



The Faculty of Sexual &  
Reproductive Healthcare

# UK MEDICAL ELIGIBILITY CRITERIA

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FOR CONTRACEPTIVE USE | UKMEC 2016

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## The UK medical eligibility criteria for contraceptive use (UKMEC)

The UK Medical Eligibility Criteria for Contraceptive Use (UKMEC) offers guidance to providers of contraception regarding *who can* use contraceptive methods safely. These evidence-based recommendations do not indicate a *best method* for a woman nor do they take into account efficacy (and this includes drug interactions or malabsorption). The recommendations allow for consideration of the possible methods that could be used safely by individuals with certain health conditions (e.g. hypertension) or characteristics (e.g. age) to prevent an unintended pregnancy.

Most contraceptive users are medically fit and can use any available contraceptive method safely. However, some medical conditions are associated with potential or theoretical increased health risks when certain contraceptive methods are used, either because the method adversely affects the condition or because the condition or its treatment affects the safety of the contraceptive. Since most trials of new contraceptive methods deliberately exclude subjects with chronic medical conditions, there is often little direct evidence on which to base accurate prescribing advice.

### Development of the UKMEC

The World Health Organization (WHO) developed a set of internationally agreed norms for providing contraception to individuals with a range of medical conditions that may contraindicate one or more contraceptive methods. The first edition of the WHO Medical Eligibility Criteria for Contraceptive Use (WHOME) was published in 1996. The fifth edition was published in 2015 and is available on the WHO website.<sup>1</sup> The WHOME is primarily intended for use in developing countries where the risks associated with pregnancy are often extremely high but it is the intention of WHO that the guidance be adapted for use in different settings in which the risk benefit ratio of contraceptive methods may differ.

The first edition of the UKMEC was published in 2006 with a grant from the Department of Health (England). The document was widely distributed to clinicians throughout the United Kingdom (UK) with funding from the Department of Health (England), the Scottish Executive (Scotland) and the Faculty of Sexual and Reproductive Healthcare (FSRH). The second edition of the UKMEC<sup>2</sup> was published in 2009. UKMEC 2016 supersedes the second version and has taken account of new evidence included in the WHOME (fifth edition).

The UKMEC update was led by the Clinical Effectiveness Unit (CEU) of the FSRH and involved a guideline development group (GDG) consisting of 19 members (see Appendix 1 for the UKMEC development process and Appendix 2 for the list of contributors). A formal consensus process<sup>3</sup> was used by the GDG with the aim of making the best use of published evidence and capturing the collective knowledge of experts in the fields of sexual and reproductive health and allied specialties to inform the recommendations included in the UKMEC classifications. The changes in UKMEC 2016 from UKMEC 2009 are summarised and highlighted at the end of Section A.

## USING THE UKMEC

The UKMEC considers the following groups of contraceptive methods: intrauterine contraception (IUC), progestogen-only contraception (POC), combined hormonal contraception (CHC) and emergency contraception (EC). The UKMEC categories for each of these groups can be found in Section B, together with evidence summaries and clarifications. Additional comments can be found at the end of each method section. References and additional resources are located in Section C. Commonly used abbreviations are listed in Appendix 3.

### The UKMEC Categories

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 1.

**Table 1: Definition of UKMEC categories**

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

When applied in a clinical setting, a UKMEC Category 1 indicates that there is no restriction for use. A UKMEC Category 2 indicates that the method can generally be used, but more careful follow-up *may* be required. A contraceptive method with a UKMEC Category 3 can be used; however, it may require expert clinical judgement and/or referral to a specialist contraception provider since use is not usually recommended unless other methods are not available or acceptable. A UKMEC Category 4 indicates that use in that condition poses an unacceptable health risk and should not be used.

### Initiation and Continuation of a Method

The initiation (I) and continuation (C) of a method of contraception can sometimes be distinguished and classified differently (see Table 2). The duration of use of a method of contraception prior to the new onset of a medical condition may influence decisions regarding continued use. However, there is no set duration and clinical judgement will be required.

**Table 2: Initiation and continuation of a method by women with a medical condition**

Initiation (I)	Starting a method by a woman with a specific medical condition.
Continuation (C)	Continuing with the method already being used by a woman who develops a new medical condition.

For example, the initiation of a progestogen-only pill (POP) is not restricted in a woman with stroke (cerebrovascular accident) as the advantages of using the method generally outweigh the theoretical or proven risks (UKMEC 2). However, if a woman has a stroke (cerebrovascular accident) while using a POP, the continuation of the method will require expert clinical judgement and/or referral to a specialist contraceptive provider because use of that method is not usually recommended unless other, more appropriate methods are not available or acceptable (UKMEC 3).

### Using the UKMEC Tables

The UKMEC tables are set out as follows (from left to right, see Table 3):

- The first column indicates the **CONDITION**. Each condition is defined as representing either an individual's characteristics (e.g. age, parity) or a known pre-existing medical condition (e.g. diabetes, hypertension). Some conditions are subdivided to differentiate between varying degrees of the condition (e.g. migraine with or without aura).
- The **CATEGORY** (UKMEC 1 to 4) for each **CONDITION** is given for each method of contraception. Occasionally, NA (not applicable) is used, which denotes a condition for which a ranking was not given but for which clarifications have been provided.
- The last column is used to provide **CLARIFICATION** or to make comment on the **EVIDENCE** for the recommendation where appropriate.

**Table 3: Example of tables in UKMEC**

METHOD OF CONTRACEPTION		
CONDITION	CATEGORY I = Initiation, C = Continuation	CLARIFICATION/EVIDENCE
Obesity	Category 1, 2, 3 or 4	Clarifications and evidence regarding the condition or classification

## It is important to note that the UKMEC categories:

- Relate to the **SAFETY** of use of a method of contraception by a woman with a particular medical condition or personal characteristic. The **EFFICACY** of contraception may be affected by the condition or by a medication required for the condition but the UKMEC category does not reflect this.
- Are intended to be applied to use of the method of contraception for contraceptive purposes. Where a method of contraception is used for a non-contraceptive indication [e.g. management of heavy menstrual bleeding (HMB)] the risk/benefit profile and eligibility criteria may differ.
- Cannot simply be added together to indicate the safety of using a method. For example, if a woman has two conditions that are each UKMEC 2 for use of CHC, these should **not** be added to make a UKMEC 4. However, if multiple UKMEC 2 conditions are present that all relate to the same risk, clinical judgement must be used to decide whether the risks of using the method may outweigh the benefits. For example, consider a 34-year-old woman wishing to use CHC who has a body mass index (BMI) of 34 kg/m<sup>2</sup> (UKMEC 2), is a current smoker (UKMEC 2), has a history of superficial venous thrombosis (UKMEC 2), and has a first-degree relative who had a venous thromboembolic event at age 50 years (UKMEC 2), all potential risk factors for venous thromboembolism (VTE). She might be better advised to consider a different method of contraception that does not increase her risk of VTE. When an individual has multiple conditions all scoring UKMEC 3 for a method, use of this method may pose an unacceptable risk; clinical judgement should be used in each individual case.

## Contraceptive Choice

Many factors determine the method of contraception an individual chooses to use. Provided the woman is medically eligible to use a particular method, she should be free to choose the method that is most acceptable to her. To be effective, contraception must be used correctly and consistently. Effective and continued use of a method is directly related to its acceptability to the user.

Women should be given accurate information about all methods for which they are medically eligible and helped to decide which might best suit their needs. Health professionals who give advice about contraception should be competent to give information about the efficacy, risks and side effects, advantages and disadvantages, and non-contraceptive benefits of all available methods.

Information on contraception for women in the UK can be found on the Family Planning Association (fpa) website.<sup>4</sup>

## Effectiveness of Contraceptive Method

Methods that require consistent and correct use by individuals have a wide range of effectiveness and can vary greatly with characteristics such as age, socioeconomic status, users' desires to prevent or delay pregnancy, and culture. Table 4 compares the percentage of women experiencing an unintended pregnancy during the first year of contraceptive use when the method is used 'typically' (which includes both incorrect and inconsistent use) or 'perfectly' (correct and consistent use).<sup>5</sup> Methods considered as long-acting reversible contraception (LARC) are highlighted in Table 4.

**Table 4: Percentage of women experiencing an unintended pregnancy within the first year of use with typical use and perfect use (modified from Trussell et al.)<sup>5</sup>**

Method	Typical use (%)	Perfect use (%)
No method	85	85
Fertility awareness-based methods	24	0.4–5
Female diaphragm	12	6
Male condom	18	2
Combined hormonal contraception (CHC)*	9	0.3
Progestogen-only pill (POP)	9	0.3
<b>Progestogen-only injectable (DMPA)</b>	<b>6</b>	<b>0.2</b>
<b>Copper-bearing intrauterine device (Cu-IUD)</b>	<b>0.8</b>	<b>0.6</b>
<b>Levonorgestrel-releasing intrauterine system (LNG-IUS)</b>	<b>0.2</b>	<b>0.2</b>
<b>Progestogen-only implant (IMP)</b>	<b>0.05</b>	<b>0.05</b>
Female sterilisation	0.5	0.5
Vasectomy	0.15	0.1

\*Includes combined oral contraception (COC), transdermal patch (patch) and vaginal rings.

A pictorial chart on the effectiveness of family planning methods is available from the Centers for Disease Control and Prevention (CDC) website.<sup>6</sup>

## Drug Interactions with Hormonal Contraception

Use of other medications may increase or decrease serum levels of contraceptive hormones; likewise, hormonal contraception may increase or decrease serum levels of other medications. This can potentially cause adverse effects. Health professionals providing hormonal contraception should ask women about their current and previous drug use including prescription, over-the-counter, herbal, recreational drugs, and dietary supplements. Women should be advised to use the most effective methods for them; this may include the additional use of non-hormonal barrier methods when potential drug interactions pose concern.

For further guidance and resources regarding specific contraceptive method/formulation, please refer to

- FSRH guidance on drug interactions with hormonal contraception,<sup>7</sup> available on the FSRH website
- The British National Formulary (BNF) publications and website.<sup>8</sup>
- Summary of product characteristics (SPC), available on electronic Medicine Compendium (eMC) website.<sup>9</sup>

## Online Drug Interaction Checkers

There are online drug interaction checkers available which give useful information on drug interactions. For up-to-date information on the potential drug interactions between hormonal contraception and antiretroviral (ARV) drugs, please refer to the online HIV drugs interaction checker.<sup>10</sup>

For up-to-date information on the potential drug interactions between hormonal contraception and other drugs, please refer to Stockley's Drug Interactions website.<sup>11</sup>

Please note that the contraceptive effectiveness of DMPA and the LNG-IUS is not reduced by concurrent use of enzyme-inducing medications.

If in doubt please refer to the current FSRH Guideline on Drug Interactions with Hormonal Contraception.<sup>7</sup>

## Conditions that May Pose a Significant Health Risk During Pregnancy

Women with conditions that may pose a significant health risk during pregnancy should be advised to consider using the most effective LARC methods, which provide a highly reliable and effective method of contraception (failure rate <1 pregnancy per 100 women in a year). The sole use of barrier methods and user-dependent methods of contraception (e.g. oral contraception) may not be the most appropriate choice for these women given their relatively higher typical-use failure rates.

Some conditions that expose a woman to increased risk as a result of unintended pregnancy include but are not limited to:

- Bariatric surgery within the past 2 years
- Breast cancer
- Cardiomyopathy
- Complicated valvular heart disease
- Cystic fibrosis
- Diabetes: insulin-dependent, or with nephropathy/retinopathy/neuropathy or other vascular disease
- Endometrial or ovarian cancer
- Epilepsy
- Gestational trophoblastic neoplasia
- HIV-related diseases
- Hypertension (systolic >160 mmHg or diastolic >100 mmHg)
- Ischaemic heart disease
- Malignant liver tumours (hepatocellular carcinoma)
- Morbid obesity (BMI  $\geq 40 \text{ kg/m}^2$ )
- Organ failure/transplant
- Rheumatoid arthritis
- Severe (decompensated) cirrhosis
- Sickle cell disease
- Stroke
- Systemic lupus erythematosus (SLE)
- Systemic sclerosis
- Thrombogenic conditions
- Tuberculosis
- Teratogenic drugs (see below)

Women using teratogenic drugs (e.g. methotrexate, some anti-epileptic drugs and retinoids) or drugs with potential teratogenic effects should also be advised to use reliable and effective contraception both during treatment and for the recommended timeframe after discontinuation to avoid unintended pregnancies. More information is available from the UK Teratology Information Service (UKTIS) website.<sup>12</sup>

## Summary of Changes from UKMEC 2009

A total of 27 topics and more than 126 recommendations were reviewed as part of the UKMEC revision. Changes from UKMEC 2009 include the exclusion of some methods and conditions, inclusion of new conditions and ulipristal acetate (UPA) as a new method of EC, removal of split UKMEC categories, revision of sub-conditions and the reordering of the contraceptive methods in the UKMEC tables.

### Method Sections No Longer Included

Comprehensive, method-specific FSRH guidance on barrier methods for contraception and sexually transmitted infection (STI) prevention<sup>13</sup>, fertility awareness methods<sup>14</sup> [including the lactational amenorrhoea method (LAM)], and male and female sterilisation<sup>15</sup> is available on the FSRH website. The GDG considered the sections on these methods in the UKMEC as not particularly helpful and so agreed to remove them.

### Conditions No Longer Included

The following conditions are no longer included in the UKMEC:

**Schistosomiasis and malaria:** These infectious diseases are uncommon in the UK population. Evidence suggests no contraindication to hormonal contraception use with both conditions (UKMEC 1 for all methods in UKMEC 2009). Please refer to the WHOME<sup>1</sup> if required.

**Raynaud's disease/phenomenon:** Expert opinion from UK rheumatologists was that the UKMEC classification given in the UKMEC 2009 was unhelpful/no longer appropriate since the risks associated with Raynaud's disease relate to the underlying disease process rather than the condition itself. Raynaud's disease/phenomenon is therefore no longer included in the UKMEC.

**Drug interactions:** Drug interactions are no longer presented at the end of each method section since the recommendations quickly become outdated as new drugs become available. Where appropriate to a specific condition (e.g. HIV infection or epilepsy), references to the section on drug interactions with hormonal contraception and to relevant online drug interaction checkers are made.

## Inclusion of New Conditions

The new conditions added to the UKMEC include history of bariatric surgery, organ transplant, cardiomyopathy, cardiac arrhythmias, rheumatoid arthritis, and positive antiphospholipid antibodies.

The inclusion of these conditions into the UKMEC reflects increasing prevalence of women with these conditions requesting contraception and the need of contraception providers for guidance.

## Conditions for which there is a Revision of Sub-condition Description

Conditions where the sub-conditions have been revised include postpartum, gestational trophoblastic disease, cervical cancer, HIV infection, and SLE.

Revisions to the sub-condition descriptions have been made to provide guidance that is more specific/ relevant to the sub-population of women with each condition based on new evidence or development of clinical practice/opinion.

## Removal of Split Categories

As they were considered unhelpful, split categories (e.g. UKMEC 2/3 or 3/4) are no longer used in the UKMEC for the following conditions: multiple risk factors for cardiovascular disease, known dyslipidaemias, viral hepatitis (acute or flare) and diabetes (nephropathy/retinopathy/neuropathy and other vascular disease).

Clarifications have been added or expanded upon to aid clinicians in their judgement regarding whether a particular method of contraception is safe and appropriate for a woman.

## Reordering of the Method Categories Presented in the UKMEC Tables

The order of contraceptive methods presented in the UKMEC has been changed to broadly reflect (from left to right) long-acting, medium-acting and short-acting methods of contraception.

## Inclusion of Ulipristal Acetate as New Method of Emergency Contraception

The UKMEC now includes ulipristal acetate (UPA) as a method of EC. The order of the methods presented in the UKMEC table reflects the effectiveness of the method (from left to right): copper-bearing IUD (Cu-IUD), UPA and levonorgestrel (LNG).

Changes to the UKMEC 2009 in the EC section include the addition of obesity as a new condition (UKMEC 1 for all methods) and the expansion of the sub-conditions and UKMEC classification recommendations for gestational trophoblastic disease (GTD).

## SUMMARY OF CHANGES FROM UKMEC 2009

Conditions for which there has been a classification change for one or more methods or a major modification to the condition description are highlighted. Conditions that do not appear below remain unchanged.

Cu-IUD = Copper-bearing intrauterine device; LNG-IUS = Levonorgestrel-releasing intrauterine system; IMP = Progestogen-only implant; DMPA = Progestogen-only injectable: depot medroxyprogesterone acetate; POP = Progestogen-only pill; CHC = Combined hormonal contraception

CONDITION	Cu-IUD	LNG-IUS	IMP	DMPA	POP	CHC
I = Initiation, C = Continuation						

## PERSONAL CHARACTERISTICS AND REPRODUCTIVE HISTORY

<b>Breastfeeding</b>						
a) 0 to <6 weeks	See below	1	2	1	4	
b) ≥6 weeks to <6 months (primarily breastfeeding)		1	1	1	2	
c) ≥6 months		1	1	1	1	
<b>Postpartum</b> (in non-breastfeeding women)						
a) 0 to <3 weeks	See below					
(i) With other risk factors for VTE		1	2	1	4	
(ii) Without other risk factors		1	2	1	3	
b) 3 to <6 weeks	See below					
(i) With other risk factors for VTE		1	2	1	3	
(ii) Without other risk factors		1	1	1	2	
c) ≥6 weeks		1	1	1	1	
<b>Postpartum</b> (in breastfeeding or non breastfeeding women, including post caesarean section)						
a) 0 to <48 hours	1	1	See above			
b) 48 hours to <4 weeks	3	3				
c) ≥4 weeks	1	1				
d) Postpartum sepsis	4	4				

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

CONDITION	Cu-IUD	LNG-IUS	IMP	DMPA	POP	CHC
	I = Initiation, C = Continuation					

History of bariatric surgery						
a) With <30 kg/m <sup>2</sup> BMI	1	1	1	1	1	1
b) With ≥30–34 kg/m <sup>2</sup> BMI	1	1	1	1	1	2
c) With ≥35 kg/m <sup>2</sup> BMI	1	1	1	1	1	3
Organ transplant						
a) Complicated: graft failure (acute or chronic), rejection, cardiac allograft vasculopathy	I	C	I	C	2	2
	3	2	3	2		
b) Uncomplicated	2	2	2	2	2	2
CARDIOVASCULAR DISEASE (CVD)						
Multiple risk factors for cardiovascular disease (such as smoking, diabetes, hypertension, obesity and dyslipidaemias)	1	2	2	3	2	3
Known dyslipidaemias	1	2	2	2	2	2
Cardiomyopathy						
a) Normal cardiac function	1	1	1	1	1	2
b) Impaired cardiac function	2	2	2	2	2	4

Cardiac arrhythmias						
a) Atrial fibrillation	1	2	2	2	2	4
b) Known long QT syndrome	I	C	I	C	1	2
	3	1	3	1		
NEUROLOGICAL CONDITIONS						
Idiopathic intracranial hypertension (IIH)	1	1	1	1	1	2

UKMEC	Definition of category
Category 1	A condition for which there is no restriction for the use of the method
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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

CONDITION	Cu-IUD	LNG-IUS	IMP	DMPA	POP	CHC
	I = Initiation, C = Continuation					

Epilepsy	1	1	1	1	1	1
Taking anti-epileptic drugs	<p>Certain anti-epileptic drugs have the potential to affect the bioavailability of steroid hormones in hormonal contraception. In addition, hormonal contraception may affect the levels of certain anti-epileptic drugs with potential adverse effects.</p> <p>For up-to-date information on the potential drug interactions between hormonal contraception and anti-epileptic drugs, please refer to the online drug interaction checker available on Stockley's Interaction Checker website.<sup>11</sup></p>					

