FSRH The Faculty of Sexual & Reproductive Healthcare

FSRH Guideline

Contraception for Women Aged Over 40 Years

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Since this guideline was first published, the following changes have been made:

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- Section 6.1.2, “with amenorrhoea” added to “women over 50 using POC”
- Section 6.1.3, “with amenorrhoea” added to “women over 50 using POC”
- Table 8, “with amenorrhoea” added to “If a woman over 50 wishes to stop before age 55”

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Abbreviations Used

BMD	bone mineral density
BMI	body mass index
BP	blood pressure
CEU	Clinical Effectiveness Unit
CHC	combined hormonal contraception/contraceptive
CI	confidence interval
COC	combined oral contraception/contraceptive
Cu-IUD	copper intrauterine device
CVD	cardiovascular disease
DMPA	depot medroxyprogesterone acetate
DSG	desogestrel
EC	emergency contraception
ED	erectile dysfunction
EE	ethinylestradiol
FSH	follicle-stimulating hormone
FSRH	Faculty of Sexual & Reproductive Healthcare
GDG	guideline development group
GP	general practitioner
HCP	healthcare practitioner
HFI	hormone-free interval
HMB	heavy menstrual bleeding
HRT	hormone replacement therapy
IMP	progestogen-only implant
IUC	intrauterine contraception
LARC	long-acting reversible contraception/contraceptive
LH	luteinising hormone
LMP	last menstrual period
LNG-EC	levonorgestrel emergency contraception
LNG-IUS	levonorgestrel intrauterine system
MI	myocardial infarction
NICE	National Institute for Health and Care Excellence
OR	odds ratio
POC	progestogen-only contraception/contraceptive
POP	progestogen-only pill
RCOG	Royal College of Obstetricians and Gynaecologists
RCT	randomised controlled trial
RR	relative risk
SIGN	Scottish Intercollegiate Guidelines Network
SRH	sexual and reproductive healthcare
STI	sexually transmitted infection
UKMEC	UK Medical Eligibility for Contraceptive Use
UPA-EC	ulipristal acetate emergency contraception
UPSI	unprotected sexual intercourse (no contraception used or contraception used incorrectly)
VTE	venous thromboembolism

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Grading of Recommendations

Refer to **Appendix 1** for a full explanation of the classification of evidence level and grading of recommendations.

A	**At least one meta-analysis, systematic review or randomised controlled trial (RCT) rated as 1++, and directly applicable to the target population;** ***or*** **A systematic review of RCTs or a body of evidence consisting principally of studies rated as 1+, directly applicable to the target population and demonstrating overall consistency of results.**
B	**A body of evidence including studies rated as 2++ directly applicable to the target population and demonstrating overall consistency of results;** ***or*** **Extrapolated evidence from studies rated as 1++ or 1+.**
C	**A body of evidence including studies rated as 2+ directly applicable to the target population and demonstrating overall consistency of results;** ***or*** **Extrapolated evidence from studies rated as 2++.**
D	**Evidence level 3 or 4;** ***or*** **Extrapolated evidence from studies rated as 2+.**
✓	**Good Practice Point based on the clinical experience of the guideline development group.**

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Executive Summary of Recommendations

What are the main sexual and reproductive health issues facing women over 40?

✓	Women should be informed that although a natural decline in fertility occurs with age and spontaneous pregnancy is rare after age 50, effective contraception is required until menopause to prevent an unintended pregnancy.
B	Healthcare practitioners (HCPs) should advise women that pregnancy and childbirth after age 40 confer a greater risk of adverse maternal and neonatal outcomes than in women under 40.
D	HCPs should discuss sexually transmitted infections (STIs) and sexual health with women over 40. This population should be advised about condom use and protection from STIs even after contraception is no longer required.
✓	Women over 40 with a significant change in their bleeding pattern should have appropriate gynaecological assessment and investigations, whether or not they are using a contraceptive method.
✓	Women over 40 should be asked about any urogenital symptoms or sexual issues they may be experiencing.

Why do women over 40 need separate guidance?

✓	HCPs should inform women over 40 of the age-related increased background risk of cardiovascular disease, obesity and of breast and most gynaecological cancers as this may affect choice of contraceptive method.

Suitability of contraceptive methods for women over 40

C	Women should be informed that contraception does not affect the onset or duration of menopausal symptoms but may mask the signs and symptoms of menopause.
D	The FSRH supports extended use of the copper intrauterine device until menopause when inserted at age 40 or over.
✓	Women who have undergone endometrial ablation should be advised about the potential risk of complications if intrauterine contraception (IUC) is used.
✓	The FSRH supports extended use of a Mirena® levonorgestrel intrauterine system (LNG-IUS) for contraception until the age of 55 if inserted at age 45 or over, provided it is not being used as the progestogen component of hormone replacement therapy (HRT) for endometrial protection.

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D	Women can be informed that the progestogen-only implant (IMP) is not associated with increased risks of venous thromboembolism (VTE), stroke or myocardial infarction (MI) and has not been shown to affect bone mineral density (BMD).
✓	Women over 40 using depot medroxyprogesterone acetate (DMPA) should be reviewed regularly to assess the benefits and risks of use. Women over 50 should be counselled on alternative methods of contraception.
D	Compared to non-DMPA users, women using DMPA experience initial loss of bone density due to the hypoestrogenic effects of DMPA but the evidence suggests that this initial bone loss is not repeated or worsened by onset of menopause.
B	Women can be informed that the progestogen-only pill (POP) is not associated with increased risks of VTE, stroke or MI and has not been shown to affect BMD.
✓	Combined oral contraception (COC) with levonorgestrel or norethisterone should be considered first-line COC preparations for women over 40 due to the potentially lower VTE risk compared to formulations containing other progestogens.
C	COC with ≤30 µg ethinylestradiol should be considered first-line COC preparations for women over 40 due to the potentially lower risks of VTE, cardiovascular disease and stroke compared to formulations containing higher doses of estrogen.
A	Combined hormonal contraception (CHC) can reduce menstrual bleeding and pain, which may be particularly relevant for women over 40.
A	HCPs can offer an extended or continuous CHC regimen to women for contraception and also to control menstrual or menopausal symptoms.
✓	Women aged 50 and over should be advised to stop taking CHC for contraception and use an alternative, safer method.
A	COC is associated with a reduced risk of ovarian and endometrial cancer that lasts for several decades after cessation.
A	CHC may help to maintain BMD compared with non-use of hormones in the perimenopause.
B	Meta-analyses have found a slight increased risk of breast cancer among women using COC, but with no significant risk of breast cancer by 10 years after cessation.
✓	Women who smoke should be advised to stop CHC at age 35 as this is the age at which excess risk of mortality associated with smoking starts to become clinically significant.

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D	HCPs should advise women that sterilisation does not alter or eliminate menstrual periods. Women who have been using another method of contraception should be made aware that bleeding patterns may well change after sterilisation because they have stopped a contraceptive method.
✓	Women over 40 who still require contraception should be offered emergency contraception after unprotected sexual intercourse if they do not wish to become pregnant.

When is contraception no longer needed?

✓	Menopause is usually a clinical diagnosis made retrospectively after 1 year of amenorrhoea. Most women do not require measurement of their serum hormone levels to make the diagnosis.
D	If needed, women over 50 using progestogen-only contraception, including DMPA, can have serum follicle-stimulating hormone (FSH) measurements undertaken to check menopausal status.
D	Women using CHC or HRT have suppressed levels of estradiol and gonadotrophins; measuring these hormones does not give accurate information on which to base advice regarding menopausal status and when to stop contraception.
✓	In general, all women can cease contraception at age 55 as spontaneous conception after this age is exceptionally rare even in women still experiencing menstrual bleeding.
✓	If a woman aged 55 or over does not wish to stop a particular method, consideration can be given to continuation providing the benefits and risks for her as an individual have been assessed and discussed with her.
D	IUC should not be left *in situ* indefinitely after it is no longer required as it could become a focus of infection.

Can hormone replacement therapy be used alongside or in place of contraception?

D	Women using sequential HRT should be advised not to rely on this for contraception.
D	Women may use a Mirena with estrogen for up to 5 years for endometrial protection as part of an HRT regimen. Women using Mirena for this purpose must have the device changed every 5 years.
✓	At the present time, POP, IMP and DMPA are not licensed for and cannot be recommended as endometrial protection with estrogen-only HRT.

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✓	**All progestogen-only methods of contraception are safe to use as contraception alongside sequential HRT.**
✓	**CHC can be used in eligible women under 50 as an alternative to HRT for relief of menopausal symptoms and prevention of loss of BMD.**

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FSRH Guideline (August 2017)
Contraception for Women Aged Over 40 Years

(Revision due by August 2022)

1 Purpose and Scope

This document updates previous Faculty of Sexual & Reproductive Healthcare (FSRH) guidance[1] and aims to summarise the available evidence on contraception for women over 40. The guidance is intended for use by healthcare practitioners (HCPs) working in sexual and reproductive healthcare (SRH), general practice, and obstetric and gynaecology settings.

This guideline covers contraception: when it is needed, what is available, the suitability and safety of each method, how it should be used and when it can be stopped. Topics such as assisted reproductive technology (ART), managing menopause and alternative treatments for hormone replacement therapy (HRT) are not within the scope of this guideline. The National Institute for Health and Care Excellence (NICE) provides comprehensive guidance on ART, *Fertility: Assessment and Treatment for People with Fertility Problems*,[2] and diagnosing and managing menopause, *Menopause: Full Guideline*.[3]

1.1 Identification and assessment of the evidence

This guideline was developed in accordance with standard methodology for developing FSRH clinical guidelines. The recommendations made within this document are based on the best available evidence and the consensus opinion of experts and the guideline development group (GDG). The methodology used in developing this guideline and a list of GDG members and other contributors can be found in **Appendix 1**.

The recommendations included should be used to guide clinical practice but are not intended to serve alone as a standard of medical care or to replace clinical judgement in the management of individual cases.

2 Summary of Guidance and Changes from Previous Guideline

Women over 40 experience a natural decline in fertility yet require contraception until they reach menopause if they wish to avoid an unplanned pregnancy. As women in the perimenopause often experience symptoms relating to fluctuating hormone levels (e.g. vasomotor symptoms, mood changes, irregular/heavy menstrual cycles) (**Section 3**) and have different background risks than younger women (**Section 4**), HCPs need to consider contraceptive options specifically with this population in mind.

This updated guideline for women over 40 provides comprehensive overviews of each contraceptive method and its eligibility, benefits and risks for this age group (**Section 5**). No method is contraindicated by age alone for women in their 40s. However, once women reach 50, they should no longer use combined hormonal contraception (CHC) as there are greater risks compared to estrogen-free methods which are at least as effective for contraception at this stage. Women over 50 should also be encouraged to choose an alternative to the progestogen-only injectable (depot medroxyprogesterone acetate, DMPA) due to concerns around bone health. **Table 8** provides a brief overview of method appropriateness for women in their 40s and 50s.

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This guideline updates information relating to when women no longer require contraception (Section 6). Progestogen-only pills (POP), progestogen-only implants (IMP), levonorgestrel intrauterine systems (LNG-IUS) and copper intrauterine devices (Cu-IUD) can safely be used until the age of 55 – when natural loss of fertility can be assumed – and may confer non-contraceptive benefits (e.g. reduced menstrual pain/bleeding, endometrial protection). While many women want to know definitively if they have reached menopause, HCPs should focus on a woman's *symptoms and needs* rather than follicle-stimulating hormone (FSH) levels unless they are concerned about premature menopause. During perimenopause, isolated serum estradiol, FSH and luteinising hormone (LH) levels can be misleading and should not be used as the basis for advice about stopping contraception; ovulation may still occur with a risk of pregnancy. Table 8 contains guidance on when to stop contraception based on age and method.

HRT is often prescribed to women over 40. As HRT is not a contraceptive method, effective contraception should be maintained in conjunction with sequential HRT if women are still perimenopausal or their menopausal status is uncertain (Section 7). Table 9 provides information on using HRT alongside contraception.

