wishes to stop hormonal contraception before age 50 years she should be advised to switch to a non-hormonal method and to stop once she has been amenorrhoeic for 2 years (or 3 years if switched from DMPA due to the potential delay in return of ovulation).

CHC, combined hormonal contraception; DMPA, depot medroxyprogesterone acetate; FSH, follicle-stimulating hormone; IU, international unit; LNG-IUS, levonorgestrel-releasing intrauterine system; POP, progestogen-only pill.

12.3 Removing the LNG-IUS

In women using the LNG-IUS, over 75% of women will continue to ovulate,¹⁵⁶ yet amenorrhoea or light bleeding is common after the first year of use. Women who have had an LNG-IUS inserted at the age of 45 years or over may continue to use the method for 7 years if their bleeding pattern is acceptable. NICE guidance advises that if women have an LNG-IUS inserted at or after the age of 45 years and are amenorrhoeic they may continue to use the LNG-IUS until they are postmenopausal.¹² Given the reduced likelihood of spontaneous pregnancy in women over the age of 50 years, the CEU supports this option, for women who are amenorrhoeic. Women should be informed about the efficacy of the LNG-IUS, the risks of pregnancy over the age of 50 years, and the risks of removal and replacement. If bleeding/spotting occurs, this indicates ovarian follicular activity and the CEU advises that the device is removed and replaced or alternative contraception provided.

Women who had the LNG-IUS inserted at the age of 45 years or over and who are using the LNG-IUS solely for heavy menstrual bleeding can continue with the LNG-IUS until the menopause. If bleeding is not controlled it may be necessary to exclude pathology before or at the time of replacing the LNG-IUS.



Women who have their LNG-IUS inserted for contraception at the age of 45 years or over can use the device for 7 years (off licence) or if amenorrhoeic until the menopause, after which the device should be removed.

13 Hormone Replacement Therapy and Contraception

The Summaries of Product Characteristics (SPCs) for HRT regimens do not support their use as contraception and a separate contraceptive method must be recommended for sexually

active women who are not yet postmenopausal.¹⁵⁷ In a small study of sequential HRT users aged 42–52 years, HRT inhibited ovulation in only 40% of women with regular cycles and some women who had been anovulatory or had irregular cycles prior to HRT did subsequently ovulate on HRT.¹⁵⁸ Measurement of FSH is largely unreliable whilst taking HRT. Most perimenopausal women will use sequential HRT. Continuous combined regimens are not appropriate in the perimenopause due to a high chance of irregular bleeding.

Randomised trials have shown that the LNG-IUS is effective in providing endometrial protection from the stimulatory effects of estrogen replacement therapy.^{159–164} Data presented to the regulatory authorities from these trials provided evidence of endometrial protection with a duration of just under 5 years. Therefore the LNG-IUS is only licensed for use for 4 years with HRT¹²⁷ but may be used off licence for up to 5 years.

Theoretically replicating the dose of progestogen found in HRT preparations via POC may provide sufficient endometrial protection against the effects of estrogen replacement. However, there is currently no evidence to show that the POP, implant and injectable provide such protection and no contraceptive other than the LNG-IUS is licensed to be used for such a purpose.

- C** Women using HRT should be advised not to rely on this as contraception.
- ✓** Women can be advised that a POP can be used with HRT to provide effective contraception but the HRT must include progestogen in addition to estrogen.
- A** Women using estrogen replacement therapy may use the LNG-IUS to provide endometrial protection. When used as the progestogen component of HRT, the LNG-IUS should be changed no later than 5 years after insertion (the licence states 4 years), irrespective of age at insertion.

14 Follow Up

In addition to the method-specific recommendations, women should be advised that they may return at any point if they experience any problems with their contraception, or change in medical history that may influence contraceptive choice, or when they reach 50 years of age.

Menstrual bleeding problems are common in women aged over 40 years, as is gynaecological pathology. Women should be advised to seek medical advice at any time if they develop new symptoms of pain, irregular or heavy bleeding, or if bleeding problems do not settle within 3–6 months of IUD/IUS insertion.

After the menopause it is advised that intrauterine methods are removed, rather than left *in situ*. Cases of actinomyces-like organisms (ALOs) and pyometra have very occasionally been reported in postmenopausal women with IUDs. If the IUD/IUS cannot be removed easily in an outpatient setting, individuals should be referred for specialist review.

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APPENDIX 1: DEVELOPMENT OF CEU GUIDANCE

GUIDELINE DEVELOPMENT GROUP

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Gilly Andrews is an advisory board member for Bayer Schering Pharma. Marian Everett has received payment for lecturing from Bayer Schering Pharma, Schering Plough, Novo Nordisk and Wyeth. No other competing interests were noted by members of the multidisciplinary group.

Administrative support to the CEU team was provided by **Ms Janice Paterson**.