### BREAST AND REPRODUCTIVE TRACT CONDITIONS

Gestational trophoblastic disease (GTD)								
a) Undetectable hCG levels	1	1	1	1	1	1	1	
b) Decreasing hCG levels	3	3	1	1	1	1	1	
c) Persistently elevated hCG levels or malignant disease	4	4	1	1	1	1	1	
Cervical cancer								
a) Awaiting treatment	I 4	C 2	I 4	C 2	2	2	1	2
b) Radical trachelectomy	3	3	2	2	1	1	2	
Breast conditions								
a) Undiagnosed mass/breast symptoms	1	2	2	2	2	I 3	C 2	
b) Benign breast conditions	1	1	1	1	1	1	1	
c) Family history of breast cancer	1	1	1	1	1	1	1	
d) Carriers of known gene mutations associated with breast cancer (e.g. BRCA1/BRCA2)	1	2	2	2	2	3		
e) Breast cancer								
(i) Current breast cancer	1	4	4	4	4	4	4	
(ii) Past breast cancer	1	3	3	3	3	3	3	

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

CONDITION	Cu-IUD	LNG-IUS	IMP	DMPA	POP	CHC
I = Initiation, C = Continuation						

<b>Ovarian cancer</b>	1	1	1	1	1	1
<b>Sexually transmitted infections (STIs)</b>						
a) Chlamydial infection (current)	I	C	I	C		
(i) Symptomatic	4	2	4	2	1	1
(ii) Asymptomatic	3	2	3	2	1	1
b) Purulent cervicitis or gonorrhoea (current)	4	2	4	2	1	1
c) Other current STIs (excluding HIV and hepatitis)	2		2		1	1
d) Vaginitis (including <i>Trichomonas vaginalis</i> and bacterial vaginosis) (current)	2		2		1	1
e) Increased risk for STIs	2		2		1	1
<b>HIV INFECTION</b>						
<b>HIV Infection</b>						
a) High risk of HIV infection	2		2		1	2
b) HIV infected						
(i) CD4 count ≥200 cells/mm <sup>3</sup>	2		2		1	1
(ii) CD4 count <200 cells/mm <sup>3</sup>	I	C	I	C	1	1
	3	2	3	2		
c) Taking antiretroviral (ARV) drugs	<p>Certain ARV drugs have the potential to affect the bioavailability of steroid hormones in hormonal contraception.</p> <p>For up-to-date information on the potential drug interactions between hormonal contraception and ARV drugs, please refer to the online HIV drugs interaction checker.<sup>10</sup></p>					

UKMEC	Definition of category
<b>Category 1</b>	A condition for which there is no restriction for the use of the method
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<b>Category 4</b>	A condition which represents an unacceptable health risk if the method is used

CONDITION	Cu-IUD	LNG-IUS	IMP	DMPA	POP	CHC
I = Initiation, C = Continuation						

<b>ENDOCRINE CONDITIONS</b>						
<b>Diabetes</b>						
a) History of gestational disease		1	1	1	1	1
b) Non-vascular disease						
(i) Non-insulin dependent	1	2	2	2	2	2
(ii) Insulin-dependent	1	2	2	2	2	2
c) Nephropathy/retinopathy/neuropathy	1	2	2	2	2	3
d) Other vascular disease	1	2	2	2	2	3
<b>Viral hepatitis</b>						
a) Acute or flare	1	1	1	1	1	I 3
						C 2
b) Carrier	1	1	1	1	1	1
c) Chronic	1	1	1	1	1	1

<b>RHEUMATIC DISEASES</b>						
<b>Rheumatoid arthritis</b>		1	2	2	2	2
<b>Systemic lupus erythematosus (SLE)</b>						
a) No antiphospholipid antibodies	1	2	2	2	2	2
b) Positive antiphospholipid antibodies	1	2	2	2	2	4
<b>Positive antiphospholipid antibodies</b>	1	2	2	2	2	4
<b>DRUG INTERACTIONS</b>						
<b>Taking medication</b>	See section on drug interactions with hormonal contraception.					

UKMEC	Definition of category
<b>Category 1</b>	A condition for which there is no restriction for the use of the method
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<b>Category 4</b>	A condition which represents an unacceptable health risk if the method is used

## SECTION B: METHODS OF CONTRACEPTION

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## INTRAUTERINE CONTRACEPTION (IUC)

Intrauterine contraception (IUC) is highly effective and long-acting. The licensed duration of use of IUC ranges from 3 to 10 years. IUC is significantly more cost effective than shorter-acting methods due to very low failure rates and requirement for very minimal action by the user apart from undergoing the initial insertion procedure.

IUC comprises two types:

- Copper-bearing intrauterine device (Cu-IUD)
- Levonorgestrel-releasing intrauterine system (LNG-IUS).

FSRH guidance on IUC<sup>1</sup> is available on the FSRH website.

### **Copper-bearing intrauterine device (Cu-IUD)**

Cu-IUDs have copper on their central stems and may also be banded with copper sleeves on the arms. The surface area from which copper is released varies between devices. In general, banded Cu-IUDs which have the higher surface areas of copper are the most effective and long-lasting so are recommended as the first-choice copper devices.

### **Levonorgestrel-releasing intrauterine system (LNG-IUS)**

Several LNG-IUS devices are now available with two dosages of LNG. The 13.5 mg LNG-IUS (releasing 6 µg LNG/day) is licensed for 3 years and the 52 mg LNG-IUS (releasing 20 µg LNG/day) for 5 years. Although there are significantly more data for the 52 mg LNG-IUS, the categories within the UKMEC can be extrapolated to the 13.5 mg LNG-IUS.

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	Cu-IUD	LNG-IUS	

PERSONAL CHARACTERISTICS AND REPRODUCTIVE HISTORY			
<b>Pregnancy</b>	NA	NA	<p><b>Clarification:</b> Most pregnancies which occur in women using IUC will be intrauterine, but ectopic pregnancy must be excluded.</p> <p>Women who become pregnant whilst using IUC should be informed of the increased risks of second-trimester septic miscarriage, preterm delivery and infection if the IUC is left <i>in situ</i>. Women who are pregnant with IUC <i>in situ</i> and wish to continue with the pregnancy should be informed that, when possible, IUC removal reduces the risk of an adverse outcome. However, removal itself carries a small risk of miscarriage. Whether or not IUC is removed, pregnant women should be advised to seek medical care if they develop heavy bleeding, cramping pain, abnormal vaginal discharge or fever.<sup>1</sup></p>
<b>Age</b>			
a) Menarche to <20 years	2	2	<p><b>Evidence:</b> Risks of pregnancy, infection and perforation are low among IUC users of all ages. Removals for bleeding issues do not appear to be related to age. Younger women using IUC may have an increased risk of expulsion compared with older women.<sup>2-18</sup></p>
b) ≥20 years	1	1	
<b>Parity</b>			
a) Nulliparous	1	1	<p><b>Evidence:</b> Risks for expulsion, perforation, pregnancy and infection are low among all IUC users and differences by parity may not be clinically meaningful. Data do not suggest an increased delay in return to fertility for nulliparous IUC users.<sup>2,4,8-11</sup></p>
b) Parous	1	1	

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<b>Postpartum</b> (in breastfeeding or non-breastfeeding women, including post-caesarean section)			
a) 0 to <48 hours	1	1	<b>Evidence:</b> A systematic review concludes that insertion of an IUC within the first 48 hours of vaginal or caesarean delivery is safe. Post-placental insertion and insertion between 10 minutes and 48 hours after delivery result in higher expulsion rates than insertion 4–6 weeks postpartum or non-postpartum insertion. Insertion at the time of a caesarean section is associated with lower expulsion rate than post-placental insertion at the time of vaginal delivery. <sup>19</sup>
b) 48 hours to <4 weeks	3	3	There are limited data on insertion between 48 hours and 4 weeks. Three cohort studies <sup>20–22</sup> of poor to fair quality compare outcomes of post-placental Cu-IUD insertion with insertion between 10 minutes and 72 hours after delivery. The studies show a wide range of expulsion rates; one study reports an expulsion rate of >70%. <sup>22</sup>
c) ≥4 weeks	1	1	The rate of uterine perforation associated with IUC use is very low. The most important risk factors for uterine perforation are insertion during lactation and insertion in the 36 weeks after giving birth. <sup>23</sup>
d) Postpartum sepsis	4	4	The majority of studies show no significant differences in breastfeeding outcomes in women using LNG-IUS with insertion either immediately postpartum or after 4 weeks. <sup>24–30</sup>  <b>Clarification:</b> Immediate insertion of an IUC may substantially worsen the condition.

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<b>Post-abortion</b>			
a) First trimester	1	1	
b) Second trimester	2	2	<p><b>Evidence:</b> IUC can be inserted immediately after first- or second-trimester, surgical or medical abortion.<sup>31</sup></p> <p><b>Evidence:</b> There is no difference in risk of complications for immediate versus delayed insertion of an IUC after abortion. Expulsion may be greater when an IUC is inserted following a second-trimester abortion versus following a first-trimester abortion.<sup>31-50</sup></p>
c) Post-abortion sepsis	4	4	<b>Clarification:</b> Immediate insertion of an IUC may substantially worsen the condition.
<b>Past ectopic pregnancy</b>	1	1	
<b>History of pelvic surgery</b>	1	1	
<b>Smoking</b>			<p><b>Clarification:</b> UKMEC currently does not include use of e-cigarettes, as risks associated with their use are not yet established.</p> <p><b>Evidence:</b> COC users who smoke are at an increased risk of CVD, especially MI, compared with those who do not smoke. Studies also show an increased risk of MI with an increasing number of cigarettes smoked per day.<sup>23-34</sup></p> <p>The 35 year age cut off is identified because any excess mortality associated with smoking is only apparent from this age.<sup>51</sup> The mortality rate from all causes (including cancers) decreases to that of a non-smoker within 20 years of smoking cessation. The cardiovascular disease (CVD) risk associated with smoking decreases within 1 to 5 years of smoking cessation.<sup>51-53</sup></p>
a) Age <35 years	1	1	
b) Age ≥35 years			
(i) <15 cigarettes/day	1	1	
(ii) ≥15 cigarettes/day	1	1	
(iii) Stopped smoking <1 year	1	1	
(iv) Stopped smoking ≥1 year	1	1	

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<b>Obesity</b>				
a) BMI $\geq 30\text{--}34 \text{ kg/m}^2$	1	1		
b) BMI $\geq 35 \text{ kg/m}^2$	1	1		
<b>History of bariatric surgery</b>				
a) With BMI $<30 \text{ kg/m}^2$	1	1		
b) With BMI $\geq 30\text{--}34 \text{ kg/m}^2$	1	1		
c) With BMI $\geq 35 \text{ kg/m}^2$	1	1		
<b>Organ transplant</b>				
a) Complicated: graft failure (acute or chronic), rejection, cardiac allograft vasculopathy	<b>I</b>	<b>C</b>	<b>I</b>	<b>C</b>
	3	2	3	2
b) Uncomplicated	2		2	
<b>CARDIOVASCULAR DISEASE (CVD)</b>				
<b>Multiple risk factors for CVD</b> (such as smoking, diabetes, hypertension, obesity and dyslipidaemias)	1	2		

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<b>Hypertension*</b>				<b>Clarification:</b> For all categories of hypertension, classifications are based on the assumption <b>that no other risk factor for CVD exists</b> . When multiple risk factors do exist, risk of CVD may increase substantially.  <i>Vascular disease</i> includes coronary heart disease presenting with angina, peripheral vascular disease presenting with intermittent claudication, hypertensive retinopathy and TIA.
a) Adequately controlled hypertension	1	1		
b) Consistently elevated blood pressure (BP) levels (properly taken measurements)				
(i) Systolic >140–159 mmHg or diastolic >90–99 mmHg	1	1		
(ii) Systolic ≥160 mmHg or diastolic ≥100 mmHg	1	1		
c) Vascular disease	1	2		
<b>History of high BP during pregnancy</b>	1	1		<b>Clarification:</b> When current BP is measurable and normal.
<b>Current and history of ischaemic heart disease*</b>	1	I 2	C 3	<b>Clarification:</b> LNG-IUS may be continued if women develop ischaemic heart disease while using the method. Clinical judgement and assessment of pregnancy risk and other factors are required.
<b>Stroke*</b> [history of cerebrovascular accident, including transient ischaemic attack (TIA)]	1	I 2	C 3	
<b>Known dyslipidaemias</b>	1	2		<b>Clarification:</b> Routine screening for these genetic mutations is not cost effective. Increased levels of total cholesterol, low-density lipoproteins (LDL) and triglycerides, as well as decreased levels of high-density lipoproteins (HDL), are known risk factors for CVD. Women with known, severe, genetic lipid disorders are at a much higher lifetime risk for CVD and may warrant further clinical consideration.

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<b>Venous thromboembolism (VTE)*</b>			
a) History of VTE	1	2	<b>Clarification:</b> VTE includes deep vein thrombosis (DVT) and pulmonary embolism (PE) of any aetiology.
b) Current VTE (on anticoagulants)	1	2	<b>Evidence:</b> Limited evidence indicates that insertion of the LNG-IUS does not pose major bleeding risks in women on long-term anticoagulant therapy. <sup>58-60</sup>
c) Family history of VTE			
(i) First-degree relative age <45 years	1	1	
(ii) First-degree relative age ≥45 years	1	1	
d) Major surgery			<b>Clarifications:</b>
(i) With prolonged immobilisation	1	2	<b>Major surgery:</b> Includes major elective surgery (>30 minutes' duration) and all surgery on the legs, or surgery which involves prolonged immobilisation of a lower limb. <sup>61</sup>
(ii) Without prolonged immobilisation	1	1	<b>Minor surgery:</b> Includes operations lasting <30 minutes with a short duration of anaesthesia (e.g. laparoscopic sterilisation or tooth extraction). <sup>61</sup>
e) Minor surgery without immobilisation	1	1	
f) Immobility (unrelated to surgery) (e.g. wheelchair use, debilitating illness)	1	1	
<b>Superficial venous thrombosis</b>			
a) Varicose veins	1	1	
b) Superficial venous thrombosis	1	1	
<b>Known thrombogenic mutations</b> (e.g. factor V Leiden, prothrombin mutation, protein S, protein C and antithrombin deficiencies)	1	2	<b>Clarification:</b> Routine screening for these genetic mutations is not cost effective. <sup>62-89</sup>

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<b>Valvular and congenital heart disease</b>			
a) Uncomplicated	1	1	<p><b>Clarification:</b> Uncomplicated cases can be considered where: there is (i) no requirement for cardiac medication, (ii) the woman is asymptomatic and (iii) a cardiology review is required annually or less. If in doubt, discussion with a specialist cardiologist is advised.</p> <p><i>Valvular heart disease:</i> Occurs when any of the heart valves are stenotic and/or incompetent (e.g. aortic stenosis, mitral regurgitation, tricuspid valve abnormalities, pulmonary stenosis).<sup>90</sup></p> <p><i>Congenital heart disease:</i> Aortic stenosis, atrial septal defects, atrioventricular septal defect, cardiomyopathy (hypertrophic or dilated), coarctation of the aorta, complex transposition of the great arteries, Ebstein's anomaly; Eisenmenger syndrome, patent ductus arteriosus, pulmonary atresia, pulmonary stenosis, tetralogy of Fallot, total anomalous pulmonary venous connection, tricuspid atresia, truncus arteriosus, ventricular septal defect.<sup>90</sup></p> <p>Prophylaxis against bacterial endocarditis is no longer indicated for women with artificial heart valves or previous endocarditis when inserting or removing IUC.<sup>91,92</sup> However, this does not necessarily mean that there is no risk.<sup>1</sup></p>
b) Complicated (e.g. pulmonary hypertension, history of subacute bacterial endocarditis)	2	2	

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<b>Cardiomyopathy</b>			
a) Normal cardiac function	1	1	<b>Clarification:</b> A woman who is not on cardiac medication can be considered as having normal cardiac function.
b) Impaired cardiac function	2	2	<b>Evidence:</b> No direct evidence exists on the safety of IUC among women with cardiomyopathy. Limited indirect evidence from non-comparative studies does not demonstrate any cases of arrhythmia or infective endocarditis in women with cardiac disease who used IUC. <sup>93,94</sup>  <b>Clarification:</b> IUC insertion may induce cardiac arrhythmias in women with cardiomyopathy. The IUC should be fitted in a hospital setting as a vasovagal reaction presents a particularly high risk of cardiac events. <sup>91</sup>
<b>Cardiac arrhythmias</b>			
a) Atrial fibrillation	1	2	
b) Known long QT syndrome	<b>I</b> 3	<b>C</b> 1	<b>Clarification:</b> Cervical stimulation during the insertion of intrauterine methods can cause a vasovagal reaction including bradycardia, which increases the risk of a cardiac event in women with long QT syndrome. The IUC should be fitted in a hospital setting if vasovagal reaction presents a particularly high risk of cardiac events. <sup>91</sup>

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NEUROLOGICAL CONDITIONS			
<b>Headaches</b>			
a) Non-migrainous (mild or severe)	1	1	<b>Clarification:</b> Headache is a common condition affecting women of reproductive age. There is no identified evidence which specifically considers migraine in women using an LNG-IUS.
b) Migraine without aura, at any age	1	2	
c) Migraine with aura, at any age	1	2	Classification depends on making an accurate diagnosis of those severe headaches that are migrainous and, in addition, those complicated by aura. <sup>95-97</sup>
d) History ( $\geq 5$ years ago) of migraine with aura, any age	1	2	See additional resource on diagnosis of migraines with or without aura.
<b>Idiopathic intracranial hypertension (IIH)</b>	1	1	
<b>Epilepsy</b>	1	1	
Taking anti-epileptic drugs	Certain anti-epileptic drugs have the potential to affect the bioavailability of steroid hormones in hormonal contraception. Additionally, hormonal contraception may affect the levels of certain anti-epileptic drugs with potential adverse effects.  For up-to-date information on the potential drug interactions between hormonal contraception and anti-epileptic drugs, please refer to the online drug interaction checker available on Stockley's Interaction Checker website. <sup>98</sup>		
DEPRESSIVE DISORDERS			
<b>Depressive disorders</b>	1	1	<b>Clarification:</b> The classification is based on data for women with selected depressive disorders. No data are available on bipolar disorder or postpartum depression.

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<b>BREAST AND REPRODUCTIVE TRACT CONDITIONS</b>					
<b>Vaginal bleeding patterns*</b>					
a) Irregular pattern without heavy bleeding	1		1		<b>Clarification:</b> Abnormal menstrual bleeding should raise suspicion of a serious underlying condition and be investigated appropriately. <sup>99–102</sup>
b) Heavy or prolonged bleeding (includes regular and irregular patterns)	2	I 1	C 2		<b>Evidence:</b> Evidence from studies examining the treatment effects of the 52 mg LNG-IUS among women with heavy or prolonged bleeding report no increase in adverse effects and finds the 52 mg LNG-IUS beneficial in treating heavy menstrual bleeding (HMB). <sup>103–110</sup>
<b>Unexplained vaginal bleeding (suspicious for serious condition) before evaluation</b>	I 4	C 2	I 4	C 2	<b>Clarification:</b> If pregnancy or an underlying pathological condition (such as pelvic malignancy) is suspected, it must be evaluated and the category adjusted accordingly. The IUC does not need to be removed before evaluation.
<b>Endometriosis*</b>	2		1		<b>Evidence:</b> 52 mg LNG-IUS use among women with endometriosis decreases dysmenorrhoea, pelvic pain and dyspareunia. <sup>111–115</sup>
<b>Benign ovarian tumours (including cysts)</b>	1		1		
<b>Severe dysmenorrhoea*</b>	2		1		

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<b>Gestational trophoblastic disease (GTD)*</b>				<b>Clarification:</b> Includes hydatidiform mole (complete and partial) and gestational trophoblastic neoplasia.
a) Undetectable hCG levels	1	1		
b) Decreasing hCG levels	3	3		
c) Persistently elevated hCG levels or malignant disease	4	4		<b>Evidence:</b> Limited evidence suggests that women using an IUC after uterine evacuation for a molar pregnancy are at no greater risk for gestational trophoblastic neoplasia than are women using other methods of contraception. <sup>116–119</sup>
<b>Cervical ectropion</b>	1	1		
<b>Cervical intraepithelial neoplasia (CIN)*</b>	1	2		
<b>Cervical cancer*</b>				
a) Awaiting treatment	I	C	I	C
	4	2	4	2
b) Radical trachelectomy	3	3		<b>Clarification:</b> Insertion of IUC should be conducted with caution in a specialist setting due to abnormal anatomy.