3 What are the Main Sexual and Reproductive Health Issues Facing Women Over 40?

3.1 Fertility

✓	**Women should be informed that although a natural decline in fertility occurs with age and spontaneous pregnancy is rare after age 50, effective contraception is required until menopause to prevent an unintended pregnancy.**

Fertility naturally decreases as age increases, with women experiencing a relatively steep decline from the mid-30s onwards mainly due to diminishing quality and quantity of oocytes. A number of reviews[4–8] assess that the chance of pregnancy for a woman having unprotected sexual intercourse (UPSI) over the course of a year is around 10–20% for women aged 40–44 and closer to 12% for women 45–49. Spontaneous pregnancy is rare in women over 50. Women over 40 who are sexually active should use contraception if they do not wish to become pregnant.

3.2 Pregnancy

B	**Healthcare practitioners (HCPs) should advise women that pregnancy and childbirth after age 40 confer a greater risk of adverse maternal and neonatal outcomes than in women under 40.**

3.2.1 Rates

There continues to be a trend for women to have children later in life, with many women choosing to start families in their 30s and 40s. The number of live births per year to women over 40 in England and Wales has nearly doubled from 2000-2015 from 15 066 to 29 241.[9] A retrospective cohort study[10] of 583 847 nulliparous women delivering a live-born baby between 1980 and 2005 found that over the study period, the proportion of women having their first birth when aged 30–34 increased 3-fold, the proportion aged 35–39 increased 7-fold and the proportion aged 40 and older increased 10-fold.

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HCPs should be aware that contraception discussions with women over 40 may be part of a wider fertility agenda; NICE provides further guidance on preconception advice and management.[11]

However, in common with women of all ages, women aged 40 and older experience unintended pregnancies and this age group of women have one of the highest rates of abortion compared to live births. In 2015, 28.1% of recorded pregnancies in women aged 40 years and older in England and Wales resulted in therapeutic abortion; the statistics do not however include miscarriages or ectopic pregnancies.[12] There were no comparable data in Scotland, but available statistics show that 4% of all therapeutic abortions in 2016 were to women aged 40 or over.[13]

3.2.2 Outcomes

Evidence level 2++

Pregnancy and childbirth after age 40 confer a greater risk of adverse maternal and child outcomes than they do before age 40. In the UK, the maternal mortality rate for women over 40 is three times greater than that of women aged 20–24.[14] Advanced maternal age is also associated with higher rates of postpartum haemorrhage, placental praevia, gestational diabetes, pregnancy-induced hypertension and Caesarean section.[10,15–21]

Increased age is associated with significantly increased rates of miscarriage.[22–26] Women 40 and over are twice as likely to have a miscarriage than younger women.[27] The miscarriage rate is 10–20% for women up to age 39 and rises to over 50% for women over 45.[28] One large cohort study of the Danish population over a 15-year period found an 84% miscarriage rate for women over 47.[29]

The risk of ectopic pregnancy also rises with age.[29,30] Women over 40 are nearly three times as likely to experience an ectopic pregnancy than younger women.[31] In the UK, 1.1% of pregnancies are ectopic,[32] hence the risk for women over 40 is still very low overall.

Women over 40 have significantly higher risks of stillbirth and perinatal mortality[17,21,29,33–35] as well as rates of preterm delivery[18,19,33–39], with rates increasing steadily with age.[19,36]

Increased age is associated with rising rates of congenital anomalies. The 2012 British and Irish Network of Congenital Anomaly Researchers report showed that women over 40 had higher birth prevalence of non-chromosomal and chromosomal anomalies compared with younger women, with Down syndrome constituting over half of the chromosomal anomalies.[40] Data from the National Down Syndrome Cytogenetic Register, which details Down syndrome diagnosis in England and Wales in the 1990s, show the risk of having a baby with Down syndrome for a woman aged 20 is 1 in 1544, a woman aged 30 is 1 in 909, a woman aged 40 is 1 in 146, and a woman aged 45 is 1 in 28.[41]

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3.3 Sexual relationships

D	**HCPs should discuss sexually transmitted infections (STIs) and sexual health with women over 40. This population should be advised about condom use and protection from STIs even after contraception is no longer required.**

Many individuals over 40 may be entering new relationships, either casual or long-term. A 2013 UK survey found that 8.9% of women aged 45–54 and 4.4% of women aged 55–64 had at least one new sexual partner in the previous year.[42]

3.3.1 Sexually transmitted infections

The number of women aged 45–64 diagnosed with chlamydia, gonorrhoea, herpes and genital warts has risen in England in recent years while syphilis diagnoses have remained stable.[43] HIV acquisitions have also been increasing. In England, there were 66 new HIV diagnoses in 2000 for women aged 50–64 yet over 200 new diagnoses in this group each year since 2010. Since 2011, the number of women aged 45–64 attending sexual health services [excluding enhanced general practitioner (GP) services] in England has risen over 140%.[44]

Evidence indicates that individuals over 40 are less likely to use condoms than their younger counterparts,[45] yet HCPs do not generally consider this group to be at risk of sexually transmitted infections (STIs).[46,47] It is essential that HCPs facilitate discussion about safe sex practices with individuals over 40. This population should be reminded about condom use and protection from STIs even after contraception is no longer required.

Evidence level 2-

A recent, small qualitative study in Scotland found that individuals aged 45–65 prioritised intimacy above STI concerns, engaging in UPSI in order to fulfil emotional needs. In addition, study participants reported that they felt STIs were not relevant to their lives and once the risk of pregnancy was gone, many did not think about STI risk.[48] It is therefore important that HCPs proactively discuss contraception and sexual health with women over 40. HCPs should also explain the importance of STI testing when there has been a change of partner.

3.4 Transition to menopause

✓	**Women over 40 with a significant change in their bleeding pattern should have appropriate gynaecological assessment and investigations, whether or not they are using a contraceptive method.**
✓	**Women over 40 should be asked about any urogenital symptoms or sexual issues they may be experiencing.**

NICE produced updated guidance in 2015 regarding diagnosing and managing menopause.[3] The FSRH recommends that HCPs refer to the NICE document for comprehensive guidance on this topic.

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3.4.1 What is perimenopause

Perimenopause is the transition phase preceding menopause and ending 1 year after the last menstrual period (LMP) during which women move from normal ovulatory menstrual cycles to the cessation of ovulation and menstruation. It typically starts in a woman's mid-to-late-40s and lasts 4–5 years.[4,49–51]

Endocrinological changes during perimenopause include fluctuating levels of estrogen, progesterone and FSH.[49,52–55] The slightly increased FSH level stimulates ovarian folliculogenesis, which occurs at an accelerated rate up until menopause when all functional follicles are depleted.[56–58] Estrogen levels eventually decrease in the late perimenopause in tandem with a sustained increase in FSH and LH.[49,59]

3.4.2 Perimenopausal symptoms

It is important to emphasise that all women experience perimenopause individually with different combinations, frequency and intensity of symptoms. HCPs need to consider each woman's personal situation when discussing any contraceptive and other therapeutic or lifestyle options.

Due to the changing and often erratic hormone levels, perimenopausal women frequently experience intermittent or persistent vasomotor symptoms, such as hot flushes and night sweats, and mood changes, including mood swings, anxiety and depression.[3,49,60] Sleep disturbance and chronic tiredness are common complaints also, primarily influenced by nocturnal vasomotor symptoms and mood changes.[3] Women may experience joint and/or muscular pain[3,61] and/or changes in the severity of pre-existing migraines.[61]

Bleeding patterns

Perimenopause is characterised by irregular menstrual cycles. As intermittent ovulation and anovulation occur, women going through perimenopause experience a rise in FSH levels and a shortening and/or lengthening of their menstrual cycle.[3,4] Women may experience changes in blood loss as well as bleeding patterns during this time. Heavy menstrual bleeding (HMB), postcoital bleeding and intermenstrual bleeding may require appropriate gynaecological assessment and investigations irrespective of whether women are using a contraceptive method or not.

Problems surrounding sexual function

Loss of libido is also a common symptom presenting at this time. Women may often attribute this to hormone levels, but libido is multifactorial. Tiredness, work and family stress, self-image as the body ages, and physical changes in their partner all contribute to how a woman feels about sexual activity. Many women begin to experience urogenital issues such as vaginal dryness, dyspareunia and bladder problems during this stage, which can further affect both the woman's desire to have sex and her sexual function.[3] However, women are often hesitant to present with these symptoms due to embarrassment. HCPs should ask women about urogenital symptoms associated with the hypoestrogenic state during consultations with women in the perimenopause and menopause, as these symptoms can effectively be treated with simple lubricants and local vaginal estrogen. The NICE menopause guideline states that vaginal estrogen may be used long term as the systemic absorption from the small dose is unlikely to cause adverse effects. It can be used alongside systemic HRT if required.[3]

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Concurrently, a male partner may be ageing as well and potentially experiencing problems such as erectile dysfunction (ED). There are no available data on ED rates by age in the UK, but an American community-based study found that 52.3% of men aged between 40 and 70 years reported some degree of ED.[62]

HCPs should be prepared to discuss a variety of issues around sexual function related to ageing and hormonal changes.

4 Why do Women Over 40 Need Separate Guidance?

As women age they have an increased risk of certain health conditions which, combined with the symptoms and treatments for any perimenopausal symptoms, means they may have a distinctly different set of needs from younger women. Choosing and stopping appropriate contraception requires an understanding of the health benefits and risks of each method, and the non-contraceptive advantages and disadvantages for this age group.

4.1 Increased background risks

✓ **HCPs should inform women over 40 of the age-related increased background risk of cardiovascular disease, obesity and of breast and most gynaecological cancers as this may affect choice of contraceptive method.**

Risk of cardiovascular disease (CVD) begins to rise in women during perimenopause;[49,63] early menopause (i.e. between 40 and 45 years) is associated with increasing risk of CVD.[3]. According to the Scottish Intercollegiate Guidelines Network (SIGN), the annual incidence of venous thromboembolism (VTE) rises significantly between the ages of 40 and 60 from 1/10 000 to 1/1000.[64] One recent American study of non-Hispanic Caucasian women found an incidence rate of 4.2/10 000 for women aged 45–49, 1.03/1000 for women aged 50–54 and 1.44 for women aged 55–59.[65] Two population-based American studies from the 1990s found that the rate of stroke doubled every 10 years from the age of 45 onward.[66,67]

The risks of breast, endometrial and ovarian cancer also increase with age while the risk of cervical cancer decreases. About 80% of breast cancer cases are in women aged 50 or older.[68] Ovarian cancer is much less common than breast cancer but rates increase exponentially with age.[69] Endometrial cancer is primarily a disease of old age but can occasionally affect younger women with risk factors such as a history of polycystic ovarian syndrome, obesity or a genetic mutation.[70] Conversely, incidence rates of cervical cancer in the UK are highest in women aged 25–29, with over half of diagnoses each year in women under 45.[71] **Table 1** gives lifetime risks of reproductive cancers by age.

Women over 40 have a higher risk of osteoporotic fractures than their younger counterparts because of lower bone mineral density (BMD), due to declining estrogen levels.[3] The risk of osteoporosis increases with age and women are more prone to the disease than men due to a lower baseline BMD and the accelerated loss of bone mass at the time of menopause.[72]

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Table 1: Risk of reproductive cancers by age in the UK[*68,69,71,73–77]

Type of cancer	Lifetime risk in UK	New cases per year by age (years)					
		25–29	30–34	40–44	45–49	50–54	55–59
Breast	1 in 8	226	636	2777	5261	6160	5137
Endometrial	1 in 41	15	41	160	329	720	1130
Ovarian	1 in 52	125	142	301	465	628	672
Cervical	1 in 135	448	410	355	295	230	208

*Data from England and Wales is from 2015, Scotland from 2014 and Northern Ireland 2013.

4.2 Perimenopause and HRT

As many of the symptoms of perimenopause are associated with fluctuating and declining endogenous estrogen levels, some women opt to take exogenous estrogen in the form of HRT in order to treat or alleviate these symptoms.

Alternative prescribed options for menopausal symptoms (most of which are unlicensed for this indication) include selective serotonin or norepinephrine reuptake inhibitors, clonidine, gabapentin or progestogen-only therapies. The evidence base for their effectiveness is limited but small randomised trials suggest some short-term benefit for antidepressant therapies.