INDEPENDENT PEER REVIEWERS

Dr Heather Currie – Associate Specialist Gynaecologist, Dumfries & Galloway Royal Infirmary, Dumfries

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

Evidence is identified using a systematic literature review and electronic searches are performed for: MEDLINE (CD Ovid version) (1996–2010); EMBASE (1996–2010); PubMed (1996–2010); The Cochrane Library (to 2010) 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 the topic under consideration. Previously existing guidelines from the FSRH (formerly the Faculty of Family Planning and Reproductive Health Care), the Royal College of Obstetricians and Gynaecologists (RCOG), the World Health Organization (WHO) and the British Association for Sexual Health and HIV (BASHH), and reference lists of identified publications, are also searched. Similar search strategies have been used in the development of other national guidelines. Selected key publications are appraised using standard methodological checklists similar to those used by the National Institute for Health and 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 on the inside front cover of this document using a scheme similar to that adopted by the RCOG and other guideline development organisations. The clinical recommendations within this guidance are based on evidence whenever possible. Summary evidence tables are available on request from the CEU. An outline of the guideline development process is given in the table on the inside back cover of this guidance document.

Discussion Points for Contraception for Women Aged Over 40 Years

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

Discussion Points

- 1 Discuss fertility issues in a woman aged over 40 years.
- 2 Discuss how you would diagnose the menopause in a woman aged over 40 years who is using combined hormonal contraception.
- 3 Discuss bone health in a woman aged over 40 years who is using depot medroxyprogesterone acetate.

Questions for Contraception for Women Aged Over 40 Years

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 No method of contraception is contraindicated on the grounds of age alone.	<input type="checkbox"/>	<input type="checkbox"/>
2 Women using combined oral contraception (COC) have a reduced incidence of ovarian cysts.	<input type="checkbox"/>	<input type="checkbox"/>
3 In women with a family history of breast cancer the use of COC increases the risk of developing breast cancer.	<input type="checkbox"/>	<input type="checkbox"/>
4 The risks of the progestogen-only pill (POP) use outweigh the benefits in women aged over 50 years.	<input type="checkbox"/>	<input type="checkbox"/>
5 A raised follicle-stimulating hormone (FSH) level is a good indicator of the perimenopause in women over 40 years.	<input type="checkbox"/>	<input type="checkbox"/>
6 All women can be advised to stop contraception at age 55 years.	<input type="checkbox"/>	<input type="checkbox"/>
7 A woman who has an intrauterine system (IUS) inserted at or after the age 45 years and is amenorrhoeic may retain the device until she is postmenopausal.	<input type="checkbox"/>	<input type="checkbox"/>
8 The IUS may be used as the progestogen component of hormone replacement therapy (HRT) for 5 years.	<input type="checkbox"/>	<input type="checkbox"/>
9 A POP can be used with HRT to provide effective contraception in women aged over 40 years.	<input type="checkbox"/>	<input type="checkbox"/>
10 The intrauterine device (IUD) should be removed 1 year after the last menstrual period in women aged over 50 years.	<input type="checkbox"/>	<input type="checkbox"/>

Answers

10 True
5 False

9 True
4 False

8 True
3 False

7 True
2 True

6 False
1 True

STEPS INVOLVED IN THE DEVELOPMENT OF THIS GUIDANCE DOCUMENT

STEP	TIME TAKEN
<p>Formulation of key clinical questions by the Clinical Effectiveness Unit (CEU).</p> <p>Systematic literature review involving searching electronic, bibliographic databases by CEU researcher.</p> <p>Obtaining and reviewing copies of the full papers of all relevant publications identified through the searches.</p> <p>Formal, critical appraisal of key papers and development of short evidence tables.</p>	<p>This process must be completed in a maximum of 8 weeks.</p>
<p>Draft one guidance document is written providing recommendations and good practice points based on the literature review.</p>	<p>The CEU has overall responsibility for writing the guidance document. The multidisciplinary group and other peer reviewers should highlight inconsistencies, errors, omissions or lack of clarity.</p>
<p>Peer review by multidisciplinary group 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.</p>	<p>At this stage the CEU convenes a one-day meeting of the multidisciplinary group.</p>
<p>Preparation of draft two guidance document based on written comments of the multidisciplinary group.</p>	
<p>Peer review of draft two guidance document by the multidisciplinary group, the FSRH CEC and two independent peer reviewers.</p>	
<p>Preparation of draft three guidance document based on written comments from the peer review process.</p>	<p>Minor comments can be accepted at this stage.</p>
<p>The final guidance document is published by the FSRH.</p>	<p>Proofreading of guidance document by three members of the CEU team independently and comments collated by the Unit Director. A pdf version of the guidance is available on the FSRH website.</p>

COMMENTS AND FEEDBACK ON PUBLISHED GUIDANCE

All comments on published guidance can be sent directly to the Clinical Effectiveness Unit (CEU) at ceu.members@ggc.scot.nhs.uk.

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 8459/8460] 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 are reviewed by the Clinical Effectiveness Committee and any necessary amendments made.