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<b>Intrauterine Contraception (IUC)</b>  Copper-bearing IUD (Cu-IUD) Levonorgestrel-releasing IUS (LNG-IUS)	<b>IUC does not protect against STI/HIV. If there is a risk of STI/HIV (including during pregnancy or postpartum), the correct and consistent use of condoms is recommended, either alone or with another method of contraception. Male condoms reduce the risk of STI/HIV.</b>		
<b>CONDITION</b>  *See additional comments at end of section	<b>CATEGORY</b> <b>I = Initiation, C = Continuation</b>		<b>CLARIFICATION/EVIDENCE</b>
	<b>Cu-IUD</b>	<b>LNG-IUS</b>	

<b>Breast conditions</b>				
a) Undiagnosed mass/breast symptoms	1	2		<b>Clarification:</b> Breast cancer is a hormonally sensitive tumour. Concerns about progression of the disease may be less with LNG-IUS than with COC or higher-dose POC.
b) Benign breast conditions	1	1		
c) Family history of breast cancer	1	1		
d) Carriers of known gene mutations associated with breast cancer (e.g. BRCA1/BRCA2)	1	2		Use of the LNG-IUS in women with breast cancer for gynaecological reasons can be considered on an individual basis in consultation with the woman's oncology team. <sup>1</sup>
e) Breast cancer				
(i) Current breast cancer	1	4		
(ii) Past breast cancer	1	3		
<b>Endometrial cancer*</b>	I 4	C 2	I 4	C 2
<b>Ovarian cancer*</b>	1		1	
<b>Uterine fibroids</b>				
a) Without distortion of the uterine cavity	1	1		<b>Evidence:</b> Among women with uterine fibroids, evidence shows no adverse health events with 52 mg LNG-IUS use and a decrease in symptoms and size of fibroid. Most women experience improvements in serum levels of haemoglobin, haematocrit, ferritin and menstrual blood loss. <sup>120–131</sup>

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b) With distortion of the uterine cavity	3	3	<p><b>Clarification:</b> In women with a distorted uterine cavity it may be appropriate to attempt insertion of IUC after discussion.</p> <p><b>Evidence:</b> Available studies show that rates of 52 mg LNG-IUS expulsion are higher in women with uterine fibroids than in women without fibroids; however, these findings are either not statistically significant or significance testing was not conducted.<sup>129, 132</sup> Rates of expulsion from non-comparative studies ranged from 0% to 20%.<sup>126-131</sup></p>
<b>Anatomical abnormalities</b>			
a) Distorted uterine cavity	3	3	<p><b>Clarification:</b> Includes any congenital or acquired uterine abnormality distorting the uterine cavity in a manner that is incompatible with IUC insertion.</p> <p>In some women with a distorted uterine cavity it may be appropriate to attempt insertion of IUC after discussion.</p>
b) Other abnormalities	2	2	<p><b>Clarification:</b> Includes cervical stenosis or cervical lacerations not distorting the uterine cavity or interfering with IUC insertion.</p>

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	Cu-IUD	LNG-IUS		

Pelvic inflammatory disease (PID)	1		1		<b>Clarification:</b> <b>Initiation:</b> For routine IUC insertion, women with symptomatic pelvic infection should be tested for and treated. Insertion should be delayed until symptoms have resolved. Appropriate provision of alternative contraception should be provided until the IUC can be inserted. <sup>1</sup>  <b>Continuation:</b> For women with symptomatic pelvic infection, treat using appropriate antibiotics and perform testing for STIs. There is usually no need to remove the IUC if the woman wishes to continue its use. <sup>1</sup> Continued use of an IUC depends on the woman's informed choice and her current risk factors for STIs and PID. Among IUC users treated for PID, there is no difference in clinical course if the IUC is removed or left in place. <sup>133–135</sup>
a) PID (assuming no current risk factors for STIs)	1		1		
b) Current PID	I 4	C 2	I 4	C 2	

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<b>Sexually transmitted infections (STIs)</b>				
a) Chlamydial infection (current)	I 4 (i) Symptomatic	C 2 (ii) Asymptomatic	I 4 b) Purulent cervicitis or gonorrhoea (current)	C 2 c) Other current STIs (excluding HIV and hepatitis)
d) Vaginitis (including <i>Trichomonas vaginalis</i> and bacterial vaginosis) (current)	2	2	2	2

**Clarification for chlamydia:** In a woman with asymptomatic infection in an emergency situation (i.e. EC), the IUC can be inserted without delay on the same day as treatment is instituted.<sup>1</sup>

**Clarification for Initiation:** Screening for STIs in advance of insertion (when indicated or requested) will allow infection to be treated before insertion. If results are unavailable before insertion then prophylactic antibiotics should be considered for women at higher risk of STIs at time of insertion. The antibiotic regimen chosen should cover *Chlamydia trachomatis*.

**Clarification for continuation:** Treat the STI using appropriate antibiotics. The IUC usually does not need to be removed if the woman wishes to continue using it. Continued use of an IUC depends on the woman's informed choice and her current risk factors for STIs and PID.<sup>1</sup>

**Evidence:** There is no evidence whether IUC insertion among women who contract STIs increases the risk for PID over that of women with no IUC insertion. Among women who have IUC inserted, the absolute risk for subsequent PID is low among women with an STI at the time of insertion but greater than among women with no STI at the time of IUC insertion.<sup>136–145</sup>

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e) Increased risk for STIs	2	2	<p><b>Clarification:</b> IUC insertion may further increase the risk of PID among women at increased risk of STIs, although limited evidence suggests that this risk is low. Risk of STIs varies by individual behaviour and local STI prevalence. Therefore, while many women at increased risk of STIs can have IUC inserted, some women at very high risk of STIs may be advised to wait appropriate testing and treatment occur.</p> <p><b>Evidence:</b> One small study shows a low incidence of PID after IUC insertion (2.2%) in a cohort of women considered to be high risk.<sup>137</sup> Another study reports that 11% of women classed as at high STI risk experienced IUC-related complications compared with 5% of those not classified as high risk.<sup>141</sup></p>
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<b>HIV INFECTION</b>			
HIV infection*			
a) High risk of HIV infection	2	2	<p><b>Evidence:</b> Among women at risk for HIV, Cu-IUD use does not increase risk of HIV acquisition.<sup>146–156</sup></p>
b) HIV infected			

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(i) CD4 count ≥200 cells/mm <sup>3</sup>	2	2	<b>Clarification:</b> The initiation of an IUC method may be appropriate in some women with low CD4 counts who have an undetectable viral load.  <b>Evidence:</b> Among IUC users, limited evidence shows no increased risk of infection or overall complications when comparing HIV-infected with non-infected women. IUC use is not found to adversely affect progression of HIV when compared to hormonal contraception use among HIV-infected women. IUC use among HIV-infected women is not associated with increased risk of transmission to sexual partners. <sup>157–165</sup> No difference is found in antiretroviral therapy initiation or CD4 count between users and non-users of the LNG-IUS. <sup>166</sup>			
(ii) CD4 count <200 cells/mm <sup>3</sup>	I 3	C 2	I 3	C 2		
c) Taking antiretroviral (ARV) drugs	Certain ARV drugs have the potential to affect the bioavailability of steroid hormones in hormonal contraception.  For up-to-date information on the potential drug interactions between hormonal contraception and ARV drugs, please refer to the online HIV drugs interaction checker. <sup>167</sup>					
<b>OTHER INFECTIONS</b>						
<b>Tuberculosis*</b>						
a) Non-pelvic	1	1				
b) Pelvic	I 4	C 3	I 4	C 3		

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<b>ENDOCRINE CONDITIONS</b>			
<b>Diabetes</b>			
a) History of gestational disease	1	1	
b) Non-vascular disease			
(i) Non-insulin dependent	1	2	
(ii) Insulin-dependent	1	2	<b>Evidence:</b> Limited evidence on the use of the LNG-IUS among women with insulin-dependent or non-insulin-dependent diabetes suggests that these methods have little effect on short- or long-term diabetes control (e.g. glycosylated haemoglobin levels), haemostatic markers or lipid profile. <sup>168,169</sup>
c) Nephropathy/retinopathy/neuropathy	1	2	
d) Other vascular disease	1	2	
<b>Thyroid disorders</b>			
a) Simple goitre	1	1	
b) Hyperthyroid	1	1	
c) Hypothyroid	1	1	
<b>GASTROINTESTINAL CONDITIONS</b>			
<b>Gallbladder disease</b>			
a) Symptomatic			
(i) Treated by cholecystectomy	1	2	
(ii) Medically treated	1	2	
(iii) Current	1	2	
b) Asymptomatic	1	2	

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<b>History of cholestasis</b>			
a) Pregnancy related	1	1	
b) Past-COC related	1	2	
<b>Viral hepatitis*</b>			
a) Acute or flare	1	1	
b) Carrier	1	1	
c) Chronic	1	1	
<b>Cirrhosis*</b>			
a) Mild (compensated without complications)	1	1	<b>Clarification:</b> Severe ( <i>decompensated cirrhosis</i> : development of major complications (ascites, jaundice, encephalopathy or gastrointestinal haemorrhage). <sup>170</sup> )
b) Severe (decompensated)	1	3	
<b>Liver tumours*</b>			
a) Benign			
(i) Focal nodular hyperplasia	1	2	
(ii) Hepatocellular adenoma	1	3	
b) Malignant (hepatocellular carcinoma)	1	3	
<b>Inflammatory bowel disease (IBD)*</b> (including Crohn's Disease and ulcerative colitis)	1	1	
<b>ANAEMIAS</b>			
<b>Thalassaemia*</b>	2	1	
<b>Sickle cell disease*</b>	2	1	

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<b>Iron deficiency anaemia*</b>	2	1	
<b>RHEUMATIC DISEASES</b>			
<b>Rheumatoid arthritis</b>	1	2	
<b>Systemic lupus erythematosus (SLE)</b>			<b>Clarification:</b> People with SLE are at increased risk of ischaemic heart disease, stroke and VTE and this is reflected in the categories given.
a) No antiphospholipid antibodies	1	2	
b) Positive antiphospholipid antibodies	1	2	Available evidence indicates that many women with SLE can be considered good candidates for most methods of contraception, including hormonal contraception. <sup>171–189</sup>
<b>Positive antiphospholipid antibodies</b>	1	2	<b>Clarification:</b> Positive antiphospholipid antibodies (aPL) is not itself a disease state and in the absence of manifestations of the antiphospholipid syndrome a stratification of risk with specialist advice if necessary is recommended. In particular, persistence of aPL positivity, high titre of aPL, lupus anticoagulant (LA) positivity, triple positivity for anticardiolipin antibodies (aCL), anti-β2-glycoprotein I (β2gPI) and LA and immunoglobulin G (IgG) aPL have greater risk for future events. <sup>190–192</sup>
<b>DRUG INTERACTIONS</b>			
<b>Taking medication</b>	See section on drug interactions with hormonal contraception.		

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## Additional Comments

### HYPERTENSION, CURRENT AND HISTORY OF ISCHAEMIC HEART DISEASE, STROKE

There is theoretical concern about the effect of LNG on lipids. There is no restriction for Cu-IUD.

### VENOUS THROMBOEMBOLISM (VTE)

The LNG-IUS may be a useful treatment for HMB in women on long-term anticoagulation therapy.

### VAGINAL BLEEDING PATTERNS

LNG-IUS use frequently causes changes in menstrual bleeding patterns. Over time, LNG-IUS users are more likely than non-users to become amenorrhoeic particularly if they have a 52 mg LNG-IUS fitted. 52mg LNG-IUS are used as a treatment for HMB.

### ENDOMETRIOSIS

Cu-IUD use may worsen dysmenorrhoea associated with the condition.

### SEVERE DYSMENORRHOEA

Dysmenorrhoea may intensify with Cu-IUD use. LNG-IUS use has been associated with reduction of dysmenorrhoea.

### GESTATIONAL TROPHOBLASTIC DISEASE (GTD)

There is theoretical concern about increased risk of perforation in the presence of persistent molar tissue.

### CERVICAL INTRAEPITHELIAL NEOPLASIA (CIN)

There is some theoretical concern that progestogens may enhance progression of CIN.

### CERVICAL CANCER

**Awaiting treatment:** There is concern about the increased risk of infection and bleeding at insertion. The IUC may need to be removed at the time of treatment but, until then, the woman is at risk of pregnancy.

### ENDOMETRIAL CANCER

There is concern about the increased risk of infection, perforation and bleeding at insertion.

The IUC may need to be removed at the time of treatment but, until then, the woman is at risk of pregnancy.

## **OVARIAN CANCER**

The IUD may need to be removed at the time of treatment but, until then, the woman is at risk of pregnancy.

## **HIV INFECTION**

Women with HIV infection often have co-morbidities that may influence their choice of contraception.

## **TUBERCULOSIS**

**Pelvic:** Insertion of an IUC may substantially worsen the condition.

## **VIRAL HEPATITIS AND CIRRHOSIS**

POC are metabolised by the liver and their use may adversely affect women whose liver function is compromised.

## **LIVER TUMOURS**

POC are metabolised by the liver and their use may adversely affect women whose liver function is compromised. No evidence is available regarding hormonal contraceptive use in women with hepatocellular adenoma. COC use is associated with growth of hepatocellular adenoma, but it is still unknown whether other hormonal contraceptives have similar effects.

## **INFLAMMATORY BOWEL DISEASE (IBD)**

Risk of VTE may increase in women who are unwell, bed-bound or undergoing emergency or major surgery and prolonged immobilisation. Under these circumstances the use of the Cu-IUD or LNG-IUS is safe.

## **THALASSAEMIA, SICKLE CELL DISEASE, IRON-DEFICIENCY ANAEMIA**

There is concern about an increased risk of blood loss with Cu-IUD. However, LNG-IUS is generally associated with reduced blood loss.

## Progestogen-only Contraception (POC)

The section on progestogen-only contraception (POC) includes the following methods:

- Progestogen-only implant (IMP)
- Progestogen-only injectable: depot medroxyprogesterone acetate (DMPA)
- Progestogen-only pill (POP).

FSRH guidance on the IMP,<sup>1</sup> progestogen-only injectable<sup>2</sup> and POP<sup>3</sup> is available on the FSRH website.

### Progestogen-only implant (IMP)

The recommendations in the UKMEC refer to the single-rod implant containing 68 mg etonogestrel licensed for 3 years of use in the UK. For women using LNG implants the UKMEC categories are considered the same as for etonogestrel implants.

### Progestogen-only injectables: depot medroxyprogesterone acetate (DMPA)

The recommendations in the UKMEC refer to DMPA given intramuscularly (IM) or subcutaneously (SC) at 13-weekly intervals.<sup>2</sup>

The available evidence reviewed by the UKMEC GDG suggests that DMPA-SC and DMPA-IM appear to be therapeutically equivalent with similar safety profiles when used by healthy women. The GDG considers the evidence available for DMPA-IM to be applicable to DMPA-SC and, therefore, DMPA-SC should have the same categories as DMPA-IM. This is presented in the UKMEC tables as the method 'DMPA'. For women using intramuscular norethisterone enantate (NET-EN), which is not licensed in the UK for long-term contraception, the UKMEC categories are considered the same as for DMPA.

There are theoretical concerns that higher doses of progestogen in injectables and longer duration of action may be associated with increased risk compared to IMP and POP in some conditions. The higher UKMEC classifications reflect this.

### **Progestogen-only pill (POP)**

The recommendations in the UKMEC refer to the POP currently available in the UK which contain either norethisterone (NET) 350 µg, LNG 30 µg or desogestrel (DSG) 75 µg.

Theoretically, the DSG pill may be expected to be more effective than traditional POP, especially with typical use, because ovulation is suppressed more consistently and it has a longer missed pill window.<sup>4</sup>

Progestogen-only Contraception (POC) Progestogen-only pill (POP) Progestogen-only injectable: depot medroxyprogesterone acetate (DMPA) Progestogen-only implant (IMP)	POC do not protect against STI/HIV. If there is a risk of STI/HIV (including during pregnancy or postpartum), the correct and consistent use of condoms is recommended, either alone or with another contraception method. Male condoms reduce the risk of STI/HIV.		
<b>CONDITION</b> <small>*See additional comments at end of section</small>	<b>CATEGORY</b> <small>I = Initiation, C = Continuation</small>		<b>CLARIFICATION/EVIDENCE</b>
	IMP	DMPA	

PERSONAL CHARACTERISTICS AND REPRODUCTIVE HISTORY				
Pregnancy	NA	NA	NA	<b>Clarification:</b> There is no known harm to the woman, the course of pregnancy or the fetus if POC is accidentally used during pregnancy.
Age				
a) Menarche to <18 years	1	2	1	<b>Clarification:</b> A guideline from the National Institute for Health and Care Excellence (NICE) recommends that women should be informed that use of DMPA is associated with a small reduction in bone mineral density (BMD) but this usually recovers after discontinuation. Evidence for any long-term effects of DMPA on BMD in women aged <18 years is lacking. <sup>5</sup>  Evidence on long-term fracture risk is sparse but women choosing to continue DMPA should be reviewed every 2 years to assess individual situations and to discuss the risks and benefits. Women should be supported in their choice of whether or not to continue. <sup>2</sup> In women aged <18 years, DMPA can be used as a first-line option after consideration of other methods. <sup>6</sup>
b) 18–45 years	1	1	1	
c) >45 years	1	2	1	
Parity				
a) Nulliparous	1	1	1	
b) Parous	1	1	1	

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<b>Postpartum (in breastfeeding women)</b>				
a) 0 to <6 weeks	1	2	1	<b>Evidence:</b> Direct evidence demonstrates no harmful effect of POC on breastfeeding performance <sup>7-54</sup> and generally demonstrates no harmful effects on infant growth, health or development. <sup>15,30,39,45</sup>
b) ≥6 weeks to <6 months (primarily breastfeeding)	1	1	1	
c) ≥6 months	1	1	1	
<b>Postpartum (in non-breastfeeding women)</b>				
a) 0 to <3 weeks				<b>Clarification:</b> This includes any births, including stillbirths from 24 weeks' gestation.
(i) With other risk factors for VTE	1	2	1	
(ii) Without other risk factors	1	2	1	
b) 3 to <6 weeks				<b>Clarification:</b> POC may be safely used by non-breastfeeding women immediately postpartum, although they are not required for contraception until Day 21. <sup>55,56</sup>
(i) With other risk factors for VTE	1	2	1	
(ii) Without other risk factors	1	1	1	
c) ≥6 weeks	1	1	1	<b>Clarification:</b> Other risk factors for VTE, such as immobility, transfusion at delivery, BMI >30 kg/m <sup>2</sup> , postpartum haemorrhage, immediately post-caesarean delivery, pre-eclampsia or smoking may pose an additional increased risk for VTE.
<b>Post-abortion</b>				
a) First trimester	1	1	1	<b>Clarification:</b> Includes induced abortions and spontaneous miscarriages <24 weeks' gestation.
b) Second trimester	1	1	1	
c) Post-abortion sepsis	1	1	1	

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Past ectopic pregnancy	1	1	1	<b>Clarification:</b> All POC reduce the risk of pregnancy (intrauterine and extrauterine).
History of pelvic surgery	1	1	1	
Smoking				<b>Clarification:</b> UKMEC currently does not include use of e-cigarettes, as risks associated with their use are not yet established.
a) Age <35 years	1	1	1	
b) Age ≥35 years				
(i) <15 cigarettes/day	1	1	1	
(ii) ≥15 cigarettes/day	1	1	1	POC do not appear to increase the risk of CVD even in smokers. <sup>58–61</sup>
(iii) Stopped smoking <1 year	1	1	1	
(iv) Stopped smoking ≥1 year	1	1	1	The mortality rate from all causes (including cancers) decreases to that of a non-smoker within 20 years of smoking cessation. The CVD risk associated with smoking decreases within 1 to 5 years of smoking cessation. <sup>61–64</sup> The 35 year age cut-off is identified because any excess mortality associated with smoking is only apparent from this age. <sup>64</sup>
Obesity				
a) BMI ≥30–34 kg/m <sup>2</sup>	1	1	1	<b>Evidence:</b> Weight gain is common. Among adult women, there is generally no association between baseline weight and weight gain among DMPA users compared with non-users. Evidence is mixed for adolescent DMPA users, with some studies observing greater weight gain among obese women compared with normal weight users, yet other studies showing no association. Data on other POC methods and weight issues are limited. <sup>65–82</sup>
b) BMI ≥35 kg/m <sup>2</sup>	1	1	1	

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History of bariatric surgery				
a) With BMI <30 kg/m <sup>2</sup>	1	1	1	<b>Clarification:</b> Bariatric surgical procedures involving a malabsorptive component have the potential to decrease oral contraception effectiveness, perhaps further decreased by postoperative complications such as long-term diarrhoea and/or vomiting.
b) With BMI ≥30–34 kg/m <sup>2</sup>	1	1	1	
c) With BMI ≥35 kg/m <sup>2</sup>	1	1	1	<b>Evidence:</b> Limited evidence demonstrates no substantial decrease in effectiveness of oral contraception among women who underwent laparoscopic placement of an adjustable gastric band. <sup>83</sup>  Limited evidence demonstrates no substantial decrease in effectiveness of oral contraception among women who undergo a biliopancreatic diversion; <sup>84</sup> however, evidence from pharmacokinetic studies suggests conflicting results of oral contraception effectiveness among women who undergo a jejunoo-ileal bypass. <sup>85,86</sup>
Organ transplant				
a) Complicated: graft failure (acute or chronic), rejection, cardiac allograft vasculopathy	2	2	2	
b) Uncomplicated	2	2	2	
CARDIOVASCULAR DISEASE (CVD)				
Multiple risk factors for CVD (such as smoking, diabetes, hypertension, obesity and dyslipidaemias)	2	3	2	<b>Clarification:</b> When multiple major risk factors exist, the risk of CVD may increase substantially.