Women experiencing perimenopausal symptoms may also choose to use complementary or herbal therapies.[78] There is a very limited evidence base for the effectiveness of these therapies but individual women may find them helpful. HCPs should enquire about any treatment – conventional or otherwise – a woman may be using to address her perimenopausal symptoms and consider potential drug interactions when prescribing contraception.

5 Suitability of Contraceptive Methods for Women Over 40

The UK Medical Eligibility Criteria for Contraceptive Use (UKMEC) provides recommendations for the safe use of contraception including conditions particularly relevant to women over 40 such as reproductive cancers and cardiovascular conditions. For each of the personal characteristics or medical conditions considered by the UKMEC, a category 1, 2, 3 or 4 is given. The definitions of the categories are given in **Table 2**. UKMEC categories for different age groups are outlined in **Table 3**.

Table 2: Definition of UK Medical Eligibility Criteria for Contraceptive Use (UKMEC) categories[79]

UKMEC	Definition of category
Category 1	A condition for which there is no restriction for the use of the method.
Category 2	A condition where the advantages of using the method generally outweigh the theoretical or proven risks.
Category 3	A condition where 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.
Category 4	A condition which represents an unacceptable health risk if the method is used.

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Table 3: UK Medical Eligibility Criteria for Contraceptive Use (UKMEC) summary table for hormonal and intrauterine contraception methods[79]

Condition	Cu-IUD	LNG-IUS	IMP	DMPA	POP	CHC
Age (years)	Menarche to <20 = 2 ≥20 = 1	Menarche to <20 = 2 ≥20 = 1	After menarche = 1	Menarche to <18 = 2 18–45 = 1 >45 = 2	After menarche =1	Menarche to <40 = 1 ≥40 = 2

CHC, combined hormonal contraception; Cu-IUD, copper intrauterine device; DMPA, depot medroxyprogesterone acetate; IMP, progestogen-only implant; LNG-IUS, levonorgestrel intrauterine system; POP, progestogen-only pill.

Table 4: Percentage of women, by age group, using contraception*

Contraceptive method	Age (years)			
	20–24	35–39	40–44	45–49
None	22	23	25	28
Pill	54	27	10	13
Male condom	50	24	21	11
Withdrawal	7	5	6	4
LNG-IUS	4	3	3	4
Cu-IUD	6	12	9	11
Injection	6	2	2	4
Implant	5	0	0	1
Patch	0	1	1	–
Natural method	–	2	4	5
Other	3	0	0	1
Female sterilisation	3	10	18	19
Vasectomy	1	22	28	30

*Adapted from ONS survey on contraception and sexual health (2009).[80]
Cu-IUD, copper intrauterine device; LNG-IUS, levonorgestrel intrauterine system.

HCPs should discuss the effectiveness, risks, benefits (contraceptive and non-contraceptive) and side effects of all available methods. All methods become increasingly effective with age due to lower fertility and can be considered after individual assessment. The very long-acting reversible contraceptive (LARC) methods include the Cu-IUD, LNG-IUS and IMP, and these are the most effective methods of contraception with typical use.

5.1 What methods are women over 40 using?

According to the 2008/2009 data from the UK Office for National Statistics (ONS), 75% of all women aged 40–44 and 72% of women aged 45–49 are using at least one method of contraception.[80] The methods used in relation to age can be seen in Table 4.

Women over 40 were far less likely to use family planning services (both primary care and community services) than their younger counterparts; 73% of 25–29-year-olds accessed at least one service in the 5 years prior to interview compared with 33% of 45–49-year-olds. Only 31% of 40–44-year-olds and 25% of 45–49-year-olds saw their own GP or practice nurse for family planning.[80]

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5.2 Can contraception affect menopause?

C **Women should be informed that contraception does not affect the onset or duration of menopausal symptoms but may mask the signs and symptoms of menopause.**

Contraception does not affect the timing or duration of menopause[81,82] but may mask the symptoms that indicate perimenopause or the start of menopause. Some women may be hesitant to use contraception that will conceal indicators of this transition. HCPs should help women weigh the advantages and disadvantages of using contraception during this time. Many women find that certain contraceptive methods confer non-contraceptive benefits that alleviate perimenopausal symptoms.

Evidence level 2+

5.3 Copper intrauterine devices

D **The FSRH supports extended use of the copper intrauterine device until menopause when inserted at age 40 or over.**

The Cu-IUD is a highly effective LARC method without hormones or their related side effects; some women may prefer the Cu-IUD for these reasons. However, this method may be associated with heavier, more painful or prolonged bleeding and so may not be appropriate for women with HMB or perimenopausal women who experience problematic menstrual bleeding patterns.[4,50]

HCPs should always check the UKMEC to assess an individual woman's eligibility for contraceptive methods before prescribing. A sexual history should also be taken in order to identify women at risk of STI; an STI screen should be offered to all women who are identified as being at risk when requesting intrauterine contraception (IUC). The FSRH Guideline *Intrauterine Contraception* provides further guidance regarding women at risk of STI and IUC insertion.[83]

The Cu-IUDs currently available in the UK are licensed for either 5 or 10 years of use. The FSRH supports extended use of the Cu-IUD when inserted at age 40 or over. A Cu-IUD containing ≥300 mm^2 copper inserted at or after age 40 can remain *in situ* until 1 year after the LMP if it occurs when the woman is 50 or older. If a woman is under 50, the Cu-IUD can remain *in situ* for 2 years after the LMP.[83]

Evidence level 4

The FSRH Guideline *Intrauterine Contraception* provides complete guidance on IUC.[83]

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5.4 Levonorgestrel intrauterine system

D	**Women using a Mirena® levonorgestrel intrauterine system (LNG-IUS) for endometrial protection as part of a HRT combination must have the device changed every 5 years.**
✓	**Women who have undergone endometrial ablation should be advised about the potential risk of complications if intrauterine contraception (IUC) is used.**
✓	The FSRH supports extended use of a Mirena® levonorgestrel intrauterine system (LNG-IUS) for contraception until the age of 55 if inserted at age 45 or over, provided it is not being used as the progestogen component of hormone replacement therapy (HRT) for endometrial protection.

There are currently three LNG-IUS on the market in the UK: two 52 mg LNG-IUS (Mirena® and Levosert®) and one 13.5 mg LNG-IUS (Jaydess®). Mirena is licensed for 5 years for contraception and for HMB and for 4 years for endometrial protection during estrogen-only HRT.[84] (see **Section 5.4.1** and **Section 7.1.2**)**.** Levosert is licensed for 3 years for contraception and for HMB.[85] The 13.5 mg LNG-IUS is licensed for 3 years for contraception only.[86]

A comprehensive overview of the health benefits and risks related to the LNG-IUS can be found in the FSRH Guideline *Intrauterine Contraception*.[83] This guideline discusses those most pertinent to women over 40.

5.4.1 Non-contraceptive benefits

The 52 mg LNG-IUS offers very significant non-contraceptive benefits. It has been shown to be highly effective in reducing menstrual blood loss.[83] It will also reduce pain associated with primary menstrual pain, endometriosis and adenomyosis. An IUS can also be an effective medical treatment for endometrial hyperplasia.[87]

Problematic bleeding and pain

HMB and abnormal bleeding patterns are common in women over 40. Mirena and Levosert are licensed for the management of HMB and NICE recommends a 52 mg LNG-IUS as pharmaceutical treatment.[88] A 2015 Cochrane review of 21 randomised controlled trials (RCTs) evaluating various treatment options for HMB found that the LNG-IUS seems to have better results than oral medication (antifibrinolytics, oral progestogens or the contraceptive pill) in reducing menstrual blood loss and improving quality of life, with similar results to hysterectomy in improving quality of life.[89] Infrequent bleeding and amenorrhoea commonly occur during the first year of 52 mg LNG-IUS use. A 52 mg LNG-IUS may also reduce pain associated with menstruation, endometriosis or adenomyosis. The 13.5 mg LNG-IUS has a lower rate of amenorrhoea than the 52 mg dosage, but there is still a trend towards lighter bleeding over time.[83]

If bleeding is not controlled in women using a LNG-IUS for HMB after 3–6 months' duration of use, it may be necessary to exclude underlying pathology with appropriate gynaecological assessment and investigations.

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Endometrial protection

Mirena has been shown to provide endometrial protection from the stimulatory effects of exogenous estrogen, and the FSRH supports use of Mirena for up to 5 years (outside product licence) for this purpose.[83]

Evidence level 4

There is some limited evidence that the LNG-IUS protects against endometrial cancer.[90] Since Mirena does provide protection from endometrial hyperplasia – which can be a premalignant condition – it is a reasonable assumption that Mirena is likely to protect against endometrial cancer. Research suggests that Mirena could play a part in treatment of early-stage endometrial cancer.[91,92]

Ovarian cancer

There is limited evidence to suggests that the LNG-IUS may confer a protective effect against ovarian cancer. Two Finnish studies[90,93] found that, compared with the general population, women who used a LNG-IUS (unspecified dosage) had a decreased risk of ovarian cancer [standardised incidence ratio 0.59–0.6, 95% confidence interval (CI) 0.47–0.76 and 0.45–0.76]. These studies are limited by potential confounding factors and their observational nature.

5.4.2 Risks

Breast cancer

The evidence is conflicting regarding the potential link between LNG-IUS use and breast cancer risk. Two studies[94,95] looking specifically at 52 mg LNG-IUS use reported no increase in breast cancer risk, although both acknowledged that an increased risk could not be excluded due to the methodological limitations of observational research. Two large cohort studies[90,96] of women aged 30–49 in Finland found that women who used an LNG-IUS (unspecified dosage) during their reproductive years had a slight but statistically significant increase in breast cancer risk (standardised incidence ratio 1.19–1.73). However, neither study had data on how many women used the LNG-IUS in conjunction with estrogen therapy. The studies also did not adjust for confounding factors such as parity or family history. It is therefore not possible to exclude bias or confounding in these findings.

A case-control study[97] evaluating the association between HRT and the risk of breast cancer in recently postmenopausal women (aged 50–62) reported an increased risk of breast cancer in women who used a 52 mg LNG-IUS on its own or concomitantly with estradiol. The authors themselves stated that this was a surprising finding and that bias and confounding could not be excluded. Another case-control study[98] comparing women with breast cancer using a 52 mg LNG-IUS with women with breast cancer who had never used a 52 mg LNG-IUS found no increased risk of breast cancer recurrence associated with use of the LNG-IUS. A subgroup analysis found that women who developed breast cancer and continued to use the LNG-IUS had a higher risk of recurrence; however, the results were of borderline statistical significance and the authors identified potential confounding factors.

Current guidance contraindicates use of a LNG-IUS for women with previous or current breast cancer;[79] however, some HCPs may consider the benefits of LNG-IUS use outweigh the risks for some women after specialist review.[50]

A Cochrane meta-analysis[99] of four RCTs studying women with breast cancer taking tamoxifen found that women using tamoxifen with a LNG-IUS had a reduced incidence of endometrial hyperplasia in the long-term [odds ratio (OR) 0.13, 95% CI 0.03–0.67 for 24–60 months] compared with women using

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tamoxifen alone. The RCTs were not powered to detect whether a LNG-IUS significantly affects endometrial cancer risk in women using tamoxifen.

There is currently no evidence evaluating the breast cancer risks for women with a LNG-IUS taking tamoxifen for either breast cancer treatment or prophylactically for risk reduction. Specialist advice would therefore be needed if considering LNG-IUS use for women in these circumstances.