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Hypertension*				
a) Adequately controlled hypertension	1	2	1	For all categories of hypertension, classifications are based on the assumption <b>that no other risk factor for CVD exist</b> . When multiple risk factors do exist, risk of CVD may increase substantially.  <b>Clarification:</b> Women adequately treated for hypertension are at a reduced risk of acute myocardial infarction (MI) and stroke compared with untreated hypertensive women. Although there are no data, POC users with adequately controlled and monitored hypertension should be at reduced risk of acute MI and stroke compared with untreated hypertensive POC users. Antihypertensive therapy may be initiated when the BP is consistently 160/100 mmHg or greater. <sup>87</sup>
b) Consistently elevated BP levels (properly taken measurements)				
(i) Systolic >140–159 mmHg or diastolic >90–99 mmHg	1	1	1	
(ii) Systolic ≥160 mmHg or diastolic ≥100 mmHg	1	2	1	
c) Vascular disease	2	3	2	<b>Evidence:</b> Limited evidence suggests that among women with hypertension, those who used POP or DMPA have a small increased risk of cardiovascular events compared with women who do not use these methods. <sup>58</sup>

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History of high BP during pregnancy	1	1	1	Clarification: Where current BP is measurable and normal.
Current and history of ischaemic heart disease*	I	C	3	Clarification: The duration of use of POC in relation to the onset of disease should be carefully considered when deciding whether or not continuation of the method is appropriate.
	2	3		
Stroke* (history of cerebrovascular accident, including TIA)	I	C	3	Evidence: Cohort studies do not show an increased risk of MI and stroke in users of POC. <sup>58,88</sup>
	2	3		
Known dyslipidaemias	2	2	2	Clarification: Routine screening for these genetic mutations is not cost effective.  Increased levels of total cholesterol, LDL and triglycerides, as well as decreased levels of HDL, are known risk factors for CVD. Women with known, severe, genetic lipid disorders are at much higher lifetime risk for CVD and may warrant further clinical consideration.
Venous thromboembolism (VTE)				
a) History of VTE	2	2	2	Clarification: Includes DVT and PE.
b) Current VTE (on anticoagulants)	2	2	2	Evidence: There is no direct evidence on the use of POC among women with DVT/PE on anticoagulant therapy. Although evidence on the risk of VTE with the use of POC is inconsistent in otherwise healthy women, any small increased risk is substantially less than that with COC. <sup>58,88,89</sup> Limited evidence indicates that DMPA-IM in women on chronic anticoagulation therapy does not pose a significant risk of haematoma at the injection site or increase the risk of heavy or irregular vaginal bleeding. <sup>90,91</sup>

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c) Family history of VTE				
(i) First-degree relative age <45 years	1	1	1	
(ii) First-degree relative age ≥45 years	1	1	1	
d) Major surgery				<b>Major surgery:</b> Includes major elective surgery (>30 minutes' duration) and all surgery on the legs, or surgery which involves prolonged immobilisation of a lower limb. <sup>92</sup>
(i) With prolonged immobilisation	2	2	2	
(ii) Without prolonged immobilisation	1	1	1	
e) Minor surgery without immobilisation	1	1	1	
f) Immobility (unrelated to surgery) (e.g. wheelchair use, debilitating illness)	1	1	1	<b>Minor surgery:</b> Includes operations lasting <30 minutes with short duration of anaesthesia (e.g. laparoscopic sterilisation or tooth extraction). <sup>92</sup>
<b>Superficial venous thrombosis</b>				
a) Varicose veins	1	1	1	
b) Superficial venous thrombosis	1	1	1	
<b>Known thrombogenic mutations</b> (e.g. factor V Leiden, prothrombin mutation, protein S, protein C and antithrombin deficiencies)	2	2	2	<b>Clarification:</b> Routine screening for these genetic mutations is not cost effective. <sup>93–95</sup>

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Valvular and congenital heart disease*				
a) Uncomplicated	1	1	1	<p><b>Clarification:</b> Uncomplicated cases can be considered where: there is (i) no requirement for cardiac medication, (ii) the woman is asymptomatic and (iii) a cardiology review is required annually or less. If in doubt, discussion with a specialist cardiologist is advised.</p> <p><i>Valvular heart disease:</i> Occurs when any of the heart valves are stenotic and/or incompetent (e.g. aortic stenosis, mitral regurgitation, tricuspid valve abnormalities, pulmonary stenosis).<sup>96</sup></p> <p><i>Congenital heart disease:</i> Aortic stenosis, atrial septal defects, atrioventricular septal defect, cardiomyopathy (hypertrophic or dilated), coarctation of the aorta, complex transposition of the great arteries, Ebstein's anomaly, Eisenmenger syndrome, patent ductus arteriosus, pulmonary atresia, pulmonary stenosis, tetralogy of Fallot, total anomalous pulmonary venous connection, tricuspid atresia, truncus arteriosus, ventricular septal defect.<sup>96</sup></p>
b) Complicated (e.g. pulmonary hypertension, history of subacute bacterial endocarditis)	1	1	1	

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Cardiomyopathy				
a) Normal cardiac function	1	1	1	<b>Clarification:</b> A woman who is not on cardiac medication can be considered as having normal cardiac function.
b) Impaired cardiac function	2	2	2	<b>Evidence:</b> No direct evidence exists on the safety of POC among women with cardiomyopathy. Limited indirect evidence from non-comparative studies of women with cardiac disease demonstrates few cases of hypertension, thromboembolism and heart failure in women with cardiac disease using POP and DMPA. <sup>97,98</sup>
Cardiac arrhythmias				
a) Atrial fibrillation	2	2	2	
b) Known long QT syndrome	1	2	1	<b>Evidence:</b> Case reports suggest exacerbation of LQTS2 with use of DMPA as postpartum contraception. <sup>99,100</sup>

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NEUROLOGICAL CONDITIONS			
<b>Headaches</b>			
a) Non-migrainous (mild or severe)	1	1	1
b) Migraine without aura, at any age	2	2	<b>I</b> <b>C</b> 1    2
c) Migraine with aura, at any age	2	2	2
d) History ( $\geq 5$ years ago) of migraine with aura, any age	2	2	2
<b>Idiopathic intracranial hypertension (IIH)</b>	1	1	1
<b>Epilepsy</b>	1	1	1
Taking anti-epileptic drugs	<p>Certain anti-epileptic drugs have the potential to affect the bioavailability of steroid hormones in hormonal contraception. In addition, hormonal contraception may affect the levels of certain anti-epileptic drugs with potential adverse effects.</p> <p>For up-to-date information on the potential drug interactions between hormonal contraception and anti-epileptic drugs, please refer to the online drug interaction checker available on Stockley's Interaction Checker website.<sup>104</sup></p>		
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<b>Depressive disorders</b>	1	1	1	<p><b>Clarification:</b> The classification is based on data for women with selected depressive disorders. No data are available on bipolar disorder or postpartum depression.</p> <p><b>Evidence:</b> POC use is not shown to increase depressive symptoms in women with depression compared with baseline.<sup>105-108</sup></p>
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<b>BREAST AND REPRODUCTIVE TRACT CONDITIONS</b>				
<b>Vaginal bleeding patterns</b>				
a) Irregular pattern without heavy bleeding	2	2	2	<p><b>Clarification:</b> Abnormal menstrual bleeding should raise suspicion of a serious underlying condition and be investigated appropriately.<sup>109,110</sup></p> <p>Bleeding patterns in women using POC are often altered particularly in the initial months of use and may not settle with time.<sup>110</sup></p>
b) Heavy or prolonged bleeding (includes regular and irregular patterns)	2	2	2	
<b>Unexplained vaginal bleeding*</b> (suspicious for serious condition) before evaluation	3	3	2	<p><b>Clarification:</b> If pregnancy or an underlying pathological condition (such as pelvic malignancy) is suspected, it must be evaluated and the category adjusted after evaluation.<sup>110</sup></p>
<b>Endometriosis</b>	1	1	1	
<b>Benign ovarian tumours</b> (including cysts)	1	1	1	
<b>Severe dysmenorrhoea</b>	1	1	1	

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<b>Gestational trophoblastic disease (GTD)</b>				
a) Undetectable hCG levels	1	1	1	<b>Clarification:</b> Includes hydatidiform mole (complete and partial) and gestational trophoblastic neoplasia.  A small study which included women using POP and DMPA concluded that current use of hormonal contraception is not associated with development of gestational trophoblastic neoplasia or delayed time to hCG remission. <sup>111</sup>
b) Decreasing hCG levels	1	1	1	
c) Persistently elevated hCG levels or malignant disease	1	1	1	
<b>Cervical ectropion</b>	1	1	1	
<b>Cervical intraepithelial neoplasia (CIN)</b>	1	2	1	<b>Evidence:</b> Among women with persistent human papilloma virus (HPV) infection, long-term DMPA use ( $\geq 5$ years) may increase the risk of carcinoma <i>in situ</i> and invasive carcinoma. <sup>112</sup>
<b>Cervical cancer*</b>				
a) Awaiting treatment	2	2	1	<b>Clarification:</b> There is some theoretical concern that POC use could affect prognosis of the existing disease. While awaiting treatment, women may use POC.
b) Radical trachelectomy	2	2	1	

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<b>Breast conditions</b>				
a) Undiagnosed mass/breast symptoms	2	2	2	<b>Clarification:</b> Breast cancer is a hormonally sensitive tumour and therefore the prognosis of women with current or past breast cancer may be affected by hormonal methods of contraception.
b) Benign breast conditions	1	1	1	
c) Family history of breast cancer	1	1	1	
d) Carriers of known gene mutations associated with breast cancer (e.g. BRCA1/BRCA2)	2	2	2	
e) Breast cancer				<b>Clarification:</b> For women with a history of breast cancer, the decision to initiate hormonal contraception may be best made in consultation with the local oncology team.
(i) Current breast cancer	4	4	4	
(ii) Past breast cancer	3	3	3	
<b>Endometrial cancer*</b>	1	1	1	
<b>Ovarian cancer*</b>	1	1	1	
<b>Uterine fibroids</b>				
a) Without distortion of the uterine cavity	1	1	1	
b) With distortion of the uterine cavity	1	1	1	
<b>Pelvic inflammatory disease (PID)</b>				
a) Past PID (assuming no current risk factors for STIs)	1	1	1	
b) Current PID	1	1	1	

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<b>CONDITION</b> <small>*See additional comments at end of section</small>	<b>CATEGORY</b> <small>I = Initiation, C = Continuation</small>		<b>CLARIFICATION/EVIDENCE</b>
	IMP	DMPA	

Sexually transmitted infections (STIs)				
a) Chlamydial infection (current)				
(i) Symptomatic	1	1	1	<b>Evidence:</b> Limited evidence suggests that there may be an increased risk of chlamydial cervicitis among DMPA users at high risk of STIs. For other STIs, there is either evidence of no association between DMPA use and STI acquisition or evidence that is too limited to draw any conclusions. There is no evidence for other POC. <sup>113-119</sup>
(ii) Asymptomatic	1	1	1	
b) Purulent cervicitis or gonorrhoea (current)	1	1	1	
c) Other current STIs (excluding HIV and hepatitis)	1	1	1	
d) Vaginitis (including <i>Trichomonas vaginalis</i> and bacterial vaginosis) (current)	1	1	1	
e) Increased risk for STIs	1	1	1	

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<b>HIV INFECTION</b>				
<b>HIV infection*</b>				
a) High risk of HIV infection	1	2	1	<p><b>Clarification:</b> There continues to be evidence of a possible increased risk of acquiring HIV among progestogen-only injectable users. Uncertainty exists about whether this is due to methodological issues with the evidence or a real biological effect. In many settings, unintended pregnancies and/or pregnancy-related morbidity and mortality are common, and progestogen-only injectables are among the few types of methods widely available. Women should not be denied the use of progestogen-only injectables because of concerns about the possible increased risk. Women considering progestogen-only injectables should be advised about these concerns, about the uncertainty over whether there is a causal relationship, and about how to minimise their risk of acquiring HIV.</p> <p><b>Evidence:</b> Evidence from 13 observational studies of DMPA, NET-EN or non-specified progestogen-only injectables, which were considered to be "informative but with important limitations",<sup>120</sup> continue to show some association between use of progestogen-only injectables and risk of HIV acquisition, but it remains unclear whether this results from a causal relationship or methodological limitation. Two small studies assessing levonorgestrel implants, which were considered to be "informative but with important limitations"<sup>120</sup> did not suggest an elevated risk, although the risk estimates were imprecise. One study reported no association between use of progestogen-only pills and HIV acquisition.<sup>120</sup></p>

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b) HIV infected				<b>Evidence:</b> Five studies suggest no association between use of progestogen-only injectables and progression of HIV, as measured by CD4 count <200 cells/mm <sup>3</sup> , initiation of ART or mortality. <sup>121–127</sup> One randomised trial shows an increased risk of a composite outcome of declining CD4 count or death among oral contraceptive users (COC and POP) when compared with users of Cu-IUDs, but has significant confounders limiting its interpretation. <sup>128,129</sup>  Most indirect studies measuring whether various hormonal contraception methods affect plasma HIV viral load find no effect. <sup>130–146</sup>
(i) CD4 count ≥200 cells/mm <sup>3</sup>	1	1	1	
(ii) CD4 count <200 cells/mm <sup>3</sup>	1	1	1	
c) Taking antiretroviral (ARV) drugs				Certain ARV drugs have the potential to affect the bioavailability of steroid hormones in hormonal contraception.  For up-to-date information on the potential drug interactions between hormonal contraception and ARV drugs, please refer to the online HIV drugs interaction checker. <sup>147</sup>
<b>OTHER INFECTIONS</b>				
Tuberculosis				
a) Non-pelvic	1	1	1	
b) Pelvic	1	1	1	

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ENDOCRINE CONDITIONS				
<b>Diabetes*</b>				
a) History of gestational disease	1	1	1	<b>Evidence:</b> POC has no adverse effects on serum lipid levels in women with a history of gestational diabetes according to two small studies. <sup>148,149</sup> Limited evidence is inconsistent regarding the development of non-insulin dependent diabetes among users of POC with a history of gestational diabetes. <sup>150–154</sup>
b) Non-vascular disease				
(i) Non-insulin dependent	2	2	2	<b>Evidence:</b> Among women with insulin or non-insulin dependent diabetes, limited evidence on the use of POC suggests that these methods have little effect on short-term or long-term diabetes control (e.g. HbA1c levels), haemostatic markers or lipid profile. <sup>154–157</sup>
(ii) Insulin-dependent	2	2	2	
c) Nephropathy/retinopathy/neuropathy	2	2	2	
d) Other vascular disease	2	2	2	
<b>Thyroid disorders</b>				
a) Simple goitre	1	1	1	
b) Hyperthyroid	1	1	1	
c) Hypothyroid	1	1	1	

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<b>GASTROINTESTINAL CONDITIONS</b>				
<b>Gallbladder disease</b>				
a) Symptomatic				
(i) Treated by cholecystectomy	2	2	2	
(ii) Medically treated	2	2	2	
(iii) Current	2	2	2	
b) Asymptomatic	2	2	2	
<b>History of cholestasis*</b>				
a) Pregnancy related	1	1	1	
b) Past-COC related	2	2	2	
<b>Viral hepatitis*</b>				
a) Acute or flare	1	1	1	
b) Carrier	1	1	1	
c) Chronic	1	1	1	
<b>Cirrhosis*</b>				
a) Mild (compensated without complications)	1	1	1	<b>Clarification:</b> Severe ( <i>decompensated</i> ) cirrhosis: development of major complications (ascites, jaundice, encephalopathy or gastrointestinal haemorrhage). <sup>158</sup>
b) Severe (decompensated)	3	3	3	

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Liver tumours*				
a) Benign				
(i) Focal nodular hyperplasia	2	2	2	
(ii) Hepatocellular adenoma	3	3	3	
b) Malignant (hepatocellular carcinoma)	3	3	3	<b>Evidence:</b> There is limited direct evidence that hormonal contraception use does not influence either progression or regression of liver lesions among women with focal nodular hyperplasia. <sup>159-161</sup> There is no evidence relating to use of hormonal contraception by women with other liver tumours.
<b>Inflammatory bowel disease (IBD)*</b> (including Crohn's disease and ulcerative colitis)	1	1	2	<b>Evidence:</b> Risk for disease relapse among women with IBD using oral contraception (most studies do not specify whether it is POP or COC) does not increase significantly from that for non-users. <sup>162-166</sup>
<b>ANAEMIAS</b>				
<b>Thalassaemia</b>	1	1	1	
<b>Sickle cell disease</b>	1	1	1	<b>Evidence:</b> One systematic review concludes that among women with sickle cell disease, POC use does not have adverse effects on haematological parameters and, in some studies, proves beneficial with respect to clinical symptoms. <sup>167-175</sup>
<b>Iron deficiency anaemia</b>	1	1	1	

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<b>RHEUMATIC DISEASES</b>				
Rheumatoid arthritis	2	2	2	<p><b>Clarification:</b> Risk of CVD is increased among women with rheumatoid arthritis.<sup>176</sup> There is no evidence that POC are associated with reduced BMD or fragility fractures in women with rheumatoid arthritis.</p> <p><b>Evidence:</b> Limited evidence shows no consistent pattern of improvement or worsening of rheumatoid arthritis with use of oral contraception.<sup>177-184</sup> (most studies do not specify whether it is POP or COC).</p>
Systemic lupus erythematosus (SLE)				<p><b>Clarification:</b> Women with SLE are at an increased risk of ischaemic heart disease, stroke and VTE and this is reflected in the categories given.</p>
a) No antiphospholipid antibodies	2	2	2	
b) Positive antiphospholipid antibodies	2	2	2	Available evidence indicates that many women with SLE can be considered good candidates for most methods of contraception, including hormonal contraception. <sup>185-204</sup>
Positive antiphospholipid antibodies	2	2	2	<p><b>Clarification:</b> Positive antiphospholipid antibodies (aPL) is not itself a disease state and in the absence of manifestations of the antiphospholipid syndrome a stratification of risk with specialist advice, if necessary, is recommended. In particular, persistence of aPL positivity, high titre of aPL, lupus anticoagulant (LA) positivity, triple positivity for anticardiolipin antibodies (aCL), anti-β2-glycoprotein I (β2gPI) and LA and immunoglobulin G (IgG) aPL have greater risk for future events.<sup>205-207</sup></p>
<b>DRUG INTERACTIONS*</b>				
Taking medication	See section on drug interactions with hormonal contraception.			