The FSRH recommends that any consideration of the LNG-IUS for women with a history of breast cancer be carried out in consultation with the woman's cancer specialist.[83]

Cardiovascular health

Current evidence suggests there is little or no increased risk of VTE, stroke or myocardial infarction (MI) associated with the use of LNG-IUS.[83] A 2016 systematic review of 21 studies investigating the risk of VTE, stroke and MI among women using progestogen-only contraception found no increased risk for women using LNG-IUS.[100] A retrospective review of medical notes that included 410 women with cardiac conditions using LNG-IUS found no reduction in efficacy or safety of the method compared to the general population.[101]

5.4.3 Assessment and investigations prior to insertion

HCPs should always check the UKMEC to assess an individual woman's eligibility for contraceptive methods before prescribing. A sexual history should also be taken in order to identify women at risk of STI; an STI screen should be offered to all women who are identified as being at risk when requesting IUC. The FSRH Guideline *Intrauterine Contraception* provides further guidance regarding women at risk of STI and IUC insertion.[83]

Most women will not need investigation prior to IUC insertion. However, women over 40 are more likely to have gynaecological pathology than their younger counterparts. Additional investigations such as full blood count, pelvic ultrasound scan and endometrial biopsy may be indicated prior to or at the same time as IUC insertion in women with heavy or irregular bleeding, particularly if other treatments have not been effective or if a woman has risk factors for gynaecological disease.[83] Investigations and management of bleeding problems should be considered according to local guidelines.

Women who have had endometrial ablation

Endometrial ablation is not contraceptive, therefore ongoing contraception is required unless a woman has been confirmed to be postmenopausal or has undergone female sterilisation.

There is very limited evidence in the literature regarding IUS use in women who have undergone endometrial ablation. One survey[102] included 150 women who underwent endometrial ablation combined with immediate LNG-IUS insertion for HMB. One hundred and five (70%) women completed questionnaires 6–54 months later (mean follow up was 25 months) regarding the efficacy and complications of this treatment. Six women had the LNG-IUS removed soon after insertion due to side effects. One hundred and one women (96%) stated they were satisfied with the treatment. There were no reports of complications. Ease of device removal after years *in situ* was not considered in this study but could be technically difficult or impossible.

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No evidence is identified relating to IUS insertion after an interval following endometrial ablation when the cavity could be partially or completely obliterated by adhesions. Insertion could in theory be technically difficult or impossible and there could be a higher risk of perforation. The procedure might require access to hysteroscopy and also ultrasound to check the IUS position in the cavity.

The Clinical Effectiveness Unit (CEU) sought expert opinion, which suggested that:

- Insertion of a LNG-IUS at the time of ablation is possible but can be complicated by the resulting intrauterine adhesions. Hysteroscopy years after ablation can be a difficult procedure as the whole cavity may not be visible and removal of an LNG-IUS may be problematic.
- Insertion of a LNG-IUS after an interval post-ablation can be achieved with concurrent hysteroscopy, but may be complicated by adhesions and is not always technically possible.

HCPs should use clinical judgement as to whether LNG-IUS insertion with hysteroscopy following endometrial ablation should be attempted. Women should be carefully counselled regarding the potential risks of the procedure.

5.4.4 When the LNG-IUS should be removed or replaced

Mirena is licensed for 5 years of use but there is evidence that it may provide effective contraception for up to 7 years.[103–105] NICE guidance advises that if women have a LNG-IUS inserted at or after age 45 and are amenorrhoeic, they may continue to use the LNG-IUS until they are postmenopausal.[106] The GDG agreed that when it is being used for contraception and inserted at or after age 45, Mirena can remain *in situ* until menopause even if the woman is not amenorrhoeic. Women using Mirena for HMB only can keep the device *in situ* for as long as it is effective in controlling symptoms, irrespective of the age at which it was inserted. Women using Mirena for endometrial protection in an HRT regimen must have their device changed every 5 years.

Women using a Mirena for contraception who were under 45 at the time of Mirena insertion may have an immediate replacement of their device between 5 and 7 years if a pregnancy test is negative. If they have had intercourse in the preceding 3 weeks then, for completeness, another pregnancy test is advised no sooner than 3 weeks after the last episode of intercourse. If more than 7 years have elapsed, replacement should be delayed until the woman has a negative pregnancy test at least 3 weeks after the last episode of intercourse.[83]

There is insufficient evidence at present to recommend using Levosert or the 13.5 mg LNG-IUS beyond their licensed durations and they should be replaced every 3 years for women of all ages. New data are likely to emerge that may support longer duration of usage.

As the risk of pregnancy is extremely low once a woman reaches age 55, contraception can be stopped at that age even in women still experiencing menstrual bleeding. For personal reasons, an individual woman may wish to continue using a LNG-IUS beyond this age for reasons relating to perceived non-contraceptive benefits The FSRH recommends always removing IUC ultimately as those devices left *in situ* may be a focus for complications in later years. For further information regarding when contraception is no longer needed, see **Section 6.2**.

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5.5 Progestogen-only implant

D	**Women can be informed that the progestogen-only implant (IMP) is not associated with increased risks of venous thromboembolism (VTE), stroke or myocardial infarction (MI) and has not been shown to affect bone mineral density (BMD).**

The IMP is the most effective form of contraception available with a 0.05% failure rate[107] and there is no age restriction to its use. Nexplanon® IMP contains 68 mg etonogestrel and is licensed for contraception for 3 years. A 2015 observational study[103] has suggested it may be effective for up to 4 years; however, the CEU does not currently recommend extended use regardless of a woman's age at insertion.[108]

5.5.1 Non-contraceptive benefits and risks

A comprehensive overview of the health benefits and risks related to the IMP can be found in the FSRH Guideline *Progestogen-only Implants*.[108] This guideline discusses those most pertinent to women over 40.

The main non-contraceptive benefit of the IMP is that it may alleviate menstrual and ovulatory pain.[108–112] The IMP is not associated with increased risks of VTE, stroke or MI and has not been shown to significantly affect BMD.[108] There are currently insufficient data to make recommendations regarding the effect of implants on the risk of reproductive cancers.

Evidence level 4

The implant causes irregular bleeding in most women and there is no evidence that bleeding patterns are different in women over 40. Some women may prefer a method that confers more predictable bleeding patterns or with higher levels of amenorrhoea.

5.5.2 When the implant should be stopped

As the risk of pregnancy is extremely low once a woman reaches age 55, contraception can be stopped at that age. For personal reasons, an individual woman may wish to continue IMP beyond this age for reasons relating to perceived non-contraceptive benefits. For further information regarding when contraception is no longer needed, see **Section 6.2**. For more information regarding implant removal, refer to the FSRH Guideline *Progestogen-only Implants*.[108]

5.6 Progestogen-only injectable

✓	**Women over 40 using depot medroxyprogesterone acetate (DMPA) should be reviewed regularly to assess the benefits and risks of use. Women over 50 should be counselled on alternative methods of contraception.**
D	**Compared to non-DMPA users, women using DMPA experience initial loss of bone density due to the hypoestrogenic effects of DMPA but the evidence suggests that this initial bone loss is not repeated or worsened by onset of menopause.**

There are currently two DMPA contraceptive injections in common use in the UK: Depo Provera® and Sayana Press®. The former contains 150 mg medroxyprogesterone acetate and is administered

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intramuscularly (IM) every 12 or 13 weeks[113] while the later contains 104 mg and is administered subcutaneously (SC) every 13 weeks. This guideline discusses issues regarding DMPA that are most pertinent to women over 40. The FSRH Guideline *Progestogen-only Injectable Contraception* provides further comprehensive guidance regarding DMPA.[113]

5.6.1 Non-contraceptive benefits

Bleeding patterns

Many women find DMPA helpful in relation to bleeding patterns. Women commonly experience infrequent, irregular or prolonged bleeding with initial DMPA use. The majority of women become amenorrhoeic over time.[113–115] Current evidence suggests that bleeding patterns are similar with DMPA-IM and DMPA-SC.[116] Because amenorrhoea is likely, NICE lists DMPA as a potential treatment for the management of HMB.[88] DMPA has been shown to alleviate menstrual pain and endometriosis symptoms.[113]

Reproductive cancers

Data from observational studies indicate that DMPA may have a potentially protective effect on risk of endometrial or ovarian cancer.[113] One case-control study found that DMPA reduced the risk of epithelial ovarian cancer by 39% (95% CI 0.44–0.85, p=0.002).[117] Another small case-control study found DMPA reduced the risk of endometrial cancer by 79% (95% CI 0.06–0.79).[118] These studies were limited by their small size and observational nature.

Current, limited evidence indicates that there is no clear association between DMPA and cervical cancer risk and, extrapolating from combined oral contraception (COC) data, any effect on risk would be minimal and/or reversible.[119,120] The FSRH advises that there is a weak association between cervical cancer and use of DMPA for 5 years or longer and any increased risk appears to reduce with time after stopping and could be due to confounding factors.[113]

Vasomotor symptoms

The evidence regarding the effect of DMPA on vasomotor symptoms is conflicting. One small, comparative study found that women using DMPA reported no difference in vasomotor symptoms compared to women using COC, norethisterone enanthate or non-hormonal contraception.[121] Two older, smaller studies found that DMPA appeared to alleviate vasomotor symptoms in perimenopausal and postmenopausal women.[122,123] There is not enough evidence for the CEU to make a recommendation regarding the potential benefits of DMPA on vasomotor symptoms.

5.6.2 Risks

Bone health

DMPA use is associated with a small loss of BMD which is usually recovered after discontinuation. Several observational studies have examined the effects of DMPA use (past or present) on BMD in women over 40.[124–131] One small study included a control group and two groups of women who had used DMPA until menopause; one DMPA group concomitantly used HRT and one did not. Women who were never-users of DMPA experienced rapid bone loss at menopause compared to the two groups of DMPA users who experienced very little loss.[124] It is suggested that women using DMPA experience initial bone loss due to the hypoestrogenic effects of DMPA but that this initial bone loss is not repeated or worsened by menopause.[124,127]

Evidence level 2-

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However, women over 40 with additional risk factors for osteoporosis (e.g. smoking, inactivity, family history, vitamin D deficiency, etc.) are advised to consider alternative methods. Routine bone density scans, monitoring of serum lipids or use of estrogen in DMPA users over 40 has not been established.

Cardiovascular health

A 2016 systematic review found that there may be a slight increased risk of VTE for women using DMPA; however, the evidence is limited and the potential risk may only affect women with other risk factors for VTE (e.g. smoking, family history).[100] The FSRH currently advises that a causal relationship between DMPA and VTE has not been demonstrated.[113] The limited available evidence regarding stroke and MI risk for women using DMPA does not confirm or exclude an association.[113] However, a recent systematic review was reassuring in that it found no evidence of a link.[100]

Breast cancer

The evidence regarding DMPA and increased breast cancer risk is conflicting. There is possibly a weak association between current use and breast cancer, but any increased risk is likely to be small and reduce with time after stopping.[113]

5.6.3 When the injectable should be stopped

After age 45, DMPA moves from UKMEC Category 1 to Category 2.[79] Women of all ages using DMPA should be reviewed every 2 years to assess the benefits and risks of use. Women over 50 should be counselled on alternative methods of contraception as there are safer methods that are equally effective. If a woman over 50 does not wish to stop using DMPA, consideration should be given to continuation providing the benefits and risks for her as an individual have been assessed and discussed with her. The decision to continue above age 50 should be regularly reassessed at review visits.

5.7 Progestogen-only pills

B **Women can be informed that the progestogen-only pill (POP) is not associated with increased risks of VTE, stroke or MI and has not been shown to affect BMD.**

There are a number of POPs licensed in the UK. Formulations either include desogestrel (DSG), norethisterone or levonorgestrel (LNG). Women using a DSG pill are more likely to become anovulatory than women using traditional preparations (97% of DSG users vs 60% of LNG users).[113] With the decline in fertility with age, the traditional POP becomes increasingly effective in older users.

A comprehensive overview of the health benefits and risks related to the POP can be found in the relevant FSRH Guideline *Progestogen-only Pills*.[132] This guideline discusses those most pertinent to women over 40.

5.7.1 Non-contraceptive benefits and risks

The DSG pill may offer some benefits in the management of pain associated with endometriosis, menstruation and ovulation as it suppresses ovulation in most women.[133–135]

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There is currently no evidence of an association between POP use and VTE, stroke or MI.[100,113] The limited available evidence shows no association between POP and BMD.[136,137]

Evidence level 2++

The available evidence does not support an association between breast cancer and POP use.[138] However, due to the fact the evidence is limited, an increased risk cannot be completely excluded. Any increased risk is likely to be small and to reduce with time after cessation.[113]

One consideration regarding POP use for women over 40 is the potential for altered bleeding patterns, which affect nearly half of women using POP.[132] While frequent and irregular bleeding are common with POP use, women over 45 who experience a sudden change of bleeding patterns during POP use should be investigated in accordance with the advice given in the FSRH Guideline *Problematic Bleeding for Women Using Hormonal Contraception*.[139]

5.7.2 When POP should be stopped

As the risk of pregnancy is extremely low once a woman reaches age 55, contraception can be stopped at that age. For personal reasons, an individual woman may wish to continue POP beyond this age for reasons relating to perceived non-contraceptive benefits. For further information regarding when contraception is no longer needed, see **Section 6.2**.

5.8 Combined hormonal contraception

✓	**Combined oral contraception (COC) with levonorgestrel or norethisterone should be considered first-line COC preparations for women over 40 due to the potentially lower VTE risk compared to formulations containing other progestogens.**
C	**COC with ≤30 µg ethinylestradiol should be considered first-line COC preparations for women over 40 due to the potentially lower risks of VTE, cardiovascular disease and stroke compared to formulations containing higher doses of estrogen.**
A	**Combined hormonal contraception (CHC) can reduce menstrual bleeding and pain, which may be particularly relevant for women over 40.**
A	**HCPs can offer an extended or continuous CHC regimen to women for contraception and also to control menstrual or menopausal symptoms.**
✓	**Women aged 50 and over should be advised to stop taking CHC for contraception and use an alternative, safer method.**
A	**COC is associated with a reduced risk of ovarian and endometrial cancer that lasts for several decades after cessation.**
A	**CHC may help to maintain BMD compared with non-use of hormones in the perimenopause.**

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B	**Meta-analyses have found a slight increased risk of breast cancer among women using COC, but with no significant risk of breast cancer by 10 years after cessation.**
✓	**Women who smoke should be advised to stop CHC at 35 as this is the age at which excess risk of mortality associated with smoking starts to become clinically significant.**

There are three types of CHC currently available in the UK: COC, combined transdermal patch (patch) and combined vaginal ring (ring). There is a lack of specific evidence available regarding the short- and long-term safety of the patch and ring for women with medical conditions. The FSRH therefore extrapolates from the available evidence on COC and considers it applicable to all CHC.[79]

A 2013 Cochrane review of 18 RCTs comparing the patch, ring and COC found no significant differences in contraceptive effectiveness between the methods.[140] Data showed that patch users were less likely than COC users to experience breakthrough bleeding and spotting but more likely to report breast discomfort, nausea, vomiting and menstrual pain. Trials comparing the ring and COC found conflicting data regarding bleeding patterns, with three trials showing less breakthrough bleeding and spotting amongst ring users and one trial showing more. There were fewer reports of nausea, acne, irritability and depression in ring users but more complaints of vaginitis and genital pruritis. There were not enough instances of serious adverse events (e.g. VTE) within the studies to assess differential risk.

A comprehensive overview of the health benefits and risks related to CHC can be found in the relevant FSRH Guideline *Combined Hormonal Contraception*.[141] This guideline discusses those most pertinent to women over 40.

5.8.1 Non-contraceptive benefits

CHC regimens usually comprise 21 days of active hormones followed by a hormone-free interval (HFI) of 7 days. Women using CHC to control bleeding patterns or alleviate menopausal symptoms often experience unwanted symptoms during the HFI. While off licence, HCPs can offer continuous or extended dosing regimens of CHC in order to maintain the non-contraceptive benefits experienced during active hormone use. A Cochrane review[142] of 12 RCTs determined that continuous or extended dosing regimens are safe, effective and well tolerated.

Managing menstrual problems

Women over 40 are more likely to have gynaecological problems, some of which may be effectively treated by CHC.

CHC may help reduce menstrual pain.[141] In a Cochrane review[142] looking at continuous and extended regimens, the RCTs that reported menstrual symptoms found that women following a continuous regimen experienced less menstrual pain than women on extended or traditional regimens. Bleeding patterns were just as favourable if not improved in women following continuous or extended regimens in 11/12 RCTs. Eliminating the pill-free interval with continuous pill use enables women to reduce menstrual problems significantly, including menstrual headache. Continuous pill-taking also improves efficacy due to exceptionally low risk of breakthrough ovulation.

Evidence level 1++

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Women are likely to experience regular, predictable, relatively light bleeding when using CHC. A Cochrane review of 21 RCTs found that lower-dose COC [≤20 µg ethinylestradiol (EE)] may confer poorer cycle control than those containing >20 µg EE; however, cycle control may also be influenced by the progestogen used.[143]

Evidence level 1++

The COC estradiol valerate/dienogest (Qlaira®) is currently the only CHC licensed for HMB;[144] however, NICE does include all COC as a treatment option for HMB in their guidance on the topic and it is widely regarded as a highly effective treatment.[88] Comparisons between different formulations in respect of management of HMB have not been undertaken.

Drospirenone-containing COC is considered a first-line treatment for women who suffer from premenstrual syndrome although is not licensed for this indication. While not specifically aimed at women over 40, the current Royal College of Obstetricians and Gynaecologists (RCOG) guideline on managing premenstrual syndrome recommends continuous instead of cyclical regimens for this purpose. For further information, see the RCOG Green-top Guideline *Management of Premenstrual Syndrome*.[145]

Reproductive cancers

COC is associated with a reduced risk of ovarian and endometrial cancer that lasts for several decades after cessation of the method.[141,146–149] A collaborative reanalysis of 45 epidemiological studies found a 20% reduction in ovarian cancer risk for every 5 years of COC use.[150] One meta-analysis included studies with both high and low doses of EE and found that there was no differential effect on ovarian cancer benefit related to estrogen dose.[151] The risk of endometrial cancer has been estimated to be reduced by over 50% for ever-users of COC;[147,152] however, the studies evaluating endometrial cancer did not have the data to differentiate between higher or lower doses of estrogen in the COC studied.

Evidence level 1++

Bone health

Overall, there is evidence of a positive effect of CHC on BMD[136,153–155] which may be particularly relevant in the perimenopause. A Cochrane review of 19 RCTs found generally low-quality evidence that CHC can increase BMD.[156]

Evidence level 1++

Vasomotor symptoms

There is some evidence that CHC may improve vasomotor symptoms associated with perimenopause,[157–159] particularly with extended or continuous regimens.

5.8.2 Risks

VTE

The risk of VTE has been found to increase sharply around age 40. A large Danish cohort study found that the incidence of VTE in COC users rose from 8.7 per 10 000 woman-years for women aged 30–34 to 20.8 per 10 000 women-years for women aged 45–49.[160] A case-control study of 2550 women over 50 found that COC users had a 6.3-fold relative risk of VTE compared with non-users.[161] Another large case-control study found the incidence rate of VTE in COC users increased nearly 3-fold between ages 20–29 and over 40.[162]

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Women using CHC are at increased risk of VTE (which includes deep vein thrombosis, pulmonary embolism and cerebral venous sinus thrombosis). For women of reproductive age using CHC, the risk of VTE also depends on the progestogen used (see Table 5).[163] COCs with low doses of EE (20 µg) may confer a lower VTE risk than those with higher doses (30–40 µg).[164]

Evidence level 2+

Table 5: Venous thromboembolism (VTE) risk for all women by type of combined hormonal contraception (CHC) used[165,166]

Type of CHC used	Risk of VTE per 10 000 healthy women over 1 year
No CHC, not pregnant	**2**
No CHC, pregnant	**29**[167]
Ethinylestradiol with levonorgestrel, norgestimate or norethisterone	**5–7**
Ethinylestradiol with etonogestrel (ring) or norelgestromin (patch)	**6–12**
Ethinylestradiol with gestodene, desogestrel, drospirenone or cyproterone acetate	**9–12**
CHC containing dienogest, nomegestrol or mestranol	**Unknown**

Table 6: UK Medical Eligibility Criteria (UKMEC) categories for the use of combined hormonal contraception with venous thromboembolism and obesity[79]

Condition	UKMEC Category*
Venous thromboembolism	
History of VTE	**4**
Current VTE (on anticoagulants)	**4**
Family history: first-degree relative <45 years old	**3**
Family history: first-degree relative ≥45 years old	**2**
Major surgery: with prolonged immobilisation	**4**
Major surgery: without prolonged immobilisation	**2**
Minor surgery without immobilisation	**1**
Immobility unrelated to surgery	**3**
Obesity	
BMI ≥30–34 kg/m^2	**2**
BMI ≥35 kg/m^2	**3**

***Definition of UKMEC Category. UKMEC 1:** A condition for which there is no restriction for the use of the 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. 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. **UKMEC 4:** A condition which represents an unacceptable health risk if the method is used.

BMI, body mass index; VTE, venous thromboembolism.

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HCPs are advised to consider carefully the risk factors for VTE (e.g. obesity, smoking, family history) when prescribing CHC to a woman over 40, especially when initiating CHC. **Table 6** outlines the UKMEC categories for CHC use with common VTE risk factors. HCPs need to counsel women over 40 on the symptoms and signs of VTE.[168] The risk of VTE increases whenever a woman first starts CHC; if a woman stops CHC for any reason, including to measure FSH levels, she potentially incurs a higher risk of VTE if she restarts again after a break of more than 1 month.[165,169] The FSRH does not advise repeated episodes of stopping and restarting CHC, particularly for women over 40.

Women in their 40s frequently gain weight due to lifestyle factors; the evidence on how perimenopause influences weight gain is conflicting.[170–173] HCPs should discuss with women the increased risk of VTE with higher body weight and age, and monitor body mass index (BMI) regularly if she is using CHC.

Cardiovascular disease and stroke

HCPs are, as always, advised to consider carefully the risk factors for CVD (e.g. diabetes, smoking, hypertension, obesity, hyperlipidaemia) when prescribing CHC to a woman over 40 as the baseline background risks of these conditions are higher than in younger women.

There is a potential increased risk of stroke and MI for women who use CHC; however, the available evidence is conflicting and these events are rare. A 2015 Cochrane review[174] of 24 observational studies and a 2013 meta-analysis[175] of 50 observational studies found the risk of ischaemic stroke significantly increased with current COC use [OR 1.9, 95%CI 1.24–2.91 and relative risk (RR) 1.7, 95% CI 1.5–1.9, respectively). A large Danish cohort study[176] of over 1.5 million women had comparable, non-significant findings with a RR of 1.6–1.97 (p=0.24) for current COC use depending on EE dose. Other studies have found no significant association between CHC and ischaemic stroke.[177,178] The Cochrane review[174] found a similarly increased risk of MI for women who were currently using COC (RR 1.6, 95% CI 1.2–2.1) as did the Danish study (RR 1.4–3.72, p<0.001). A 2005 meta-analysis also reported an increased risk with an OR of 1.84 (95% CI 1.38–2.44).[176] However, the 2013 meta-analysis[175] found no significant increase in MI (OR 1.34, 95% CI 0.87–2.080) or haemorrhagic stroke (OR 1.03, 95% CI 0.71–1.49) with COC use. Conversely, a WHO case-control study[177] found that women over 35 currently using COC had a higher risk of haemorrhagic stroke than women aged under 35 using COC.