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## Additional Comments

### HYPERTENSION

A single reading of BP level is not sufficient to classify a woman as hypertensive. If elevated, the BP should be reassessed at the end of the consultation. If BP is increased, it should be re-assessed and monitored according to current guidelines.

### CARDIOVASCULAR DISEASE, ISCHAEMIC HEART DISEASE AND STROKE

There is concern regarding hypoestrogenic effects and reduced HDL levels among users of DMPA. However, there is little concern about these effects with regard to POP or IMP. The effects of DMPA may persist for some time after discontinuation.

### VALVULAR AND CONGENITAL HEART DISEASE, CARDIOMYOPATHY AND CARDIAC ARRHYTHMIAS

Stasis, endothelial injury and hyperviscosity (Virchow's triad) increase the risk of clot formation. Impaired cardiac function and/or dilated heart chambers or arrhythmia increase the risk of stasis. Closure of a cardiac defect within the last 6 months or presence of a mechanical heart valve increase the risk of thrombus formation. Cyanotic defects are associated with hyperviscosity because of erythrocytosis.

### UNEXPLAINED VAGINAL BLEEDING

POC may cause irregular bleeding patterns which may mask symptoms of underlying pathology. The effects of DMPA may persist for some time after discontinuation.

### CERVICAL, ENDOMETRIAL AND OVARIAN CANCER

While awaiting treatment, women with gynaecological cancers may use POC since the period of waiting is likely to be brief and pregnancy would be contraindicated.

### CERVICAL CANCER

There is some theoretical concern that POC use could affect prognosis of cervical cancer.

### HIV INFECTION

Women at high risk of HIV infection should be informed that progestogen-only injectables may or may not increase their risk of HIV acquisition. Women and couples at high risk of HIV acquisition considering DMPA should also be informed about and have access to HIV preventive measures, including male and female condoms.

Women with HIV infection often have co-morbidities that may influence their choice of contraception.

## **DIABETES**

There is concern regarding hypoestrogenic effects and reduced HDL levels among users of DMPA. The effects of DMPA may persist for some time after discontinuation.

## **HISTORY OF CHOLESTASIS**

Theoretically, a history of COC-related cholestasis may predict subsequent cholestasis with POC use.

## **VIRAL HEPATITIS AND CIRRHOSIS**

POC are metabolised by the liver and their use may adversely affect women whose liver function is compromised. This concern is similar to, but less than, that with COC.

## **LIVER TUMOURS**

Progestogens are metabolised by the liver and use may adversely affect women whose liver function is compromised.

## **INFLAMMATORY BOWEL DISEASE (IBD)**

Risk of VTE may increase if a woman is unwell, bed-bound or undergoing acute surgery, or with major surgery and prolonged immobilisation. Under these circumstances, POC can be continued.

Oral methods may be less reliable if there is significant malabsorption or small bowel resection (particularly with Crohn's disease). Oral methods are unaffected by colectomy and ileostomy.

## **DRUG INTERACTIONS**

Generally, the safety of using POC is unaffected. Nevertheless, use of liver enzyme inducers may reduce contraception efficacy of POP and IMP, increasing the risk of an unintended pregnancy. DMPA is unaffected by liver enzyme inducing drugs and injection intervals need not be reduced. Contraception choice may depend on the likely duration of use of concurrent medications and need for additional or alternative methods.

## Combined Hormonal Contraception (CHC)

The section on combined hormonal contraception (CHC) includes the following types:

- Combined oral contraception (COC)
- Combined contraception transdermal patches
- Combined contraception vaginal rings.

FSRH guidance on CHC<sup>1</sup> is available on the FSRH website .

### Combined oral contraception (COC)

The recommendations in the UKMEC refer to low-dose combined oral contraception (COC) containing  $\leq 35 \mu\text{g}$  ethinylestradiol (EE) combined with a progestogen. Data relating to newer COC containing estradiol are very limited. Currently, UKMEC recommendations for these preparations are as for EE-containing COC. Recommendations in the UKMEC are the same for all COC formulations, irrespective of their progestogen content.

Venous thromboembolism (VTE) is rare among women of reproductive age. All COC are associated with an increased risk for VTE compared to non-use. Studies have found differences in risk for VTE associated with COC containing different progestogens. Current evidence suggests that COC containing LNG, NET and norgestimate are associated with the lowest risk. The absolute differences, however, are very small.<sup>2</sup>

### Combined contraceptive transdermal patch and vaginal rings

The combined contraceptive patch and ring are relatively new contraception methods. Limited information is available on the short- and long-term safety of these methods among women with specific medical conditions. Most of the available studies received support from the manufacturers of these methods.

After reviewing the available limited evidence, the UKMEC GDG considers the evidence available for COC to be applicable to the combined contraceptive patch and ring, and therefore should have the same categories as COC. This is presented in the UKMEC tables as the method 'CHC'.

Combined Hormonal Contraception (CHC) which includes  Combined oral contraception (COC) Combined contraceptive transdermal patch and vaginal ring	CHC do not protect against STI/HIV. If there is a risk of STI/HIV (including during pregnancy or postpartum), the correct and consistent use of condoms is recommended, either alone or with another contraception method. Male condoms reduce the risk of STI/HIV.	
<b>CONDITION</b> *See additional comments at end of section	<b>CATEGORY</b> I = Initiation C = Continuation	<b>CLARIFICATION/EVIDENCE</b> Most evidence available relates to COC use. However, this evidence is also applied to use of the contraceptive patch and ring.

<b>PERSONAL CHARACTERISTICS AND REPRODUCTIVE HISTORY</b>		
<b>Pregnancy</b>	NA	<b>Clarification:</b> There is no known harm to the woman, the course of pregnancy or the fetus if CHC is accidentally used during pregnancy.
<b>Age</b>		
a) Menarche to <40 years	1	
b) ≥40 years	2	<b>Clarification:</b> Guidance from the FSRH supports use of CHC up to age 50 years if there are no medical contraindications to use. <sup>2</sup>
<b>Parity</b>		
a) Nulliparous	1	
b) Parous	1	
<b>Postpartum (in breastfeeding women)</b>		<b>Evidence:</b> One systematic review reports that the impact of COC on breastfeeding duration and success is inconsistent. Results are conflicting on whether early initiation of COC affects infant outcomes, but generally find no negative impact on infant outcomes with later initiation of COC. <sup>3</sup>
a) 0 to <6 weeks	4	
b) ≥6 weeks to <6 months (primarily breastfeeding)	2	
c) ≥6 months	1	

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<b>Combined Hormonal Contraception (CHC) which includes</b>  <b>Combined oral contraception (COC)</b> <b>Combined contraceptive transdermal patch</b> <b>and vaginal ring</b>	<b>CHC do not protect against STI/HIV. If there is a risk of STI/HIV (including during pregnancy or postpartum), the correct and consistent use of condoms is recommended, either alone or with another contraception method. Male condoms reduce the risk of STI/HIV.</b>	
<b>CONDITION</b> *See additional comments at end of section	<b>CATEGORY</b> I = Initiation C = Continuation	<b>CLARIFICATION/EVIDENCE</b> Most evidence available relates to COC use. However, this evidence is also applied to use of the contraceptive patch and ring.

<b>Postpartum (in non-breastfeeding women)</b>		<b>Clarification:</b> This includes any births, including stillbirths from 24 weeks gestation.
a) 0 to <3 weeks		
(i) With other risk factors for VTE	4	<b>Clarification:</b> In the presence of other risk factors for VTE, such as immobility, transfusion at delivery, BMI $\geq 30 \text{ kg/m}^2$ , postpartum haemorrhage, immediately post-caesarean delivery, pre-eclampsia or smoking, use of CHC may pose an additional increased risk for VTE.
(ii) Without other risk factors	3	
b) 3 to <6 weeks		
(i) With other risk factors for VTE	3	
(ii) Without other risk factors	2	
c) $\geq 6$ weeks	1	<b>Evidence:</b> VTE risk is elevated during pregnancy and the postpartum period; this risk is most pronounced in the first 3 weeks after delivery, declining to near baseline levels by 42 days postpartum. <sup>4-8</sup> Use of CHC, which increase the risk of VTE in women of reproductive age, may pose an additional risk if used during this time. <sup>9</sup> Risk of pregnancy during the first 21 days postpartum is very low, but increases after that time in non-breastfeeding women; ovulation before first menses is common. <sup>10-14</sup>

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<b>Post-abortion</b>		
a) First trimester	1	<b>Clarification:</b> Includes induced abortions and spontaneous miscarriage <24 weeks gestation.
b) Second trimester	1	<b>Clarification:</b> CHC may be started immediately post-abortion.
c) Post-abortion sepsis	1	<b>Evidence:</b> Women who start taking COC immediately after first-trimester medical or surgical abortion do not experience more side effects, adverse vaginal bleeding outcomes or clinically significant changes in coagulation parameters compared with women who use a placebo, an IUD, a non-hormonal contraception method or delayed COC initiation. <sup>14-21</sup> Limited evidence on women using the contraceptive ring immediately after first-trimester medical or surgical abortion suggests no serious adverse events and no infection related to use of the contraceptive ring during three cycles of follow-up post-abortion. <sup>22</sup>
<b>Past ectopic pregnancy</b>	1	
<b>History of pelvic surgery</b>	1	

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<b>CONDITION</b> *See additional comments at end of section	<b>CATEGORY</b> I = Initiation C = Continuation	<b>CLARIFICATION/EVIDENCE</b> Most evidence available relates to COC use. However, this evidence is also applied to use of the contraceptive patch and ring.

<b>Smoking</b>		
a) Age <35 years	2	<b>Clarification:</b> UKMEC currently does not include use of e-cigarettes, as risks associated with their use are not yet established.
b) Age $\geq$ 35 years		
(i) <15 cigarettes/day	3	
(ii) $\geq$ 15 cigarettes/day	4	<b>Evidence:</b> COC users who smoke are at an increased risk of CVD, especially MI, compared with those who do not smoke. Studies also show an increased risk of MI with an increasing number of cigarettes smoked per day. <sup>23-34</sup>
(iii) Stopped smoking <1 year	3	
(iv) Stopped smoking $\geq$ 1 year	2	The 35 year age cut off is identified because any excess mortality associated with smoking becomes apparent from this age. <sup>35</sup> The mortality rate from all causes (including cancers) decreases to that of a non-smoker within 20 years of smoking cessation. The CVD risk associated with smoking decreases within 1 to 5 years of smoking cessation. <sup>35-37</sup>
<b>Obesity</b>		
a) BMI $\geq$ 30–34 kg/m <sup>2</sup>	2	<b>Clarification:</b> The absolute risk of VTE in women of reproductive age is low. The relative risk of VTE increases with CHC use. Nevertheless, the absolute risk of VTE in CHC users is still low.
b) BMI $\geq$ 35 kg/m <sup>2</sup>	3	<b>Evidence:</b> The risk of VTE rises as BMI increases over 30 and rises further with BMI over 35. Use of CHC raises this inherent increased risk further. <sup>28,34,38-41</sup> Limited evidence suggests that obese women who use COC do not have a higher risk of acute MI or stroke than obese non-users. <sup>34,42-44</sup>

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Combined Hormonal Contraception (CHC) which includes  Combined oral contraception (COC) Combined contraceptive transdermal patch and vaginal ring	CHC do not protect against STI/HIV. If there is a risk of STI/HIV (including during pregnancy or postpartum), the correct and consistent use of condoms is recommended, either alone or with another contraception method. Male condoms reduce the risk of STI/HIV.	
<b>CONDITION</b> *See additional comments at end of section	<b>CATEGORY</b> I = Initiation C = Continuation	<b>CLARIFICATION/EVIDENCE</b> Most evidence available relates to COC use. However, this evidence is also applied to use of the contraceptive patch and ring.

<b>History of bariatric surgery</b>		
a) With BMI <30 kg/m <sup>2</sup>	1	
b) With BMI ≥30–34 kg/m <sup>2</sup>	2	
c) With BMI ≥35 kg/m <sup>2</sup>	3	<p><b>Comment:</b> UKMEC categories relate to safety of use. Bariatric surgical procedures involving a malabsorptive component have the potential to decrease oral contraception effectiveness, perhaps further decreased by postoperative complications such as long-term diarrhoea and/or vomiting.</p> <p><b>Evidence:</b> Limited evidence demonstrates no substantial decrease in effectiveness of oral contraception among women who undergo laparoscopic placement of an adjustable gastric band or biliopancreatic diversion.<sup>45,46</sup> However, evidence from pharmacokinetic studies report conflicting results of oral contraception effectiveness among women who undergo a jejunoileal bypass.<sup>47,48</sup></p>
<b>Organ transplant</b>		
a) Complicated: graft failure (acute or chronic), rejection, cardiac allograft vasculopathy	3	<p><b>Clarification:</b> Women with Budd-Chiari syndrome should not use CHC because of the increased risk of thrombosis and graft rejection.</p>
b) Uncomplicated	2	<p><b>Evidence:</b> One study reports discontinuation of COC use in 2/26 (8%) women as a result of serious medical complications, and one case report recounts a woman developing cholestasis associated with high-dose COC use.<sup>49–52</sup></p>

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<b>Combined Hormonal Contraception (CHC) which includes</b>  <b>Combined oral contraception (COC)</b> <b>Combined contraceptive transdermal patch and vaginal ring</b>	<b>CHC do not protect against STI/HIV. If there is a risk of STI/HIV (including during pregnancy or postpartum), the correct and consistent use of condoms is recommended, either alone or with another contraception method. Male condoms reduce the risk of STI/HIV.</b>	
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<b>CARDIOVASCULAR DISEASE (CVD)</b>		
<b>Multiple risk factors for CVD (such as smoking, diabetes, hypertension, obesity and dyslipidaemias)</b>	3	<b>Clarification:</b> When a woman has multiple major risk factors, any of which alone would substantially increase the risk of CVD, use of CHC may increase her risk to an unacceptable level. However, a simple addition of categories for multiple risk factors is not intended; for example, a combination of two risk factors assigned a Category 2 may not necessarily warrant a higher category.
<b>Hypertension*</b>		
a) Adequately controlled hypertension	3	<b>Clarification:</b> For all categories of hypertension, classifications are based on the assumption that no other risk factors for CVD exist. When multiple risk factors do exist, the risk of CVD may increase substantially.
b) Consistently elevated BP levels (properly taken measurements)		
(i) Systolic >140–159 mmHg or diastolic >90–99 mmHg	3	<b>Clarification:</b> Women adequately treated for hypertension are at reduced risk of acute MI and stroke compared to untreated women. Although there are no data, CHC users with adequately controlled and monitored hypertension should be at reduced risk of acute MI and stroke compared with untreated hypertensive CHC users. Antihypertensive therapy may be initiated when the BP is consistently 160/100 mmHg or higher. <sup>53</sup>
(ii) Systolic ≥160 mmHg or diastolic ≥100 mmHg	4	<b>Evidence:</b> Among women with hypertension, COC users are at an increased risk of stroke, acute MI and peripheral arterial disease compared with non-users. <sup>23,25,28,32–34,54–69</sup> Discontinuation of COC in women with hypertension may improve BP control. <sup>70</sup>

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c) Vascular disease	4	<b>Clarification:</b> This includes coronary heart disease presenting with angina, peripheral vascular disease presenting with intermittent claudication, hypertensive retinopathy and TIA.
<b>History of high BP during pregnancy</b>	2	<b>Clarification:</b> Where current BP is measurable and normal.  <b>Evidence:</b> COC users with a history of high BP in pregnancy have an increased risk of MI and VTE, compared with COC users who do not have a history of high BP during pregnancy. The absolute risks of acute MI and VTE in this population remained small. <sup>34,56–58,60,71–76</sup>
<b>Current and history of ischaemic heart disease*</b>	4	
<b>Stroke*</b> (history of cerebrovascular accident, including TIA)	4	
<b>Known dyslipidaemias</b>	2	<b>Clarification:</b> Routine screening for these genetic mutations is not cost effective.  Increased levels of total cholesterol, LDL and triglycerides, as well as decreased levels of HDL, are known risk factors for CVD. Women with known, severe, genetic lipid disorders are at a much higher lifetime risk for CVD and may warrant further clinical consideration.