The dose of EE may influence the risk of stroke or MI. The Cochrane review[174] found the relative risk of stroke and MI to increase from 1.6 (95% CI 1.4–1.8) for 20 µg EE to 2.0 (95% CI 1.4–3.0) for 30–49 µg EE for women currently using COC. A French cohort study of nearly 5 million women found 20 µg EE to have lower risks for pulmonary embolism (RR 0.75, 95% CI 0.67–0.85), ischaemic stroke (RR 0.882, 95% CI 0.7–0.96) and MI (RR 0.56, 95% CI 0.39–0.79) compared with 30–40 µg.[164] Studies examining the difference between progestogen generations and cardiovascular risks demonstrate conflicting results and are limited by small numbers of events occurring even in large studies.[164,176,179–181]

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Table 7: UK Medical Eligibility Criteria (UKMEC) categories for the use of combined hormonal contraception with cardiovascular risk factors[79]

Condition	UKMEC Category*
Multiple risk factors for cardiovascular disease	**3**
Adequately controlled hypertension	**3**
Consistently elevated BP levels (properly taken measurements):	
Systolic >140–159 mmHg or diastolic >90–99 mmHg	**3**
Systolic ≥160 mmHg or diastolic ≥100 mmHg	**4**
Vascular disease	**4**
History of high BP during pregnancy	**2**
Current and history of ischaemic heart disease	**4**
Stroke (history of cerebrovascular accident, including transient ischaemic attack)	**4**
Known dyslipidaemias	**2**
Obesity	
BMI ≥30–34 kg/m^2	**2**
BMI ≥35 kg/m^2	**3**
Smoking	
Age <35 years	**2**
Age ≥35 years	
<15 cigarettes/day	**3**
≥15 cigarettes/day	**4**
Stopped smoking <1 year	**3**
Stopped smoking ≥1 year	**2**

***Definition of UKMEC Category. UKMEC 1:** A condition for which there is no restriction for the use of the 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. 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. **UKMEC 4:** A condition which represents an unacceptable health risk if the method is used.

BMI, body mass index; BP, blood pressure.

It is recommended practice to advise women who smoke to stop CHC at the age of 35 as the risks outweigh the benefits. This is the age at which excess risk of mortality associated with smoking starts to become apparent. Once a woman over 35 has stopped smoking for >1 year then use of CHC becomes less restrictive (UKMEC 2). Table 7 outlines the UKMEC categories for CHC use with common CVD risk factors. Although it may take up to 20 years for the mortality rate for all causes to decrease to that of a non-smoker, the cardiovascular risk decreases within 1–2 years of stopping.

Breast cancer

There is a dearth of evidence regarding CHC use and breast cancer risk that relates specifically to women over 40. Meta-analyses, sometimes using older higher-dose formulations, have found a slight increased risk of breast cancer among women currently using COC, with RR in the range 1.24–1.30.[182,183] The cancer risk was shown to decline gradually after cessation, with no significant risk of breast cancer after 10 years of non-use.[146,183]

Evidence level 1+

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One meta-analysis[184] of five cohort studies found a very small but significant increase in breast cancer risk for every 5 (RR 1.07, 95% CI 1.03–1.11) and 10 (RR 1.14, 95% CI 1.05–1.23) years of use, however many of the studies did not have statistically significant findings. Three more recent studies, including the Oxford-Family Planning Association contraceptive study, found no link between duration of COC use and breast cancer risk.[148,149,185]

Evidence level 1+

Women who are known carriers of gene mutations associated with breast cancer (e.g. BRCA1/BRCA2) have a much higher baseline risk of breast cancer and are UKMEC Category 3 for CHC use.[79] However, the existing limited evidence suggests that the risk of breast cancer among women with a family history or with known inherited gene mutations is probably not modified further by the use of COC.[186–204]

Cervical cancer

There appears to be a small increased risk of cervical cancer associated with COC use (former or current)[148,151,205,206] although the risk of cervical cancer decreases over the age of 40.[71] The increased risk associated with COC use declines after cessation, returning to the same risk as non-COC users after approximately 10 years.[146,205] Any biological cause for an increased risk is unknown. There is currently no evidence regarding whether the contraceptive ring, with its intravaginal administration, confers a different risk from COC.

5.8.3 Estradiol preparations

Estradiol/nomegestrol acetate (Zoely®) and estradiol valerate/dienogest (Qlaira) COC formulations contain natural estradiol rather than the synthetic EE that is contained in most COC. Evidence relating to their specific benefits or risks is not yet available. They share some similarities with HRT preparations, rather than COC, so have theoretical safety benefits for women over 40. However, there is currently insufficient evidence to make a specific recommendation for use of these preparations in women over 40.

5.8.4 When CHC should be stopped

Eligible women may use CHC for contraception up until the age of 50 provided there are no contraindications as outlined in the UKMEC. There are greater risks associated with CHC use compared to estrogen-free methods which are safer. Women should be counselled on the benefits and risks of CHC while in their 40s. At the age of 50, they should be advised to switch from CHC to a non-injectable progestogen-only contraception (POC) or a non-hormonal method as the risks of CHC generally outweigh the contraceptive benefits. Women taking CHC for non-contraceptive benefits who wish to continue use after the age of 50 should be considered individually using clinical judgement and informed choice.

For more information about when contraception may be discontinued, see **Section 6.2**.

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5.9 Other methods

D	**HCPs should advise women that sterilisation does not alter or eliminate menstrual periods. Women who have been using another method of contraception should be made aware that bleeding patterns may well change after sterilisation because they have stopped a contraceptive method.**

5.9.1 Sterilisation

Women considering female sterilisation should be advised that some LARC methods are as effective as sterilisation and may confer non-contraceptive benefits.[207] If a woman is nearing natural sterility, the benefits of sterilisation will be time-limited and non-surgical methods should be considered. HCPs should advise women that sterilisation does not alter or eliminate menstrual periods and that bleeding patterns may well change after sterilisation because they have stopped hormonal contraception or had their IUC removed.

Evidence level 4

Individuals considering sterilisation should be informed that vasectomy is safer, quicker to perform and associated with less morbidity than laparoscopic sterilisation. See the FSRH Guideline *Male and Female Sterilisation* for further information.[207]

5.9.2 Barrier methods

Barrier methods include male condoms, female condoms, diaphragms and cervical caps. There are no age restrictions to the use of barrier methods and there are few contraindications.[208] Barrier methods often have high effectiveness in women over 40 due to declining fertility and more consistent usage.

The spermicidal preparation nonoxinol-9 can be associated with increased risks of HIV transmission due to vaginal mucosal irritation. Individuals of all ages at higher risk of HIV infection should be advised not to use contraceptive methods which require concurrent use of spermicide.[209]

Condom use, whether alone or in combination with another contraceptive method, is important for individuals who may be at risk of STIs (see **Section 3.3**). Latex condoms should no longer be used with the spermicidal product nonoxinol-9 due to the risks of HIV transmission associated with mucosal irritation. Oil-based lubricants and moisturisers can damage latex condoms and non-oil-based products or plastic condoms should be used with these.[208]

While condoms and other barrier methods can offer effective contraception, they are highly user-dependent. This may be an issue for women with older partners who experience ED or women who have vaginal prolapse.[4] The diaphragm and cervical cap require discipline; they should be used with spermicide, must be inserted properly and checked for positioning, they need to remain in place for 6 hours after intercourse and be removed within 24 hours.[4,50] For more information on barrier methods, refer to the FSRH Guideline *Barrier Methods for Contraception and STI Prevention*.[208]

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5.9.3 Natural family planning

Natural family planning is a term used to describe fertility awareness methods associated with periodic abstinence. According to the 2008/2009 ONS data, 4% of women aged 40–44 and 5% of women aged 45–49 use natural family planning as contraception. When approaching menopause, natural family planning becomes unreliable due to menstrual cycle irregularity and the increase in anovulatory cycles. As a consequence, interpreting cervical secretions and calendar days is more problematic.[50,210]

5.9.4 Withdrawal

Withdrawal is not promoted as a method of contraception but is used by 4–6% of women in their 40s.[80] It is estimated that with typical use, 20% of all women using withdrawal will become pregnant within 1 year versus 4% with perfect use.[107,211] Perfect use is difficult since it relies on the male partner being able to identify accurately when to withdraw and being compliant. Women should therefore be advised that withdrawal is not considered reliable contraception. Women should also be informed that withdrawal does not protect against STIs.

5.10 Emergency contraception

✓ **Women over 40 who still require contraception should be offered emergency contraception after unprotected sexual intercourse if they do not wish to become pregnant.**

There are no age-related contraindications for emergency contraception (EC) and all women over 40 who still require contraception (see **Sections 3.1** and **Section 6.2**) should be offered EC after UPSI if they do not wish to become pregnant. Women going through perimenopause may still ovulate despite erratic menstruation.

There are currently three methods of EC licensed in the UK: the Cu-IUD, ulipristal acetate EC (UPA-EC) and levonorgestrel EC (LNG-EC). The Cu-IUD is the most effective method, provides immediate ongoing contraception and does not interact with any other medications (see **Section 5.3**). For EC, it can be used up to 5 days after UPSI or up to 5 days after the estimated day of ovulation.

UPA-EC and LNG-EC are oral methods that, unlike the Cu-IUD, have only been demonstrated to be effective if taken prior to ovulation. UPA-EC has been shown to be more effective than LNG-EC; however, concomitant use of progestogen-containing contraception or HRT could reduce the effectiveness of UPA-EC.[212]

Assessing a woman's risk of pregnancy following UPSI depends greatly on where a woman is in her menstrual cycle; women who are nearing or on the day of ovulation are at the greatest risk of pregnancy. For a woman going through perimenopause with erratic menses, estimating the earliest day of ovulation may be more difficult to determine, but a Cu-IUD should always be considered when safe and acceptable as it is the most effective method of EC.

For more detailed guidance on assessing the need for EC and the suitability of the different methods, refer to the FSRH Guideline *Emergency Contraception*.[212]

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5.11 If women experience problems or changes

In addition to the method-specific recommendations, women should be advised that they should return to their HCP at any point if they experience any problems or have any concerns regarding contraception. Women should be offered the opportunity to return to discuss contraception when they reach the age of 50 or if they experience any significant change in their health, including a change in the health of a first-degree relative.

Menstrual bleeding problems and gynaecological pathology are common in women over 40; women should be advised to seek medical advice if they develop new onset of irregular or heavy bleeding or pain. If bleeding problems do not settle following IUC insertion, women should seek further advice from HCPs.[139]

6 When is Contraception No Longer Needed?

6.1 Diagnosing menopause

✓	**Menopause is usually a clinical diagnosis made retrospectively after 1 year of amenorrhoea. Most women do not require measurement of their serum hormone levels to make the diagnosis.**
D	**If needed, women over 50 using progestogen-only contraception, including DMPA, can have serum FSH measurements undertaken to check menopausal status.**
D	**Women using CHC or HRT have suppressed levels of estradiol and gonadotrophins; measuring these hormones does not give accurate information on which to base advice regarding menopausal status and when to stop contraception.**

6.1.1 What happens in perimenopause

Perimenopause is a time of fluctuating hormone levels before a woman reaches the postmenopausal state of permanent sterility. The average duration of perimenopause is around 4 years[49,213] but this can vary greatly. During perimenopause the menstrual pattern is erratic due to variable ovarian function, with spells of both ovulatory and anovulatory cycles. An early perimenopausal change in menstrual pattern is that of shortened cycles, before they lengthen and cease altogether. Anovulatory cycles are characteristically 6–8 weeks in length with heavier and longer menstrual bleeding. Some women experience no change in bleeding pattern and their menstrual periods cease abruptly. Women with a change in their bleeding patterns during perimenopause should seek advice and, if clinically indicated, have a gynaecological review to exclude underlying pathology. Postmenopausal bleeding should always be investigated according to local guidelines.

6.1.2 Measuring hormone levels

Menopause is usually a clinical diagnosis made retrospectively after 1 year of amenorrhoea. Most women do not require measurement of their serum hormone levels to make the diagnosis.[3]

The post-menopause is characterised by low levels of serum estradiol and raised levels of FSH and LH. As a general guide, a serum FSH level >30 IU/L indicates a degree of ovarian insufficiency, but not necessarily sterility.

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During perimenopause, isolated serum estradiol, FSH and LH levels can be misleading and should not be used as a basis for providing advice about stopping contraception; ovulation may still occur with risk of pregnancy, particularly in young women with a diagnosis of premature ovarian insufficiency.[56–58] For this reason, the FSRH suggests restricting measurement of serum FSH for advice about stopping contraception to women over 50 using POC who are amenorrhoeic.

6.1.3 Diagnosing menopause

Although women frequently request them, blood tests are not routinely needed to diagnose menopause. HCPs should focus on a woman's symptoms and needs rather than FSH levels unless they are concerned about premature menopause.

Women using non-hormonal contraception will experience the symptoms and signs of menopause in the same way as women not using any contraception.

Most women using hormonal contraception will have altered bleeding patterns or amenorrhoea and as a result it can be difficult to give accurate advice regarding underlying menopausal status. If needed, women over 50 using POC, including DMPA, who are amenorrhoeic can have serum FSH measurements undertaken to check menopausal status.

Studies have shown that a serum FSH measurement in a woman using any POC may indicate evidence of ovarian insufficiency.[121,214,215] This does not necessarily mean that she can stop contraception (see **Section 6.2**). If a woman is using DMPA and has elevated FSH levels, HCPs can be confident that the increased levels are due to perimenopause. However, DMPA can suppress FSH to some extent which means a woman using DMPA could be menopausal yet show no increase in FSH levels. The optimum time to measure FSH levels in a woman using DMPA is just before a repeat DMPA is administered.[215]

Evidence level 2-

Women using CHC have very suppressed levels of estradiol, FSH and LH even if measured during the HFI, so these cannot be used to inform advice regarding menopausal status.[121,216] Similarly, HRT will moderately suppress estradiol, FSH and LH and perimenopausal women taking sequential HRT will usually continue to have regular withdrawal bleeds.[217,218] Menopausal symptoms will be suppressed by the EE contained within CHC.[157–159,218]

Evidence level 2-

6.2 When should contraception be stopped?

✓	**In general, all women can cease contraception at the age of 55 as spontaneous conception after this age is exceptionally rare even in women still experiencing menstrual bleeding.**
✓	**If a woman age 55 or over does not wish to stop a particular method, consideration can be given to continuation providing the benefits and risks for her as an individual have been assessed and discussed with her.**
D	**IUC should not be left *in situ* indefinitely after it is no longer required as it could become a focus of infection.**

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Table 8: Recommendations regarding stopping contraception

Contraceptive method	Age 40–50 years	Age >50 years
Non-hormonal	Stop contraception after 2 years of amenorrhoea	Stop contraception after 1 year of amenorrhoea.
Combined hormonal contraception	Can be continued	Stop at age 50 and switch to a non-hormonal method or IMP/POP/LNG-IUS, then follow appropriate advice.
Progestogen-only injectable	Can be continued	Women ≥50 should be counselled regarding switching to alternative methods, then follow appropriate advice.
Progestogen-only implant (IMP) **Progestogen-only pill (POP)** **Levonorgestrel intrauterine system (LNG-IUS)**	Can be continued to age 50 and beyond	Stop at age 55 when natural loss of fertility can be assumed for most women. ▶ If a woman over 50 with amenorrhoea wishes to stop before age 55, FSH level can be checked. ▶ If FSH level is >30 IU/L the IMP/POP/LNG-IUS can be discontinued after 1 more year. ▶ If FSH level is in premenopausal range then method should be continued and FSH level checked again 1 year later.
		A Mirena® LNG-IUS inserted ≥45 can remain *in situ* until age 55 if used for contraception or heavy menstrual bleeding.

FSH, follicle-stimulating hormone; IU, international unit.

Although there is very little scientific evidence to inform guidance as to how and when methods of contraception can be discontinued, women often consult HCPs about this and need accurate guidance. Table 8 summarises the suggested guidance.

In general, all women can cease contraception at the age of 55, as spontaneous conception after this age is exceptionally uncommon even in women still experiencing some menstrual bleeding.[219,220] If a woman over 55 does not wish to stop a particular method, consideration can be given to continuation providing the benefits and risks for her as an individual have been assessed and discussed with her.

In terms of IUC, Cu-IUDs can remain *in situ* until diagnosis of menopause if they have been inserted at or after the age of 40.[83] IUC should always be ultimately removed as, if forgotten, it can occasionally become a focus of infection and morbidity in elderly women.[221–225] The LNG-IUS can remain *in situ* for contraception until menopause if inserted at or after the age of 45.

Evidence level 3

There are complexities associated with measuring serum hormone levels in perimenopausal women and advising when to discontinue contraception. This should generally be restricted to women over the age of 50, as they are more likely to be menopausal. For women using POC with amenorrhoea who are keen to stop contraception, it may be helpful to measure a FSH concentration.[214,215] If this is raised then women should be advised to continue contraception for one further year before discontinuing. The GDG group felt that a single FSH measurement in a woman over 50 was acceptable in this situation.

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7 Can Hormone Replacement Therapy be Used Alongside or In Place of Contraception?

D	**Women using sequential hormone replacement therapy (HRT) should be advised not to rely on this for contraception.**
D	**Women may use a Mirena levonorgestrel intrauterine system (LNG-IUS) with estrogen for up to 5 years for endometrial protection as part of an HRT regimen. Women using Mirena for this purpose must have the device changed every 5 years.**
✓	**At the present time, POP, IMP and DMPA are not licensed for and cannot be recommended as endometrial protection with estrogen-only HRT.**
✓	**All progestogen-only methods of contraception are safe to use as contraception alongside sequential HRT.**
✓	**CHC can be used in eligible women under 50 as an alternative to HRT for relief of menopausal symptoms and prevention of loss of BMD.**

7.1 Recommended combinations and duration

7.1.1 HRT

HRT is not a contraceptive method.[3,226] As a result, if women are still perimenopausal or their menopausal status is uncertain, effective contraception should be maintained in conjunction with sequential HRT if women are sexually active.

Evidence level 2-

In a small study of sequential HRT users aged 42–52, 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.[226] Measurement of FSH is unreliable whilst taking HRT as serum levels can be very variable and may be suppressed.

Postmenopausal women do not need to start contraception when they commence HRT as it does not restore fertility even if they experience cyclical bleeding. Continuous combined regimens (which administer both daily estrogen and progestogen) are not appropriate in perimenopause due to a high chance of irregular bleeding. However, because of the effect of the continuous progestogen in these regimens, many HCPs would consider them as having a contraceptive effect. There is no scientific evidence to confirm or refute this assumption but their usage is normally confined to postmenopausal women who, by definition, do not have a requirement for contraception.

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7.1.2 LNG-IUS for HRT

The Mirena LNG-IUS offers an excellent and highly convenient option for both contraception and endometrial protection as part of a HRT regimen. It is a licensed product for endometrial protection when combined with estrogen.[83,84] There are extensive data showing that it is effective in providing protection from the stimulatory effects of estrogen on the endometrium.[99,227–232] Unfortunately the data presented to the regulatory authorities from trials provided evidence of endometrial protection with duration of just less than 5 years. Therefore the LNG-IUS is only licensed for use for 4 years with HRT[84] but most clinicians endorse use for up to 5 years off-label. To guarantee endometrial protection if being used with estrogen for HRT, the device must be changed every 5 years irrespective of the age at time of insertion.

Evidence level 2-

Use of individual contraceptive methods in conjunction with HRT is summarised in **Table 9**.

Table 9: Contraceptive options in conjunction with hormone replacement therapy (HRT)

Contraceptive method	Safety with HRT	Role in HRT	
		Women aged <50	Women aged ≥50
Levonorgestrel intrauterine system (LNG-IUS)	Safe to use as contraception alongside estrogen of choice.	Mirena® is licensed for endometrial protection when combined with estrogen. It is currently the only LNG-IUS approved for this purpose. It may be used up to 5 years for endometrial protection and needs to be replaced regularly when used for this purpose, regardless of age at insertion.	
Progestogen-only injectable (DMPA)	Safe to use as contraception alongside sequential HRT but consider change to lower-dose progestogen-only method.	Highly likely to be effective for endometrial protection with estrogen as part of HRT but cannot be recommended as unlicensed for this indication.	
Progestogen-only implant (IMP)	Safe to use as contraception alongside sequential HRT.	Cannot be recommended at the present time for endometrial protection as part of HRT as no evidence to support efficacy.	
Progestogen-only pill (POP)	Safe to use as contraception alongside sequential HRT.	Cannot be recommended at the present time for endometrial protection as part of HRT as no evidence to support efficacy.	
Combined hormonal contraception (CHC)	Do not use in combination with HRT.	Can be used in eligible women <50 as an alternative to HRT.	Women should be advised to switch to a progestogen-only method of contraception at age 50; see above for alternative options as they relate to HRT.

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7.1.3 Injectable or implant with estrogen as an unlicensed combination

In theory, the progestogen contained within both IMP and DMPA could be used for endometrial protection in conjunction with estrogen as part of a HRT regimen. Bleeding patterns with an IMP and estrogen replacement in the perimenopause are likely to be very erratic, although DMPA with estrogen would almost certainly result in amenorrhoea. There are no data to support endometrial safety with these methods, and as they are not licensed for this use they cannot be recommended at the present time other than by specialist endorsement and informed choice. For convenience, a woman with an IMP could use this in conjunction with standard sequential HRT.

7.1.4 POP

A POP can be used in conjunction with standard sequential HRT to maintain contraceptive cover. This has not been scientifically studied but it is highly likely to offer effective contraception through its local effect on cervical mucus and endometrial receptivity. An older POP is perfectly acceptable in this situation and the more potent anovulatory DSG pill is not required.

7.1.5 CHC

CHC offers effective contraception to perimenopausal women and can be used in eligible women aged under 50 as an alternative to HRT. As it contains estrogen, it will alleviate menopausal symptoms, maintain BMD and control any menstrual problems (see **Section 5.8.1**). HCPs may consider extended or continuous regimens in order to avoid occurrence of menopausal symptoms in the HFI.

Recommendations for Future Research

High-quality studies are needed to inform clinical recommendations. Specific areas for future research are suggested below.

- Use of DMPA in women over 40 and risk of osteoporotic fractures.
- Safety of CHC in women over 50.
- Use of IMP in conjunction with estrogen as a HRT combination.
- Use of DMPA in conjunction with estrogen as a HRT combination.
- Safety profile of COC preparations containing natural estrogens in comparison with traditional oral contraceptive preparations.

Useful Links

- NICE Menopause Guidance
- British Menopause Society
- Menopause Matters
- National Osteoporosis Society

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Appendix 1: FSRH Clinical Guideline Development Process

Who has developed the guideline?

This guideline is produced by the Clinical Effectiveness Unit (CEU) with support from the Clinical Effectiveness Committee (CEC) of the Faculty of Sexual & Reproductive Healthcare (FSRH). The FSRH is a registered charitable organisation which funds the development of its own clinical guidelines. NHS Lothian is contracted to host the CEU in the Chalmers Centre and to provide the CEU's services using ring-fenced funding from the FSRH. No other external funding is received. Chalmers Centre supports the CEU in terms of accommodation, facilities, education, training and clinical advice for the members' enquiry service. As an organisation, NHS Lothian has no editorial influence over CEU guidelines, although staff members may be invited to join the CEU's multidisciplinary guideline development groups (GDGs), in an individual professional capacity.

Development of the guideline was led by the secretariat (CEU staff) and involved the intended users of the guidelines (contraception providers) and patient/service user representatives as part of a multidisciplinary group. The scope of the guideline was informed by a scoping survey conducted amongst members of the FSRH and amongst service users from three sexual and reproductive health services across the UK [Aberdeen Community Health Village (Aberdeen), Scotland; New Croft Centre (Newcastle upon Tyne), England; Victoria Health Centre, Contraception & Sexual Health Clinic (Nottingham), England]. The first draft of the guideline was produced based on the final scope of the guideline agreed by the GDG. The first draft of the guideline (version 0.1) was reviewed by the GDG and a revised draft guideline (version 0.2) was produced in response to comments received, after which it was sent to international and UK-based external independent reviewers suggested by the GDG at the face-to-face meeting. A further revision generated a version of the draft guideline (version 0.3) which was placed on the FSRH website for public consultation between 26 June and 24 July 2017. The revised draft guideline (version 0.4) was sent to the GDG for final comments and to reach consensus on the recommendations (details of this process are given later).

Below is the list of contributors involved in the development of this clinical guideline.