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<b>Venous thromboembolism (VTE)</b>		
a) History of VTE	4	<b>Clarification:</b> VTE includes DVT and PE.
b) Current VTE (on anticoagulants)	4	<b>On anticoagulants:</b> Women on anticoagulant therapy are at risk for gynaecological complications of therapy, such as haemorrhagic ovarian cysts and HMB. Hormonal contraception methods can be of benefit in preventing or treating these complications. When a contraception method is used as a therapy, rather than solely to prevent pregnancy, the risk/benefit ratio may differ and should be considered on a case-by-case basis.
c) Family history of VTE		<b>Family history of VTE:</b> May alert clinicians to women who may have an increased risk but alone cannot identify with certainty an underlying thrombophilia.
(i) First-degree relative age <45 years	3	
(ii) First-degree relative age ≥45 years	2	
d) Major surgery		<b>Major and minor surgery:</b> CHC should preferably be discontinued (and adequate alternative contraception arrangements made) 4 weeks before major elective surgery (>30 minutes' duration) and all surgery on the legs or surgery which involves prolonged immobilisation of a lower limb; CHC should normally be recommenced at least 2 weeks after full mobilisation. POC may be offered as an alternative and the CHC restarted after mobilisation, as above. When discontinuation of CHC is not possible (e.g. after trauma or if a patient admitted for an elective procedure is still using CHC), thromboprophylaxis (with low molecular weight heparin and graduated compression hosiery) is advised. These recommendations do not apply to minor surgery with short duration of anaesthesia (e.g. laparoscopic sterilisation or tooth extraction), or to women using estrogen-free hormonal contraception. <sup>77</sup>
(i) With prolonged Immobilisation	4	
(ii) Without prolonged Immobilisation	2	
e) Minor surgery without immobilisation	1	
f) Immobility (unrelated to surgery) (e.g. wheelchair use, debilitating illness)	3	

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<b>Superficial venous thrombosis*</b>		
a) Varicose veins	1	<b>Evidence:</b> One study suggests that among women with varicose veins, the rate of VTE and superficial venous thrombosis is higher in COC users compared with non-users, however statistical significance is not reported and the number of events in this study is small. <sup>78</sup>
b) Superficial venous thrombosis	2	<b>Clarification:</b> Superficial venous thrombosis may be associated with an increased risk of VTE.  <b>Evidence:</b> Among women with superficial venous thrombosis, the risk of VTE is higher in COC users compared with non-users. <sup>79</sup>
<b>Known thrombogenic mutations</b> (e.g. factor V Leiden, prothrombin mutation, protein S, protein C and antithrombin deficiencies)	4	<b>Clarification:</b> Routine screening for these genetic mutations is not cost effective. <sup>80-82</sup>  <b>Evidence:</b> Among women with thrombogenic mutations, COC users have a two- to twenty-fold higher risk of thrombosis than non-users. <sup>41,83-105</sup>
<b>Valvular and congenital heart disease*</b>		
a) Uncomplicated	2	<b>Clarification:</b> Uncomplicated cases could be considered to be where: there is (i) no requirement for cardiac medication, (ii) the woman is asymptomatic and (iii) a cardiology review is required annually or less. If in doubt, discussion with a specialist cardiologist is advised.
b) Complicated (e.g. pulmonary hypertension, history of subacute bacterial endocarditis)	4	<i>Valvular heart disease:</i> Occurs when any of the heart valves are stenotic and/or incompetent (e.g. aortic stenosis, mitral regurgitation, tricuspid valve abnormalities, pulmonary stenosis). <sup>106</sup>  <i>Congenital heart disease:</i> Aortic stenosis, atrial septal defects, atrioventricular septal defect, cardiomyopathy (hypertrophic or dilated), coarctation of the aorta, complex transposition of the great arteries; Ebstein's anomaly, Eisenmenger syndrome, patent ductus arteriosus, pulmonary atresia, pulmonary stenosis, tetralogy of Fallot, total anomalous pulmonary venous connection, tricuspid atresia, truncus arteriosus, ventricular septal defect. <sup>106</sup>

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<b>Cardiomyopathy*</b>			<b>Clarification:</b> A woman who is not on cardiac medication can be considered as having normal cardiac function.
a) Normal cardiac function	2		COC may increase fluid retention that may worsen heart failure in women with cardiomyopathy. Women with cardiomyopathy have a high incidence of cardiac arrhythmias which may be increased with CHC use.
b) Impaired cardiac function	4		
<b>Cardiac arrhythmias*</b>			
a) Atrial fibrillation	4		
b) Known long QT syndrome	2		
<b>NEUROLOGICAL CONDITIONS</b>			
<b>Headaches</b>			<b>Clarification:</b> Headache is a common condition affecting women of reproductive age.
a) Non-migrainous (mild or severe)	I 1	C 2	<b>Evidence:</b> Among women with migraine, women who also have aura are at a higher risk of stroke than those without aura. <sup>107,108</sup> Women with a history of migraine who use COC are about two to four times as likely to have an ischaemic stroke as non-users with a history of migraine. <sup>23,42,59,65,66,109,110</sup>
b) Migraine without aura, at any age	I 2	C 3	
c) Migraine with aura, at any age	4		
d) History ( $\geq 5$ years ago) of migraine with aura, any age	3		
<b>Idiopathic intracranial hypertension (IIH)</b>	2		Classification depends on making an accurate diagnosis of those severe headaches that are migrainous and, in addition, those complicated by aura. <sup>111–113</sup> See additional resource on diagnosis of migraines with or without aura.

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<b>Epilepsy</b>	1	
Taking anti-epileptic drugs		<p>Certain anti-epileptic drugs have the potential to affect the bioavailability of steroid hormones in hormonal contraception. In addition, hormonal contraception may affect the levels of certain anti-epileptic drugs with potential adverse effects.</p> <p>For up-to-date information on the potential drug interactions between hormonal contraception and anti-epileptic drugs, please refer to the online drug interaction checker available on Stockley's Interaction Checker website.<sup>114</sup></p>

## DEPRESSIVE DISORDERS

<b>Depressive disorders</b>	1	<p><b>Clarification:</b> The classification is based on data for women with selected depressive disorders. No data are available on bipolar disorder or postpartum depression.</p> <p><b>Evidence:</b> COC use does not increase depressive symptoms in women with depression compared to baseline or to non-users with depression.<sup>115-124</sup></p>
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## BREAST AND REPRODUCTIVE TRACT CONDITIONS

<b>Vaginal bleeding patterns*</b>		
a) Irregular pattern without heavy bleeding	1	<p><b>Clarification:</b> Abnormal menstrual bleeding should raise suspicion of a serious underlying condition and should be investigated appropriately.<sup>125-128</sup></p>
b) Heavy or prolonged bleeding (includes regular and irregular patterns)	1	<p><b>Evidence:</b> COC are shown to be an effective treatment in heavy menstrual bleeding (HMB).<sup>129-131</sup></p>
<b>Unexplained vaginal bleeding* (suspicious for serious condition) before evaluation</b>	2	<p><b>Clarification:</b> If pregnancy or an underlying pathological condition (such as pelvic malignancy) is suspected, it must be evaluated and the category adjusted after evaluation.</p>

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<b>Endometriosis*</b>	1	
<b>Benign ovarian tumours (including cysts)</b>	1	
<b>Severe dysmenorrhoea</b>	1	<b>Evidence:</b> There is no increased risk of side effects with COC use among women with dysmenorrhoea compared with women not using COC. Some COC users experience a reduction in pain and bleeding. <sup>127,128</sup>
<b>Gestational trophoblastic disease (GTD)</b>		<b>Clarification:</b> Includes hydatidiform mole (complete and partial) and gestational trophoblastic neoplasia.
a) Undetectable hCG levels	1	
b) Decreasing hCG levels	1	
c) Persistently elevated hCG levels or malignant disease	1	<b>Evidence:</b> Following molar pregnancy evacuation, the balance of evidence finds COC use does not increase the risk of gestational trophoblastic neoplasia, and some COC users experience a more rapid regression in hCG levels compared with non-users. <sup>132-140</sup> Limited evidence suggests that use of COC during chemotherapeutic treatment does not significantly affect the regression or treatment of gestational trophoblastic neoplasia compared with women who use a non-hormonal contraception method or DMPA during chemotherapeutic treatment. <sup>141</sup>
<b>Cervical ectropion*</b>	1	
<b>Cervical intraepithelial neoplasia (CIN)</b>	2	<b>Evidence:</b> Among women with persistent HPV infection, long-term COC use ( $\geq 5$ years) may increase the risk of carcinoma <i>in situ</i> and invasive carcinoma. <sup>142-144</sup>

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<b>Cervical cancer*</b>			
a) Awaiting treatment	2		
b) Radical trachelectomy	2		
<b>Breast conditions*</b>			<b>Clarification:</b> Breast cancer is a hormone-sensitive tumour and therefore the prognosis of women with current or past breast cancer may be affected by hormonal methods of contraception.
a) Undiagnosed mass/breast symptoms	I	C	
	3	2	
b) Benign breast conditions	1		
c) Family history of breast cancer	1		
d) Carriers of known gene mutations associated with breast cancer (e.g. BRCA1/BRCA2)	3		<b>Evidence:</b> Women with inherited breast cancer gene mutations (such as <i>BRCA1</i> and <i>BRCA2</i> ) have a much higher baseline risk of breast cancer than women without these genes. The very limited evidence in this area suggests that the risk of breast cancer among women with either a family history of breast cancer or with known inherited breast cancer gene mutations is probably not modified by the use of COC. <sup>145-163</sup>
e) Breast cancer			<b>Clarification:</b> For a woman with a history of breast cancer, a decision to initiate hormonal contraception may be best made in consultation with the local oncology team.
(i) Current breast cancer	4		
(ii) Past breast cancer	3		
<b>Endometrial cancer*</b>	1		
<b>Ovarian cancer*</b>	1		

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<b>Uterine fibroids*</b>		
a) Without distortion of the uterine cavity	1	
b) With distortion of the uterine cavity	1	
<b>Pelvic inflammatory disease (PID)</b>		
a) Past PID (assuming no current risk factors for STIs)	1	
b) Current PID	1	
<b>Sexually transmitted infections (STIs)</b>		
a) Chlamydial infection (current)		
(i) Symptomatic	1	
(ii) Asymptomatic	1	
b) Purulent cervicitis or gonorrhoea (current)	1	
c) Other current STIs (excluding HIV and hepatitis)	1	
d) Vaginitis (including <i>Trichomonas vaginalis</i> and bacterial vaginosis) (current)	1	
e) Increased risk for STIs	1	<b>Evidence:</b> Evidence suggests that there may be an increased risk of chlamydial cervicitis among COC users at high risk of STIs. For other STIs, there is either evidence of no association between COC use and STI acquisition or too limited evidence to draw any conclusions. <sup>164-244</sup>

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<b>HIV INFECTION</b>		
<b>HIV infection*</b>		
a) High risk of HIV infection	1	<b>Evidence:</b> A systematic review identifies eight studies which assess the use of COC. <sup>245</sup> Seven of these studies find no statistically significant association between use of COC and HIV acquisition <sup>246–253</sup> , although one study among sex workers in Kenya does. <sup>254</sup>
b) HIV infected		
(i) CD4 count ≥200 cells/mm <sup>3</sup>	1	<b>Evidence:</b> Seven studies suggest no association between use of COC and progression of HIV, as measured by CD4 count <200 cells/mm <sup>3</sup> , initiation of ART or mortality. <sup>255–261</sup> One randomised controlled trial finds an increased risk of a composite outcome of declining CD4 count or death among COC users when compared with Cu-IUDs. <sup>262,263</sup>
(ii) CD4 count <200 cells/mm <sup>3</sup>	1	The majority of indirect studies measuring whether various hormonal contraception methods affect plasma HIV viral load find no effect. <sup>264–280</sup>
c) Taking antiretroviral (ARV) drugs		Certain ARV drugs have the potential to affect the bioavailability of steroid hormones in hormonal contraception.  For up-to-date information on the potential drug interactions between hormonal contraception and ARV drugs, please refer to the online HIV drugs interaction checker. <sup>281</sup>

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<b>Category 2</b>	A condition where the advantages of using the method generally outweigh the theoretical or proven risks
<b>Category 3</b>	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
<b>Category 4</b>	A condition which represents an unacceptable health risk if the method is used

Combined Hormonal Contraception (CHC) which includes  Combined oral contraception (COC) Combined contraceptive transdermal patch and vaginal ring	CHC do not protect against STI/HIV. If there is a risk of STI/HIV (including during pregnancy or postpartum), the correct and consistent use of condoms is recommended, either alone or with another contraception method. Male condoms reduce the risk of STI/HIV.	
<b>CONDITION</b> *See additional comments at end of section	<b>CATEGORY</b> I = Initiation C = Continuation	<b>CLARIFICATION/EVIDENCE</b> Most evidence available relates to COC use. However, this evidence is also applied to use of the contraceptive patch and ring.

<b>OTHER INFECTIONS</b>		
<b>Tuberculosis</b>		
a) Non-pelvic	1	
b) Pelvic	1	
<b>ENDOCRINE CONDITIONS</b>		
<b>Diabetes*</b>		
a) History of gestational disease	1	<b>Evidence:</b> The development of non-insulin dependent diabetes in women with a history of gestational diabetes is not increased by the use of COC. <sup>282-289</sup> Likewise, lipid levels appear to be unaffected by COC use. <sup>290-292</sup>
b) Non-vascular disease		
(i) Non-insulin dependent	2	
(ii) Insulin-dependent	2	<b>Evidence:</b> Among women with insulin or non-insulin-dependent diabetes, COC use has limited effect on daily insulin requirements and no effect on long-term diabetes control (e.g. HbA1c levels) or progression to retinopathy. Changes in lipid profile and haemostatic markers are limited and most changes remain within normal values. <sup>293-302</sup>
c) Nephropathy/retinopathy/neuropathy	3	<b>Clarification:</b> The category should be assessed according to the severity of the condition.
d) Other vascular disease	3	
<b>Thyroid disorders</b>		
a) Simple goitre	1	
b) Hyperthyroid	1	
c) Hypothyroid	1	

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<b>GASTROINTESTINAL CONDITIONS</b>		
<b>Gallbladder disease*</b>		
a) Symptomatic		
(i) Treated by cholecystectomy	2	
(ii) Medically treated	3	
(iii) Current	3	
b) Asymptomatic	2	
<b>History of cholestasis*</b>		
a) Pregnancy related	2	
b) Past COC related	3	
<b>Viral hepatitis*</b>		
a) Acute or flare	I 3	C 2
b) Carrier	1	
c) Chronic	1	
<b>Cirrhosis*</b>		
a) Mild (compensated without complications)	1	
b) Severe (decompensated)	4	

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<b>CONDITION</b> *See additional comments at end of section	<b>CATEGORY</b> I = Initiation C = Continuation	<b>CLARIFICATION/EVIDENCE</b> Most evidence available relates to COC use. However, this evidence is also applied to use of the contraceptive patch and ring.
<b>Liver tumours*</b>		
a) Benign		
(i) Focal nodular hyperplasia	2	
(ii) Hepatocellular adenoma	4	
b) Malignant (hepatocellular carcinoma)	4	
<b>Inflammatory bowel disease (IBD)*</b> (including Crohn's disease and ulcerative colitis)	2	<p><b>Evidence:</b> There is limited, direct evidence that hormonal contraception use does not influence either progression or regression of liver lesions among women with focal nodular hyperplasia.<sup>311-313</sup> There is no evidence relating to use of hormonal contraception by women with other liver tumours.</p> <p><b>Clarification:</b> Continuation may need to be reviewed if the woman has an acute exacerbation, acute surgery or prolonged immobilisation (see section on VTE).</p> <p><b>Evidence:</b> Risk for disease relapse is not significantly higher among women with IBD using oral contraception (most studies do not specify whether it is POP or COC) than among non-users.<sup>314-318</sup></p> <p>Absorption of COC among women with mild ulcerative colitis and no or small ileal resections is similar to the absorption among healthy women.<sup>319,320</sup> Findings may not apply to women with Crohn's disease or more extensive bowel resections.</p> <p>No data exist that evaluate the increased risk for VTE among women with IBD using CHC. However, women with IBD are at higher risk than unaffected women for VTE.<sup>320</sup></p>

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<b>CONDITION</b> *See additional comments at end of section	<b>CATEGORY</b> I = Initiation C = Continuation	<b>CLARIFICATION/EVIDENCE</b> Most evidence available relates to COC use. However, this evidence is also applied to use of the contraceptive patch and ring.

<b>ANAEMIAS</b>		
Thalassaemia*	1	
Sickle cell disease	2	
Iron deficiency anaemia*	1	
<b>RHEUMATIC DISEASES</b>		
Rheumatoid arthritis	2	<b>Clarification:</b> Risk of CVD is increased among women with rheumatoid arthritis. <sup>321</sup>  <b>Evidence:</b> Limited evidence shows no consistent pattern of improvement or worsening of rheumatoid arthritis with use of oral contraception. <sup>321–329</sup>
Systemic lupus erythematosus (SLE)		<b>Clarification:</b> People with SLE are at an increased risk of ischaemic heart disease, stroke and VTE and this is reflected in the categories given. There is no evidence that use of CHC causes disease flare.
a) No antiphospholipid antibodies	2	
b) Positive antiphospholipid antibodies	4	Available evidence indicates that many women with SLE can be considered good candidates for most methods of contraception, including hormonal contraception. <sup>330–351</sup>

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<b>CONDITION</b> *See additional comments at end of section	<b>CATEGORY</b> I = Initiation C = Continuation	<b>CLARIFICATION/EVIDENCE</b> Most evidence available relates to COC use. However, this evidence is also applied to use of the contraceptive patch and ring.
<b>Positive antiphospholipid antibodies</b>	4	<b>Clarification:</b> Positive antiphospholipid antibodies (aPL) is not itself a disease state and in the absence of manifestations of the antiphospholipid syndrome a stratification of risk with specialist advice if necessary is recommended. In particular, persistence of aPL positivity, high titre of aPL, lupus anticoagulant (LA) positivity, triple positivity for anticardiolipin antibodies (aCL), anti-β2-glycoprotein I (βgPI) and LA and immunoglobulin G (IgG) aPL have greater risk for future events. <sup>352-354</sup>
<b>DRUG INTERACTIONS*</b>		
<b>Taking medication</b>	See section on drug interactions with hormonal contraception.	

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## **Additional Comments**

### **HYPERTENSION, CURRENT AND HISTORY OF ISCHAEMIC HEART DISEASE, STROKE**

A single reading of BP level is not sufficient to classify a woman as hypertensive. If elevated, the BP should be reassessed at the end of the consultation. If BP is increased, it should be reassessed and monitored according to current guidelines.

### **SUPERFICIAL VENOUS THROMBOSIS**

**Varicose vein:** Varicose veins are not a risk factor for VTE.

### **VALVULAR AND CONGENITAL HEART DISEASE, CARDIOMYOPATHY AND CARDIAC ARRHYTHMIAS**

Stasis, endothelial injury and hyperviscosity (Virchow's triad) increase the risk of clot formation. Impaired cardiac function and/or dilated heart chambers or arrhythmia increase the risk of stasis. Closure of a cardiac defect within the last 6 months or presence of a mechanical heart valve increases the risk of thrombus formation. Cyanotic defects are associated with hyperviscosity because of increased erythrocytosis.

**Congenital heart disease:** Surgical correction, co-existing complications and degree of cardiac disability will vary between individuals and should be taken into account when considering contraception use.

### **UNEXPLAINED VAGINAL BLEEDING**

There are no conditions that cause vaginal bleeding that will be worsened in the short term by use of CHC.

### **ENDOMETRIOSIS**

CHC do not worsen, and may alleviate, the symptoms of endometriosis.

### **CERVICAL ECTROPION**

Cervical ectropion is not a risk factor for cervical cancer and there is no need for restriction of CHC.

### **CERVICAL CANCER**

**Awaiting treatment:** There is some theoretical concern that CHC use may affect prognosis of the existing disease. While awaiting treatment, women may use CHC since the period of waiting is likely to be brief and pregnancy would be contraindicated.

### **ENDOMETRIAL AND OVARIAN CANCER**

COC use reduces the risk of developing endometrial cancer. While awaiting treatment, women may use COC.

### **UTERINE FIBROIDS**

There is no evidence that CHC affect growth of fibroids.

### **HIV INFECTION**

Women with HIV infection often have co-morbidities that may influence their choice of contraception.

### **DIABETES**

Although carbohydrate tolerance may change with CHC use, the major concerns are vascular disease due to diabetes and additional risk of arterial thrombosis due to use of CHC.

### **GALLBLADDER DISEASE**

COC may cause a small increased risk of gallbladder disease. There is also concern that COC may worsen existing gallbladder disease.

### **HISTORY OF CHOLESTASIS**

**Pregnancy-related:** History of pregnancy-related cholestasis may predict an increased risk of developing COC-associated cholestasis.

**Past COC-related:** History of COC-related cholestasis predicts an increased risk with subsequent COC use.

### **VIRAL HEPATITIS, CIRRHOSIS AND LIVER TUMOURS**

COC are metabolised by the liver, and their use may adversely affect women whose liver function is compromised.

### **INFLAMMATORY BOWEL DISEASE (IBD)**

Risk of VTE may increase if unwell, bed-bound or undergoing acute surgery or with major surgery and prolonged immobilisation. Under these circumstances the use of combined methods should be avoided and alternative methods used.

### **THALASSAEMIA**

There is anecdotal evidence from countries where thalassaemia is prevalent that COC use does not worsen the condition.

### **IRON-DEFICIENCY ANAEMIA**

CHC use may decrease menstrual blood loss.

### **DRUG INTERACTIONS**

Generally, the safety of using combined hormonal methods is unaffected. Nevertheless, use of liver enzyme inducing medication may reduce contraception efficacy, increasing risk of unintended pregnancy. Contraception choice may depend on the likely duration of use of concurrent medications and need for additional or alternative methods.

## **Emergency Contraception (EC)**

Emergency contraception (EC) provides women of all reproductive ages with a means of preventing unintended pregnancy following any unprotected sexual intercourse (UPSI).

The section on emergency contraception includes the following types:

- Copper-bearing IUD (Cu-IUD)
- Oral emergency contraception (EC).

FSRH guidance on EC<sup>1</sup> and IUC<sup>2</sup> is available on the FSRH website.

### **Copper-bearing IUD (Cu-IUD) for emergency contraception**

The Cu-IUD is the most effective form of EC. All eligible women presenting between 0 and 120 hours of UPSI or within 5 days of expected ovulation (Day 19 in a regular 28-day cycle) should be offered a Cu-IUD because of the low documented failure rate.

The eligibility criteria for interval Cu-IUD insertion also apply for the insertion of the Cu-IUD as EC. However, the risk-benefit ratio will be different for the use of the Cu-IUD as EC compared to when it is used for routine contraception.

### **Oral emergency contraception**

Two methods of oral EC are available in the UK.

Ulipristal acetate (UPA) is a progesterone receptor modulator that is a synthetic steroid derived from 19-norprogesterone and is licensed for use within 120 hours of UPSI.

Oral progestogen-only EC containing LNG 1.5 mg is licensed to be given up to 72 hours after UPSI or contraceptive failure. There is some evidence of reduced efficacy with use after 72 hours.<sup>3,4</sup>

Emergency Contraception (EC) Copper-bearing intrauterine device (Cu-IUD) Ulipristal acetate (UPA) Levonorgestrel (LNG)	EC do not protect against STI/HIV. If there is a risk of STI/HIV (including during pregnancy or postpartum), the correct and consistent use of condoms is recommended, either alone or with another contraception method. Male condoms reduce the risk of STI/HIV.		
CONDITION <small>*See additional comments at end of section</small>	CATEGORY		CLARIFICATION/EVIDENCE
	Cu-IUD	UPA	LNG

<b>Pregnancy</b>	NA	NA	NA	<b>Clarification:</b> There is no known harm to the woman, the course of her pregnancy or the fetus if UPA or LNG is accidentally used.  Cu-IUD can be inserted up to 5 days after the <i>first episode</i> of UPSI or if necessary up to 5 days after the <i>expected date of ovulation</i> (Day 19 in a regular 28-day cycle). <sup>2</sup>
<b>Postpartum</b> (in breastfeeding or non-breastfeeding women)				<b>Clarification:</b> EC is not required if UPSI or barrier method failure occurs <3 weeks pospartum. UPA and LNG are indicated from 3 weeks postpartum. Emergency Cu-IUD is indicated from 4 weeks postpartum.
a) <3 weeks	NA	NA	NA	
b) 3 to <4 weeks	3	1	1	
c) ≥4 weeks	1	1	1	<b>Clarification:</b> Breastfeeding is not recommended for 1 week after taking UPA since it is excreted in breast milk. Breast milk should be expressed and discarded during that time. <sup>5</sup>
<b>Past ectopic pregnancy</b>	1	1	1	<b>Clarification:</b> Women using contraception have a lower risk of ectopic pregnancy overall compared to women not using contraception. There does not appear to be an increased risk of ectopic pregnancy following use of Cu-IUD as EC, <sup>6</sup> UPA <sup>7</sup> or LNG <sup>8</sup> .
<b>Smoking</b>	1	1	1	

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CONDITION <small>*See additional comments at end of section</small>	CATEGORY		CLARIFICATION/EVIDENCE
	Cu-IUD	UPA	LNG

<b>Obesity</b>	1	1	1	<b>Evidence:</b> A review by the European Medicines Agency determines that data available are too limited and not robust enough to conclude with any certainty that contraceptive effect is reduced with increased body weight. The Agency's Committee for Medicinal Products for Human Use recommends that LNG and UPA could continue to be used in women of all weights as the benefits are considered to outweigh the risk. <sup>9</sup>
<b>Hypertension</b>	1	1	1	
<b>Known dyslipidaemias</b>	1	1	1	
<b>Venous thromboembolism (VTE)*</b> Current VTE (on anticoagulants)	2	2	2	<b>Clarification:</b> VTE includes DVT and PE.
<b>History of severe CVD complications</b> (Includes ischaemic heart disease, cerebrovascular attack, or other thromboembolic conditions)	1	1	1	<b>Clarification:</b> There is no evidence that UPA or LNG increase the risk of CVD.
<b>Headaches</b>	1	1	1	<b>Clarification:</b> Headache is a common condition affecting women of reproductive age.
<b>Gestational trophoblastic disease (GTD)</b>				
a) Undetectable hCG levels	1	1	1	<b>Clarification:</b> Includes hydatidiform mole (complete and partial) and gestational trophoblastic neoplasia.
b) Decreasing hCG levels	3	1	1	
c) Persistently elevated hCG levels or malignant disease	4	1	1	

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CONDITION <small>*See additional comments at end of section</small>	CATEGORY		CLARIFICATION/EVIDENCE
	Cu-IUD	UPA	

<b>Breast conditions</b>				
Breast cancer				
a) Current breast cancer	1	2	2	
b) Past breast cancer	1	2	2	
<b>Uterine fibroids*</b>				
a) Without distortion of the uterine cavity	1	1	1	
b) With distortion of the uterine cavity	3	1	1	
<b>Anatomical abnormalities*</b>				
a) Distorted uterine cavity	3	1	1	<b>Clarification:</b> Includes any congenital or acquired uterine abnormality distorting the uterine cavity in a manner that is incompatible with IUC insertion.
b) Other abnormalities	2	1	1	<b>Clarification:</b> Includes cervical stenosis or cervical lacerations not distorting the uterine cavity or interfering with IUC insertion.
<b>Inflammatory bowel disease</b> (including Crohn's disease and ulcerative colitis)	1	2	2	<b>Clarification:</b> Oral methods may be less reliable if there is significant malabsorption or small bowel resection (particularly with Crohn's disease). Oral methods are unaffected by colectomy and ileostomy.
<b>Severe liver disease*</b> (including jaundice)	1	1	1	

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CONDITION <small>*See additional comments at end of section</small>	CATEGORY		CLARIFICATION/EVIDENCE	
Cu-IUD	UPA	LNG		

<b>Acute intermittent porphyria*</b>	1	2	2	<p><b>Clarification:</b> Acute intermittent porphyria is a rare disorder characterised by acute attacks often precipitated by drugs. Estrogen and progestogen have been implicated. Around 1% of acute attacks are fatal. In one population study, almost half of women with porphyria used hormonal contraception but only 4.5% had associated acute attacks.<sup>10</sup> Combined hormonal contraception is shown to reduce attacks for some women.<sup>11</sup> Natural fluctuations in estrogen and progesterone appear to be associated with acute attacks more often than exogenous hormones.</p> <p>Women may use UPA or LNG following discussion of the risks and benefits and with clinical judgement.<sup>12-14</sup></p>
<b>Repeated use of UPA or LNG (in the same cycle)</b>	NA	1	1	<p><b>Clarification:</b> Recurrent use of EC is an indication that the woman requires further discussion about other contraceptive options. UPA or LNG can be used more than once in a cycle if clinically indicated.<sup>1</sup> Alternatively, a Cu-IUD can be inserted if repeated UPSI occurs up to 5 days after the first episode of unprotected sex or up to 5 days after expected date of ovulation.</p> <p>Frequently repeated UPA and LNG use may be harmful for women with conditions classified as Category 2, 3 or 4 for CHC or POC use.</p>
<b>Risk of sexually transmitted infections (STIs)</b>	1	1	1	<p><b>Clarification:</b> Women thought to be at higher risk of STI from their sexual history (aged &lt;25 years, or with a change in sexual partner or two or more partners in the last year) should be offered testing for STI.</p> <p>In a woman with asymptomatic chlamydia in an emergency situation (i.e. emergency contraception), the Cu-IUD could be inserted on the same day as treatment is instituted.<sup>2</sup></p>

#### DRUG INTERACTIONS

Taking medication*	See section on drug interactions with hormonal contraception.
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## Additional Comments

### POSTPARTUM

**Breastfeeding:** Although women who are fully or nearly fully breastfeeding, amenorrhoeic and <6 months postpartum can rely on LAM as an effective method of contraception, if breastfeeding frequency decreases or menstruation recurs EC may be indicated.

### VENOUS THROMBOEMBOLISM

**Current VTE taking anticoagulants:** Care should be taken when fitting a Cu-IUD in those taking anticoagulants as there may be an increased risk of bleeding.

### UTERINE FIBROIDS AND ANATOMICAL ABNORMALITIES (distorted uterine cavity)

In women with a distorted uterine cavity it may be appropriate after discussion to attempt insertion of Cu-IUD.

### SEVERE LIVER DISEASE

The duration of use of UPA or LNG is less than that of regular use of POP and thus would be expected to have less clinical impact.

### ACUTE INTERMITTENT PORPHYRIA

Cyclical symptoms have been found in relation to the menstrual cycle but seldom lead to acute attacks.

### RISK OF SEXUALLY TRANSMITTED INFECTIONS (STIs)

Women who are thought to be at higher risk for STI based on a sexual history (age <25 years or age >25 years with a change in sexual partner or two or more partners in the last year) can be offered testing for STIs and should be given prophylactic antibiotics to prevent *Chlamydia trachomatis* at the time of Cu-IUD insertion.

### DRUG INTERACTIONS

Current FSRH guidance recommends that women using liver enzyme inducers should be advised to use a Cu-IUD. If progestogen-only EC is to be used it should be given as soon as possible and within 72 hours of UPSI. In women using liver enzyme inducing drugs, two 1.5 mg LNG tablets should be taken (3 mg) as a single dose. The efficacy of LNG is not reduced by non-liver enzyme inducing antibiotics.

## UKMEC SUMMARY TABLE HORMONAL AND INTRAUTERINE CONTRACEPTION

Cu-IUD = Copper-bearing intrauterine device; LNG-IUS = Levonorgestrel-releasing intrauterine system;  
IMP = Progestogen-only implant; DMPA = Progestogen-only injectable: depot medroxyprogesterone acetate;  
POP = Progestogen-only pill; CHC = Combined hormonal contraception

CONDITION	Cu-IUD	LNG-IUS	IMP	DMPA	POP	CHC
	<b>I = Initiation, C = Continuation</b>					
<b>PERSONAL CHARACTERISTICS AND REPRODUCTIVE HISTORY</b>						
Pregnancy	NA	NA	NA	NA	NA	NA
Age	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
Parity						
a) Nulliparous	1	1	1	1	1	1
b) Parous	1	1	1	1	1	1
Breastfeeding						
a) 0 to <6 weeks postpartum	See below	1	2	1	4	
b) ≥6 weeks to <6 months (primarily breastfeeding)		1	1	1	2	
c) ≥6 months postpartum		1	1	1	1	
Postpartum (in non-breastfeeding women)						
a) 0 to <3 weeks						
(i) With other risk factors for VTE	See below	1	2	1	4	
(ii) Without other risk factors		1	2	1	3	
b) 3 to <6 weeks						
(i) With other risk factors for VTE	See below	1	2	1	3	
(ii) Without other risk factors		1	1	1	2	
c) ≥6 weeks		1	1	1	1	

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Category 4	A condition which represents an unacceptable health risk if the method is used

**UKMEC SUMMARY TABLE HORMONAL AND INTRAUTERINE CONTRACEPTION**

CONDITION	Cu-IUD	LNG-IUS	IMP	DMPA	POP	CHC
	<b>I = Initiation, C = Continuation</b>					

<b>Postpartum</b> (in breastfeeding or non-breastfeeding women, including post-caesarean section)						
a) 0 to <48 hours	1	1	See above			
b) 48 hours to <4 weeks	3	3				
c) ≥4 weeks	1	1				
d) Postpartum sepsis	4	4				
<b>Post-abortion</b>						
a) First trimester	1	1	1	1	1	1
b) Second trimester	2	2	1	1	1	1
c) Post-abortion sepsis	4	4	1	1	1	1
<b>Past ectopic pregnancy</b>	1	1	1	1	1	1
<b>History of pelvic surgery</b>	1	1	1	1	1	1
<b>Smoking</b>						
a) Age <35 years	1	1	1	1	1	2
b) Age ≥35 years						
(i) <15 cigarettes/day	1	1	1	1	1	3
(ii) ≥15 cigarettes/day	1	1	1	1	1	4
(iii) Stopped smoking <1 year	1	1	1	1	1	3
(iv) Stopped smoking ≥1 year	1	1	1	1	1	2
<b>Obesity</b>						
a) BMI ≥30–34 kg/m <sup>2</sup>	1	1	1	1	1	2
b) BMI ≥35 kg/m <sup>2</sup>	1	1	1	1	1	3

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CONDITION	Cu-IUD	LNG-IUS	IMP	DMPA	POP	CHC
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History of bariatric surgery									
a) With BMI <30 kg/m <sup>2</sup>	1	1	1	1	1	1	1		
b) With BMI ≥30–34 kg/m <sup>2</sup>	1	1	1	1	1	1	2		
c) With BMI ≥35 kg/m <sup>2</sup>	1	1	1	1	1	1	3		
Organ transplant									
a) Complicated: graft failure (acute or chronic), rejection, cardiac allograft vasculopathy	I 3	C 2	I 3	C 2	2		2		3
b) Uncomplicated	2	2	2	2	2	2	2	2	
CARDIOVASCULAR DISEASE (CVD)									
Multiple risk factors for CVD (such as smoking, diabetes, hypertension, obesity and dyslipidaemias)	1	2	2	3	2	2	3		
Hypertension									
a) Adequately controlled hypertension	1	1	1	2	1	1	3		
b) Consistently elevated BP levels (properly taken measurements)									
(i) Systolic >140–159 mmHg or diastolic >90–99 mmHg	1	1	1	1	1	1	3		
(ii) Systolic ≥160 mmHg or diastolic ≥100 mmHg	1	1	1	2	1	1	4		
c) Vascular disease	1	2	2	3	2	2	4		
History of high BP during pregnancy	1	1	1	1	1	1	2		
Current and history of ischaemic heart disease	1	I 2	C 3	I 2	C 3	3	I 2	C 3	4
Stroke (history of cerebrovascular accident, including TIA)	1	I 2	C 3	I 2	C 3	3	I 2	C 3	4
Known dyslipidaemias	1	2	2	2	2	2	2		

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UKMEC SUMMARY TABLE HORMONAL AND INTRAUTERINE CONTRACEPTION						
CONDITION	Cu-IUD	LNG-IUS	IMP	DMPA	POP	CHC
<b>I = Initiation, C = Continuation</b>						

Venous thromboembolism (VTE)						
a) History of VTE	1	2	2	2	2	4
b) Current VTE (on anticoagulants)	1	2	2	2	2	4
c) Family history of VTE						
(i) First-degree relative age <45 years	1	1	1	1	1	3
(ii) First-degree relative age ≥45 years	1	1	1	1	1	2
d) Major surgery						
(i) With prolonged immobilisation	1	2	2	2	2	4
(ii) Without prolonged immobilisation	1	1	1	1	1	2
e) Minor surgery without immobilisation	1	1	1	1	1	1
f) Immobility (unrelated to surgery) (e.g. wheelchair use, debilitating illness)	1	1	1	1	1	3
Superficial venous thrombosis						
a) Varicose veins	1	1	1	1	1	1
b) Superficial venous thrombosis	1	1	1	1	1	2
Known thrombogenic mutations (e.g. factor V Leiden, prothrombin mutation, protein S, protein C and antithrombin deficiencies)	1	2	2	2	2	4

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CONDITION	Cu-IUD	LNG-IUS	IMP	DMPA	POP	CHC
I = Initiation, C = Continuation						

Valvular and congenital heart disease								
a) Uncomplicated	1	1	1	1	1	2		
b) Complicated (e.g. pulmonary hypertension, history of subacute bacterial endocarditis)	2	2	1	1	1	4		
Cardiomyopathy								
a) Normal cardiac function	1	1	1	1	1	2		
b) Impaired cardiac function	2	2	2	2	2	4		
Cardiac arrhythmias								
a) Atrial fibrillation	1	2	2	2	2	4		
b) Known long QT syndrome	I 3	C 1	I 3	C 1	1	2	1	2
NEUROLOGICAL CONDITIONS								
Headaches								
a) Non-migrainous (mild or severe)	1	1	1	1	1	I 1	C 2	
b) Migraine without aura, at any age	1	2	2	2	I 1	C 2	I 2	C 3
c) Migraine with aura, at any age	1	2	2	2	2			
d) History ( $\geq 5$ years ago) of migraine with aura, any age	1	2	2	2	2			

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CONDITION	Cu-IUD	LNG-IUS	IMP	DMPA	POP	CHC
<b>I = Initiation, C = Continuation</b>						
<b>Idiopathic intracranial hypertension (IIH)</b>	1	1	1	1	1	2
<b>Epilepsy</b>	1	1	1	1	1	1
Taking anti-epileptic drugs	<p>Certain anti-epileptic drugs have the potential to affect the bioavailability of steroid hormones in hormonal contraception.</p> <p>For up-to-date information on the potential drug interactions between hormonal contraception and anti-epileptic drugs, please refer to the online drug interaction checker available on Stockley's Interaction Checker website (<a href="https://www.medicinescomplete.com/mc/alerts/current/drug-interactions.htm">https://www.medicinescomplete.com/mc/alerts/current/drug-interactions.htm</a>).</p>					
<b>DEPRESSIVE DISORDERS</b>						
<b>Depressive disorders</b>	1	1	1	1	1	1
<b>BREAST AND REPRODUCTIVE TRACT CONDITIONS</b>						
<b>Vaginal bleeding patterns</b>						
a) Irregular pattern without heavy bleeding	1	1	2	2	2	1
b) Heavy or prolonged bleeding (includes regular and irregular patterns)	2	I 1	C 2	2	2	1
<b>Unexplained vaginal bleeding</b> (suspicious for serious condition) before evaluation	I 4	C 2	I 4	C 2	3	3
<b>Endometriosis</b>	2	1	1	1	1	1
<b>Benign ovarian tumours</b> (including cysts)	1	1	1	1	1	1
<b>Severe dysmenorrhoea</b>	2	1	1	1	1	1
<b>Gestational trophoblastic disease (GTD)</b>						
a) Undetectable hCG levels	1	1	1	1	1	1
b) Decreasing hCG levels	3	3	1	1	1	1
c) Persistently elevated hCG levels or malignant disease	4	4	1	1	1	1

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CONDITION	Cu-IUD	LNG-IUS	IMP	DMPA	POP	CHC	
<b>I = Initiation, C = Continuation</b>							

<b>Cervical ectropion</b>	1	1	1	1	1	1	
<b>Cervical intraepithelial neoplasia (CIN)</b>	1	2	1	2	1	2	
<b>Cervical cancer</b>							
a) Awaiting treatment	I	C	I	C	2	2	1
	4	2	4	2			
b) Radical trachelectomy	3	3	2	2	1	2	
<b>Breast conditions</b>							
a) Undiagnosed mass/breast symptoms	1	2	2	2	2	3	2
b) Benign breast conditions	1	1	1	1	1	1	
c) Family history of breast cancer	1	1	1	1	1	1	
d) Carriers of known gene mutations associated with breast cancer (e.g. BRCA1/BRCA2)	1	2	2	2	2	3	
e) Breast cancer							
(i) Current breast cancer	1	4	4	4	4	4	
(ii) Past breast cancer	1	3	3	3	3	3	
<b>Endometrial cancer</b>	I	C	I	C	1	1	1
	4	2	4	2			
<b>Ovarian cancer</b>	1	1	1	1	1	1	