Guideline Development Group (GDG)

Secretariat

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Mrs Valerie Warner Findlay	Researcher, Clinical Effectiveness Unit

Multidisciplinary group

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Declaration of interests

- Dr Currie has received educational grants, advisory board, speaker and advertising fees from pharmaceutical and non-pharmaceutical companies which support the running and development of Menopause Matters Ltd.
- Dr Sauer conducted GP training with LOC IUC which was funded by Bayer.
- Dr Bateson has attended expert forums and presented at educational sessions for Bayer Healthcare and MSD; she has been supported to attend conferences by these two companies but never received any personal remuneration for these services.
- Dr Nelson declares the following interests: Grants/Research: Agile, ContraMed, Bayer, Merck; Honoraria/Speakers Bureau: Allergan, Aspen Pharma, Bayer, Merck; Consultant/Advisory Board: Allergan, Agile, Bayer, ContraMed, Intrarosa, Merck.

Public consultation contributors

The CEU would like to thank the contributors who provided valuable feedback during the public consultation.

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Guideline development methodology

This FSRH guideline was developed in accordance with the standard methodology for developing FSRH clinical guidelines (outlined in the FSRH's *Framework for Clinical Guideline Development* which can be accessed here). The methodology used in the development of this guideline has been accredited by the National Institute for Health and Care Excellence (NICE).

Systematic review of evidence

A systematic review of the literature was conducted to identify evidence to answer the clinical questions formulated and agreed by the GDG. Searches were performed using relevant medical subject headings and free-text terms using the following databases: PubMed, EMBASE, Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews, the Cumulative Index to Nursing and Allied Health Literature (CINAHL) and POPLINE®. Further, the National Guideline Clearinghouse (NGC) and Scottish Intercollegiate Guideline Network (SIGN) were also used to identify relevant guidelines produced by other organisations; these guidelines were checked to identify missing evidence. No language restrictions were applied to the searches.

Search date: The databases were initially searched up to 16 June 2017. The evidence identified up to this point was used to develop the first draft of the guideline. Any evidence published after this date was not considered for inclusion.

Search strategy: The literature search was performed separately for the different sub-categories covered in this clinical guideline. The search terms used are listed on the following page.

Articles identified from the search were screened by title and abstract and full-text copies were obtained if the articles addressed the clinical questions relevant to the guideline. A full critical appraisal of each article was conducted. Studies that did not report relevant outcomes or were not relevant to the clinical questions were excluded. Summary tables of evidence are available upon request.

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CHC use and VTE risk	(combined AND contraception) AND thromboembol* AND age NOT adolescent*
CHC and vasomotor symptoms	vasomotor AND symptoms AND contracept* AND *estrogen [humans]
CHC and bone mineral density	(combined AND hormonal AND contraception) AND bone NOT adolescent*
CHC and reproductive cancers	(combined AND contracept*) AND risk AND (ovarian OR endometrial OR uterine) AND cancer
CHC	“combined hormonal contraception” AND (cardiovascular OR stroke OR arterial OR myocardial)
HRT	"hormone replacement therapy" AND contracept* [humans]
DMPA and bone mineral density	(depot medroxyprogesterone) AND bone density NOT adolescents
DMPA and endometrial cancer	((depo* AND medroxyprogesterone) OR depo-medroxyprogesterone OR depot-medroxyprogesterone) AND contracept* AND (ovary OR ovarian) AND cancer
DMPA and reproductive cancers	Medroxyprogester* AND contracept* AND cancer AND risk NOT HIV NOT replacement
Tamoxifen	tamoxifen AND contracept* AND (breast OR endomet*) [humans]
LNG-IUS and ovarian cancer	levonorgestrel AND intrauterine AND ovarian AND cancer
LNG-IUS and endometrial cancer	(levonorgestrel AND intrauterine AND (device OR system)) AND (endometrial cancer) AND treatment NOT breast
LNG-IUS and breast cancer	levonorgestrel intrauterine AND (breast cancer) NOT tamoxifen

Synthesis of evidence and making clinical recommendation

The recommendations are graded (A, B, C, D and Good Practice Point) according to the level of evidence upon which they are based. The highest level of evidence that may be available depends on the type of clinical question asked. The CEU adopts the comprehensive methodology developed by the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) (http://www.gradeworkinggroup.org/) to assess the strength of the evidence collated and for generating recommendations from evidence.

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The evidence used in this guideline was graded using the scheme below and the recommendations formulated in a similar fashion with a standardised grading scheme.

Classification of evidence levels		Grades of recommendations	
1++	High-quality systematic reviews or meta-analysis of randomised controlled trials (RCTs) or RCTs with a very low risk of bias.	A	At least one systematic review, meta-analysis or RCT rated as 1++, and directly applicable to the target population; *or* A systematic review of RCTs or a body of evidence consisting principally of studies rated as 1+, directly applicable to the target population and demonstrating overall consistency of results.
1+	Well-conducted systematic reviews or meta-analysis of RCTs or RCTs with a low risk of bias.		
1-	Systematic reviews or meta-analysis of RCTs or RCTs with a high risk of bias.		
2++	High-quality systematic reviews of case-control or cohort studies or high-quality case-control or cohort studies with a very low risk of confounding, bias or chance and a high probability that the relationship is causal.	B	A body of evidence including studies rated as 2++ directly applicable to the target population and demonstrating overall consistency of results; *or* Extrapolated evidence from studies rated as 1++ or 1+.
2+	Well-conducted case-control or cohort studies with a low risk of confounding, bias or chance and a moderate probability that the relationship is causal.	C	A body of evidence including studies rated as 2+ directly applicable to the target population and demonstrating overall consistency of results; *or* Extrapolated evidence from studies rated as 2++.
2-	Case-control or cohort studies with a high risk of confounding, bias or chance and a significant risk that the relationship is not causal.	D	Evidence level 3 or 4; *or* Extrapolated evidence from studies rated as 2+.
3	Non-analytical studies (e.g. case report, case series).		
4	Expert opinions.	✓	Good Practice Points based on the clinical experience of the guideline development group.*

*On the occasion when the GDG finds there is an important practical point that they wish to emphasise but for which there is not, nor is there likely to be, any research evidence. This will typically be where some aspect of treatment is regarded as such sound clinical practice that nobody is likely to question it. It must be emphasised that these are NOT an alternative to evidence-based recommendations, and should only be used where there is no alternative means of highlighting the issue.

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Considerations when making recommendations

FSRH clinical guidelines are produced primarily to recommend safe and appropriate clinical practice in relation to the provision of different contraceptive methods. Therefore, when formulating the recommendations, the GDG takes into consideration the health benefits, side effects and other risks associated with implementing the recommendations, based on the available evidence and expert opinion. Further, the GDG takes into consideration the different financial and organisational barriers that clinicians and services may face in the implementation of recommendations to ensure that the recommendations are realistic and achievable.

Reaching consensus on the recommendations

When further revisions based on public consultation feedback have been made, members of the GDG were asked to complete a form to indicate whether they agree or disagree with the recommendations proposed. The consensus process is as follows:

- Consensus will be reached when 80% of the GDG members agree with the recommendation.
- Recommendations where consensus is not reached will be redrafted in light of any feedback.
- The recommendation consensus form will be sent again for all recommendations. Consensus will be reached when 80% of the GDG members agree with the recommendation.
- If consensus is not reached on certain recommendations, these will be redrafted once more.
- If after one more round of consultation, consensus is still not reached, the recommendation will be taken to the CEC for final decision.
- Any group member who is not content with the decision can choose to have their disagreement noted within the guideline.

Updating this guideline

Clinical guidelines are routinely due for update 5 years after publication. The decision as to whether update of a guideline is required will be based on the availability of new evidence published since its publication. Updates may also be triggered by the emergence of evidence expected to have an important impact on the recommendations. The final decision on whether to carry out a full or partial clinical guideline update is taken by the CEU in consultation with the CEC of the FSRH.

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Questions for Continuing Professional Development

The following questions have been developed for continuing professional development (CPD). The answers to the questions and information on claiming CPD points can be found in the 'members-only section' of the FSRH website (www.fsrh.org), which is accessible to all Diplomates, Members, Associate Members and Fellows of the FSRH.

Please choose the single best answer.

1. **Healthcare professionals (HCPs) should advise women that pregnancy and childbirth after age 40 years confer a greater risk of adverse outcomes compared with younger women because:**
    a. The maternal mortality rate for women over 40 is twice that of women aged 20.
    b. There are higher rates of pregnancy-induced hypertension.
    c. The miscarriage rate rises to over 70% for women over 45.
    d. A woman aged 45 has a 1 in 18 chance of having a baby with Down syndrome.

2. **A 44-year-old woman attends for contraception. She states that her periods have become more irregular and heavier over the past year. What can you advise?**
    a. You can advise her that heavy menstrual bleeding (HMB) and abnormal bleeding patterns are more common in women over 40.
    b. Pelvic ultrasound scan and endometrial biopsy may be indicated.
    c. Mirena® and Levosert® are licensed for the management of HMB.
    d. Combined oral contraception (COC) containing estradiol valerate/dienogest is licensed for HMB.
    e. The National Institute for Health and Care Excellence includes all COC as a treatment option for HMB.
    f. All of the above.

3. **Which statement is false? Over the age of 40, women have an increasing risk of:**
    a. Arterial disease
    b. Breast, cervical, endometrial and ovarian cancer
    c. Osteoporotic fractures
    d. Venous thromboembolism.

4. **HCPs do not need to facilitate discussions about safe sex practices with individuals over 40 because women in this age group are more likely to use condoms. This statement is:**
    a. True
    b. False.

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5. **In terms of contraception for women over 40, which statement is true?**
    a. Contraception can be stopped at age 50 as the risk of pregnancy is extremely low.
    b. The progestogen-only implant should be stopped at age 50 as the risk of pregnancy is extremely low.
    c. Women over 40 using the progestogen-only injection should be counselled regarding use of alternative methods of contraception as there are safer methods that are equally effective.
    d. Combined hormonal contraception (CHC) should be stopped at age 50 as there as there are safer methods that are equally as effective.

6. **Which statement is true?**
    a. Ulipristal acetate emergency contraception (UPA-EC) is the most appropriate choice of oral EC for women taking hormone replacement therapy (HRT).
    b. A progestogen-only implant is licensed for use as part of a HRT combination.
    c. Women using sequential HRT cannot rely on this for contraception.
    d. A copper intrauterine device (Cu-IUD) should not be inserted for contraception in women over 50.

7. **It is suggested that women using depot medroxyprogesterone acetate (DMPA) experience initial bone loss due to the hypoestrogenic effects of DMPA but that this initial bone loss is not repeated or worsened by menopause. This statement is:**
    a. True
    b. False.

8. **A 50-year-old woman attends for removal of intrauterine contraception (IUC). She is unsure which device was inserted 5 years previously. She has had irregular, light bleeding for the last couple of years. She takes no medications, but reports menopausal symptoms. Which statement is false?**
    a. A Cu-IUD containing ≥300 mm^2 copper inserted at or after age 40 can remain *in situ* until 1 year after the last menstrual period if it occurs when the woman is 50 or older.
    b. If she considers taking HRT, a Mirena used as part of a HRT combination must be changed every 5 years.
    c. If a Mirena, Levosert or the 13.5 mg levonorgestrel intrauterine system is being used for contraception, it can remain *in situ* until menopause.
    d. If her IUC is removed, she must be advised to use another method of contraception.

9. **A 41-year-old woman on low-dose CHC is concerned about the risk of breast cancer. She has no other risk factors. Which statement is true?**
    a. Meta-analyses, sometimes using older higher-dose formulations, have found a slight increased risk of breast cancer among women currently using COC.
    b. The breast cancer risk remains raised after 10 years of non-use.
    c. Lifetime risk of breast cancer in the UK is currently 1 in 4 women and increases with age.
    d. The risk of breast cancer with a known inherited gene mutation is increased by COC use.

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Auditable Outcomes

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

Auditable outcome	Target
The proportion of women over 40 who have a sexual history/sexually transmitted infection risk assessment prior to intrauterine contraception provision.	97%
The proportion of women over 45 attending to discuss contraception who are provided with information on the symptoms and treatment of common sexual issues associated with perimenopause and menopause.	97%
The proportion of women using hormonal contraception over 50 who have received advice on when to stop their contraceptive method.	97%
The proportion of women over 49 using combined hormonal contraception who have discussed a switch to an alternative, safer method.	100%

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Comments and Feedback on Published Guidelines

All comments on published guidelines 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 and any necessary amendments made subsequently.

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