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CONDITION	Cu-IUD	LNG-IUS	IMP	DMPA	POP	CHC
<b>I = Initiation, C = Continuation</b>						
<b>Uterine fibroids</b>						
a) Without distortion of the uterine cavity	1	1	1	1	1	1
b) With distortion of the uterine cavity	3	3	1	1	1	1
<b>Anatomical abnormalities</b>						
a) Distorted uterine cavity	3	3				
b) Other abnormalities	2	2				
<b>Pelvic inflammatory disease (PID)</b>						
a) Past PID (assuming no current risk factor for STIs)	1	1	1	1	1	1
b) Current PID	I	C	I	C		
	4	2	4	2	1	1
<b>Sexually transmitted infections (STIs)</b>						
a) Chlamydial infection (current)	I	C	I	C		
(i) Symptomatic	4	2	4	2	1	1
(ii) Asymptomatic	3	2	3	2	1	1
b) Purulent cervicitis or gonorrhoea (current)	4	2	4	2	1	1
c) Other current STIs (excluding HIV & hepatitis)	2		2		1	1
d) Vaginitis (including Trichomonas vaginalis and bacterial vaginosis) (current)	2		2		1	1
e) Increased risk for STIs	2		2		1	1

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HIV INFECTION						
HIV infection						
a) High risk of HIV infection						
b) HIV infected						
(i) CD4 count ≥200 cells/mm <sup>3</sup>	2	2	1	2	1	1
(ii) CD4 count <200 cells/mm <sup>3</sup>	I 3	C 2	I 3	C 2	1	1
c) Taking antiretroviral (ARV) drugs	<p>Certain ARV drugs have the potential to affect the bioavailability of steroid hormones in hormonal contraception.</p> <p>For up-to-date information on the potential drug interactions between hormonal contraception and ARV drugs, please refer to the online HIV drugs interaction checker (<a href="http://www.hiv-druginteractions.org/Interactions.aspx">www.hiv-druginteractions.org/Interactions.aspx</a>).</p>					

OTHER INFECTIONS						
Tuberculosis						
a) Non-pelvic						
b) Pelvic	I 4	C 3	I 4	C 3	1	1

ENDOCRINE CONDITIONS						
Diabetes						
a) History of gestational disease						
b) Non-vascular disease						
(i) Non-insulin dependent	1	2	2	2	2	2
(ii) Insulin dependent	1	2	2	2	2	2
c) Nephropathy/retinopathy/neuropathy	1	2	2	2	2	3
d) Other vascular disease	1	2	2	2	2	3

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<b>I = Initiation, C = Continuation</b>						
<b>Thyroid disorders</b>						
a) Simple goitre	1	1	1	1	1	1
b) Hyperthyroid	1	1	1	1	1	1
c) Hypothyroid	1	1	1	1	1	1
<b>GASTROINTESTINAL CONDITIONS</b>						
<b>Gallbladder disease</b>						
a) Symptomatic						
(i) Treated by cholecystectomy	1	2	2	2	2	2
(ii) Medically treated	1	2	2	2	2	3
(iii) Current	1	2	2	2	2	3
b) Asymptomatic	1	2	2	2	2	2
<b>History of cholestasis</b>						
a) Pregnancy related	1	1	1	1	1	2
b) Past COC related	1	2	2	2	2	3
<b>Viral hepatitis</b>						
a) Acute or flare	1	1	1	1	1	I 3 C 2
b) Carrier	1	1	1	1	1	1
c) Chronic	1	1	1	1	1	1
<b>Cirrhosis</b>						
a) Mild (compensated without complications)	1	1	1	1	1	1
b) Severe (decompensated)	1	3	3	3	3	4

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<b>Liver tumours</b>						
a) Benign						
(i) Focal nodular hyperplasia	1	2	2	2	2	2
(ii) Hepatocellular adenoma	1	3	3	3	3	4
b) Malignant (hepatocellular carcinoma)	1	3	3	3	3	4
<b>Inflammatory bowel disease (including Crohn's disease and ulcerative colitis)</b>	1	1	1	1	2	2
<b>ANAEAMIAS</b>						
Thalassaemia	2	1	1	1	1	1
Sickle cell disease	2	1	1	1	1	2
Iron deficiency anaemia	2	1	1	1	1	1
<b>RHEUMATIC DISEASES</b>						
Rheumatoid arthritis	1	2	2	2	2	2
<b>Systemic lupus erythematosus (SLE)</b>						
a) No antiphospholipid antibodies	1	2	2	2	2	2
b) Positive antiphospholipid antibodies	1	2	2	2	2	4
<b>Positive antiphospholipid antibodies</b>	1	2	2	2	2	4
<b>DRUG INTERACTIONS</b>						
Taking medication	See section on drug interactions with hormonal contraception.					

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## Additional Resources

### Diagnosis of Migraine With or Without Aura

The UK Medical Eligibility Criteria for Contraceptive Use (UKMEC) includes 'headache' as a condition, which is split into the following sub-conditions:

- a) Non-migrainous (mild or severe)
- b) Migraine without aura, at any age
- c) Migraine with aura, at any age and
- d) History ( $\geq 5$  years ago) of migraine with aura, any age.

Headache is a common condition affecting women of reproductive age. Migraine is a common disabling primary headache disorder which can be classified into two major sub-types: migraine without aura and migraine with aura. Classification depends on making an accurate diagnosis of those severe headaches that are migrainous and in addition those complicated by aura.

### Useful resources for making a migraine diagnosis

#### 1. Mayo Clinic

The Mayo Clinic has produced a video on migraine aura<sup>1</sup> that shows how an aura can present to a woman:

<http://www.mayoclinic.org/diseases-conditions/migraine-with-aura/multimedia/migraine-aura/vid-20084707>

#### 2. International Headache Society (IHS)

The International Classification of Headache Disorders (3rd edition) (ICHD-3) criteria<sup>2</sup> is the official criteria of the International Headache Society (IHS). The ICHD-3 provides the following diagnostic criteria for distinguishing between the two major sub-types of migraines. Please refer to the ICHD-3 criteria for further details on symptoms.<sup>2</sup>

## **Migraine Without Aura**

Recurring headache with at least five attacks fulfilling the following criteria:

- Headache attacks lasting 4–72 hours (treated or unsuccessfully treated)
- Headache has at least two of the following four characteristics:
  - Unilateral location
  - Pulsating quality
  - Moderate or severe pain intensity
  - Aggravation by or causing avoidance of routine physical activity (e.g. walking or climbing stairs).
- At least one of the following during headache attacks:
  - Nausea and/or vomiting
  - Photophobia and phonophobia.
- Not better accounted for by another ICHD-3 diagnosis.

### **Notes:**

1. One or a few migraine attacks may be difficult to distinguish from symptomatic migraine-like attacks. Furthermore, the nature of a single or a few attacks may be difficult to understand. Therefore, at least five attacks are required.
2. When the patient falls asleep during a migraine attack and wakes up without it, duration of the attack is reckoned until the time of awakening.
3. In children and adolescents (aged under 18 years), attacks may last 2–72 hours.

## Migraine With Aura

Must fulfil the criteria for migraine without aura, and in addition, at least two attacks fulfilling the following criteria:

- One or more of the following fully reversible aura symptoms, but no motor weakness:
  - Visual
  - Sensory
  - Speech and/or language
  - Motor
  - Brainstem
  - Retinal.
  -
- At least two of the following four characteristics:
  - At least one aura symptom spreads gradually over  $\geq 5$  minutes, and/or two or more symptoms occur in succession
  - Each individual aura symptom lasts 5–60 minutes
  - At least one aura symptom is unilateral
  - The aura is accompanied by, or followed within 60 minutes, by headache.
  -
- Not better accounted for by another ICHD-3 diagnosis, and transient ischaemic attack has been excluded.

### Notes:

1. Migraine aura is sometimes associated with a headache that does not fulfil criteria for migraine without aura, but this is still regarded as a migraine headache because of its relation to the aura. In other cases, migraine aura may occur without the headache.
2. When, for example, three symptoms occur during an aura, the acceptable maximal duration is  $3 \times 60$  minutes. Motor symptoms may last up to 72 hours.
3. **Visual symptoms:** Often presents as a fortification spectrum: a zigzag figure near the point of fixation that may gradually spread right or left and assume a laterally convex shape with an angulated scintillating edge, leaving absolute or variable degrees of relative scotoma in its wake. In other cases, scotomata without positive phenomena may occur.
4. **Sensory symptoms:** Pins and needles moving slowly from the point of origin and affecting a greater or smaller part of one side of the body/face and/or tongue. Numbness may occur in its wake, but numbness may also be the only symptom.
5. **Speech disturbance:** Usually aphasia (aphasia is always regarded as a unilateral symptom)

Motor, brainstem and retinal symptoms can constitute aura. Aura involving motor symptoms (fully reversible motor weakness lasting  $<72$  hours), brainstem symptoms (dysarthria, vertigo, tinnitus, hyperacusis, diplopia, ataxia, reduced level of consciousness) and retinal symptoms (fully reversible monocular positive and/or negative visual phenomena) is not typical aura. Please refer to ICHD-3 guideline for more details.<sup>2</sup> Specialist diagnosis may be required to allow exclusion of other diagnoses.

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## Appendices

### Appendix 1: UKMEC Development Process

In preparation for the UKMEC revision and in order to identify topics to be reviewed, the CEU conducted a consultation with FSRH stakeholders from January to March 2015, a search of the 2014 FSRH Members Enquiry Service for common themes relating to medical eligibility for contraceptive use and a comparison of the 2009 UKMEC with existing versions of the USMEC and WHOMEC.

A Guideline Steering Group (GSG), comprising the CEU secretariat and five external members, was established for the 2016 UKMEC edition to define the scope of the UKMEC revisions. A Guideline Development Group (GDG) was established consisting of the steering group and a further nine experts in contraception and relevant disciplines (see Appendix 2).

The GSG met in February 2015 to review the topics that had been proposed from the scoping exercises (above) and to approve the scope of the UKMEC revision that would be considered by the GDG at the meeting in April 2015. Priority was given to controversial topics or those in which new evidence had emerged including clarifying recommendations with 'split' MEC categories (2/3 or 3/4 classification). The topics prioritised for review and consideration by the GDG were sent to GDG members electronically together with evidence summary tables (where appropriate). GDG members were asked to respond electronically to the CEU on level of agreement with the proposed scope of the revision. These responses were considered by the GSG, in advance of the GDG meeting.

A 2-day GDG meeting at the CEU took place on 15–16 April 2015 to endorse the scope of the revised UKMEC 2016 and to review new evidence relevant to the proposed revisions, which was primarily obtained from systematic reviews of the most recent literature. Where evidence was lacking for topics, technical consultation was conducted with UK experts in the relevant area (see Appendix 2). In order for changes to be made to the UKMEC 2009 classifications, we adopted a similar process used by the WHOMEC, which required updated high-quality evidence (i.e. from randomised controlled trials) to be identified to substantiate any significant proposed changes to MEC categories. Recommendations were made following a formal consensus process.

The 2016 edition of the UKMEC was based on the recommendations agreed by the GDG at the meeting convened by the CEU in April 2015. All members of the GDG were asked to declare any conflicts of interest. There were no conflicts of interest that were judged to preclude individuals from participating in the deliberations and development of the UKMEC recommendations. A total of 27 topics (more than 126 recommendations) were reviewed as part of the MEC revision (see 'Summary of changes from UKMEC 2009' in Section A). All other existing recommendations were confirmed by the GDG and did not undergo formal review for the 2016 UKMEC.

The first draft of the 2016 UKMEC was produced in July 2015. This was reviewed by the GDG, and following changes in response to feedback, the second draft was sent to both UK stakeholder groups and international experts in contraception (see Appendix 2) in August 2015 for peer review.

Revisions that required consensus approval were made by the GSG. Editorial revisions were made by the CEU. The final version of the 2016 UKMEC was approved by the Clinical Effectiveness Committee (CEC) of the FSRH on 16 November 2015.

## Appendix 2: List of Contributors

The update of the UKMEC is guided by the UKMEC Guideline Development Group (GDG) comprising the secretariat, which includes staff from the CEU, the steering group and the multidisciplinary group of experts.

<b>Secretariat</b>	<b>Specialist area/Experience</b>
Dr Sharon Cameron (Chair)	Sexual and reproductive health; gynaecology; contraceptive research; WHOMECA
Dr Zhong Eric Chen	Evidence synthesis
Dr Ailsa Gebbie	Community gynaecology and reproductive health
Dr Sarah Hardman	Sexual and reproductive health; genitourinary medicine
Ms Kate Williams	Project management and administrative support
<b>Steering Group</b>	<b>Specialist area/Experience</b>
Dr Anne Connolly	General practice; sexual and reproductive health
Dr Kathryn Curtis	Evidence synthesis; WHOMECA; USMEC
Professor Anna Glasier	Sexual and reproductive health, contraceptive research; WHOMECA; UKMEC
Professor Phil Hannaford*	Epidemiology; general practice; WHOMECA; UKMEC
Dr Diana Mansour	Community gynaecology and reproductive health; UKMEC

<b>Multidisciplinary Group</b>	<b>Specialist area/Experience</b>
Dr Sinead Cook	Sexual and reproductive health
Dr Sarah Cooper	Obstetrics and gynaecology
Professor Ian Greer*	Obstetrics and gynaecology
Dr Sophie Khadr	Adolescent sexual and reproductive health
Dr Sue Mann	Public health; sexual and reproductive health
Ms Shelley Mehigan Raine	Nursing; sexual and reproductive health
Dr Janet Nooney	Medicine information/safety; UKMEC
Dr Sam Rowlands	Sexual and reproductive health
Professor James Trussell	Epidemiology; USMEC

\*Professor Phil Hannaford and Professor Ian Greer were not present at the face-to-face meeting but provided input before and after the meeting via email.

In the development of the UKMEC, UK experts were consulted:

<b>Experts</b>	<b>Specialist area</b>	<b>Experts</b>	<b>Specialist area</b>
Dr Nicole Amft	Rheumatic diseases	Dr John O'Sullivan	Cardiac disease
Dr Scott Fegan	Ovarian cancer	Dr Karen Schreiber	Rheumatic diseases
Dr Ian Giles	Rheumatic diseases	Dr Gordon Scott	GUM/HIV
Professor Caroline Gordon	Rheumatic diseases	Mr Richard Skipworth	Bariatric surgery
Dr Robin Grant	Neurology	Dr Charles Wallis	Anaesthesia
Ms Jo Marsden	Breast cancer	Dr Laura Waters	GUM/HIV
Ms Lorna Marson	Organ transplant	Dr David Williams	Rheumatic diseases

The UK stakeholder and international reviewers are:

<b>UK reviewers</b>	<b>Role/Affiliation</b>	<b>Specialist area</b>
Dr P S Arunakumari	Consultant Obstetrician and Gynaecologist, Basildon and Thurrock University Hospitals NHS Trust (Royal College of Obstetrics and Gynaecology)	Contraception; paediatric and adolescent gynaecology; abortion care
Ms Carmel Bagness	Professional lead for Midwifery and Women's Health (Royal College of Nursing)	Midwifery; nursing
Ms Sue Burchill	Head of Nursing (Brook)	Young people's sexual and reproductive health care
Mr Thomas Francis Corbett	Clinical Writer (British National Formulary, Royal Pharmaceutical Society of Great Britain)	Pharmacy
Dr Kate Guthrie	Clinical Director, Consultant Gynaecologist (Sexual and Reproductive Health Services, Hull and East Riding); Clinical Expert, Sexual and Reproductive Health (Public Health England)	Sexual and reproductive health; community based gynaecology
Ms Natika H Halil	Chief Executive (Family Planning Association)	Contraception; sexually transmitted infections

Mr Kin Liu	Highly specialist HIV/GUM pharmacist (Chelsea and Westminster Hospital NHS Foundation Trust, Royal Pharmaceutical Society of Great Britain)	Pharmacy; GUM/HIV
Dr Patricia A Lohr	Medical Director (British Pregnancy Advisory Service)	Obstetrics and gynaecology; family planning
Dr Nneka Nwokolo	Consultant HIV/GU Physician (Chelsea and Westminster Hospital, London; Royal College of Physicians)	Sexually transmitted infections; contraception and reproductive health; HIV medicine
Dr Dhammadika Perera	Global Medical Director (Marie Stopes International)	Reproductive health; public health
Dr Lindsey E Ross	General PractitionerP (Dingwall Medical Group, Inverness); Member of Sex, Drugs & BBV Group (Royal College of General Practitioners)	General practice; blood-borne viruses; substance misuse
Ms Louise Silverton	Director for Midwifery (The Royal College of Midwives)	Midwifery and maternity care

<b>International reviewers</b>	<b>Role/Affiliation</b>	<b>Specialist area</b>
Dr Deborah Bateson (Australia)	Medical Director (Family Planning NSW, Sydney); Clinical Associate Professor, Discipline of Obstetrics, Gynaecology and Neonatology (The University of Sydney)	Sexual and reproductive health; contraceptive research
Dr Erin Berry-Bibee (United States)	Reviewer and Guest Researcher (Centers for Disease Control and Prevention); Assistant Professor (University of Chapel Hill North Carolina)	Family planning; obstetrics and gynaecology
Dr Pritha Biswas (India)	Obstetrician and Gynaecologist, Senior Advisor, Safe Abortion, Family Planning and Sexual and Reproductive Health (Marie Stopes International)	Reproductive health
Professor Kristina Gemzell Danielsson (Sweden)	Professor and Chair, Division of Obstetrics & Gynecology, Department of Women's and Children's Health (Karolinska Institutet); Senior Consultant (Karolinska University Hospital)	Sexual and reproductive health; contraceptive research
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## Appendix 3: Commonly Used Abbreviations

<b>AIDS</b>	Acquired immune deficiency syndrome	<b>IUC</b>	Intrauterine contraception
		<b>IM</b>	Intramuscular
<b>ART</b>	Antiretroviral therapy	<b>LAM</b>	Lactational amenorrhoea method
<b>ARV</b>	Antiretroviral	<b>LARC</b>	Long-acting reversible contraception
<b>BMD</b>	Bone mineral density	<b>LDL</b>	Low-density lipoprotein
<b>BMI</b>	Body mass index	<b>LNG</b>	Levonorgestrel
<b>BNF</b>	British National Formulary	<b>LNG-IUS</b>	Levonorgestrel-releasing intrauterine system
<b>BP</b>	Blood pressure	<b>MI</b>	Myocardial infarction
<b>CEU</b>	Clinical Effectiveness Unit	<b>NET</b>	Norethisterone
<b>CHC</b>	Combined hormonal contraception	<b>NET-EN</b>	Norethisterone enantate
<b>CIN</b>	Cervical intraepithelial neoplasia	<b>PE</b>	Pulmonary embolism
<b>COC</b>	Combined oral contraception	<b>PID</b>	Pelvic inflammatory disease
<b>Cu-IUD</b>	Copper-bearing intrauterine device	<b>POC</b>	Progestogen-only contraception
<b>CVD</b>	Cardiovascular disease	<b>POP</b>	Progestogen-only pill
<b>DMPA</b>	Depot medroxyprogesterone acetate	<b>SC</b>	Subcutaneous
<b>DSG</b>	Desogestrel	<b>SLE</b>	Systemic lupus erythematosus
<b>DVT</b>	Deep vein thrombosis	<b>STI</b>	Sexually transmitted infection
<b>EC</b>	Emergency contraception	<b>TIA</b>	Transient ischaemic attack
<b>EE</b>	Ethinylestradiol	<b>UKMEC</b>	UK Medical Eligibility Criteria for Contraceptive Use
<b>FSRH</b>	Faculty of Sexual and Reproductive Healthcare	<b>UPA</b>	Ulipristal acetate
<b>GDG</b>	Guideline Development Group	<b>UPSI</b>	Unprotected sexual intercourse
<b>GTD</b>	Gestational trophoblastic disease	<b>VTE</b>	Venous thromboembolism
<b>hCG</b>	Human chorionic gonadotrophin	<b>WHO</b>	World Health Organization
<b>HDL</b>	High-density lipoprotein		
<b>HIV</b>	Human immunodeficiency virus		
<b>HMB</b>	Heavy menstrual bleeding		
<b>HPV</b>	Human papillomavirus		
<b>IBD</b>	Inflammatory bowel disease		
<b>IIH</b>	Idiopathic intracranial hypertension		
<b>IMP</b>	Progestogen-only implant		





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