FSRH The Faculty of Sexual & Reproductive Healthcare

FSRH Guideline

Overweight, Obesity & Contraception

April 2019 | FSRH

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Abbreviations used

BMD	bone mineral density
BMI	body mass index
CEU	Clinical Effectiveness Unit
CHC	combined hormonal contraception/contraceptive
CI	confidence interval
COC	combined oral contraception/contraceptive
Cu-IUD	copper intrauterine device
CVD	cardiovascular disease
DMPA	depot medroxyprogesterone acetate
DSG	desogestrel
EC	emergency contraception
EE	ethinylestradiol
ENG	etonogestrel
FSRH	Faculty of Sexual & Reproductive Healthcare
GDG	guideline development group
HCP	healthcare practitioner
HFI	hormone-free interval
HMB	heavy menstrual bleeding
HR	hazard ratio
IMP	progestogen-only implant
IUC	intrauterine contraception/contraceptive
LARC	long-acting reversible contraception/contraceptive
LNG	levonorgestrel
LNG-EC	levonorgestrel (for emergency contraception)
LNG-IUS	levonorgestrel-releasing intrauterine system
MI	myocardial infarction
NET-EN	norethisterone enanthate
NGMN	norelgestromin
OC	oral contraception/contraceptive
OR	odds ratio
POP	progestogen-only pill
RCT	randomised controlled trial
SPC	Summary of Product Characteristics
UKMEC	UK Medical Eligibility for Contraceptive Use
UPA	ulipristal acetate
UPA-EC	ulipristal acetate (for emergency contraception)
VTE	venous thromboembolism
WHO	World Health Organization

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Grading of recommendations

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

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

List of tables

Table 1	Definition of weight categories and body mass index
Table 2	Percentage of women experiencing an unintended pregnancy within the first year of use with typical use and perfect use (modified from Trussell).
Table 3	UK Medical Eligibility Criteria for Contraceptive Use (UKMEC) recommendations for contraceptive safety following bariatric surgery

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Contents

Abbreviations used iii

Grading of recommendations iv

List of tables iv

Executive summary of recommendations viii

Resources x

1 Purpose and scope 1

2 Definitions of overweight and obesity 2

3 Why is this guideline focusing on contraception and raised BMI needed? 2

4 An overview of data on fertility, sexual activity, contraceptive use and unintended pregnancy among women with raised BMI 3

5 Suitability of contraceptive methods for women who are overweight or women with obesity 4

5.1 Intrauterine contraception (IUC) 6

5.1.1 IUC effectiveness 6

5.1.2 IUC safety 7

5.1.3 Weight gain with IUC 8

5.1.4 Health benefits of IUC 8

5.1.5 Practical considerations with IUC 8

5.2 Progestogen-only implants (IMP) 8

5.2.1 Implant effectiveness 9

5.2.2 Implant safety 11

5.2.3 Weight gain with implants 11

5.2.4 Health benefits of implants 11

5.2.5 Practical considerations with implants 11

5.3 Progestogen-only injectable 12

5.3.1 DMPA effectiveness 12

5.3.2 DMPA safety 13

5.3.3 Weight gain with DMPA 14

5.3.4 Health benefits of DMPA 15

5.3.5 Practical considerations with DMPA 15

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5.4 Progestogen-only pill (POP) 15
5.4.1 POP effectiveness 15
5.4.2 POP safety 16
5.4.3 Weight gain with POP 17
5.4.4 Health benefits of POP 17
5.5 Combined hormonal contraception (CHC) 17
5.5.1 CHC effectiveness 17
5.5.2 CHC safety 20
5.5.3 Weight gain with CHC 22
5.5.4 Health benefits of CHC 22
5.6 Barrier methods of contraception 22
5.6.1 Barrier method effectiveness 22
5.6.2 Barrier method safety 22
5.7 Fertility awareness methods 23
5.8 Emergency contraception (EC) 23
5.8.1 Cu-IUD 23
5.8.2 Oral EC 23
5.9 Female surgical sterilisation 25
5.9.1 Effectiveness and safety 25
6 Contraception and weight management treatment 25
6.1 Weight-loss medication and contraception 25
6.1.1 Orlistat 26
6.1.2 Liraglutide 26
6.1.3 Naltrexone/buproprion 27
6.1.4 Laxatives 27
6.2 Weight-loss surgery and contraception 27
6.2.1 Background 27
6.2.2 UKMEC information on bariatric surgery 28
6.2.3 Effectiveness and safety of contraception after bariatric surgery 29
6.2.4 Contraception before bariatric surgery 31

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7 Approach to issues of weight in contraceptive consultations 32

Recommendations for future research 33

Considerations for implementation of this guideline 33

Useful links 33

References 34

Appendix 1: FSRH Clinical Guideline Development Process 50

Questions for continuing professional development 55

Auditable outcomes 57

Comments and feedback on published guideline 58

Information Box

Title	Overweight, Obesity and Contraception
Author/Publisher	Faculty of Sexual & Reproductive Healthcare
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Executive summary of recommendations

Suitability of contraceptive methods for women who are overweight or women with obesity

Intrauterine contraception (IUC)

Key information

C	**Intrauterine contraception (IUC) is a highly effective method of contraception and available evidence suggests that its effectiveness is not affected by body weight or body mass index (BMI).**
D	**The available evidence suggests that IUC is a safe contraceptive option for women who are overweight and women with obesity.**

Progestogen-only implants

Key information

C	**The etonogestrel (ENG) implant is a highly effective method of contraception and available evidence suggests that its effectiveness is not affected by body weight or BMI.**
✓	**The licensed duration of ENG implant use of 3 years applies to women of all weight categories.**
C	**The available evidence suggests that the ENG implant is a safe contraceptive option for women who are overweight and women with obesity.**

Progestogen-only injectable

Key information

C	**The available evidence suggests that effectiveness of depot medroxyprogesterone acetate (DMPA) is not affected by body weight or BMI.**
B	**From the limited evidence available it is not possible to confirm or exclude a causal association between DMPA use and venous thromboembolism (VTE).**
D	**Whilst obesity alone does not restrict the use of DMPA (UKMEC 1), DMPA use becomes a UKMEC 3 when obesity is one of multiple risk factors for cardiovascular disease (e.g. smoking, diabetes and hypertension).**
B	**DMPA use appears to be associated with some weight gain, particularly in women under 18 years of age with a BMI ≥30 kg/m^2.**

Clinical recommendation

✓	**For women with obesity:** ► **If using intramuscular DMPA or norethisterone enanthate injectable, consider use of a longer-length needle or deltoid administration to ensure the muscle layer is reached.** ► **Consider use of subcutaneous DMPA.**

Progestogen-only pill (POP)

Key information

D	**The available evidence suggests that effectiveness of the progestogen-only pill (POP) is not affected by body weight or BMI.**
D	**The available evidence suggests that POP is a safe contraceptive option for women who are overweight and women with obesity.**

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Clinical recommendation

✓	**Double-dose POP for contraception is not recommended for women who are overweight or women with obesity.**

Combined hormonal contraception (CHC)

Key information

C	**Most evidence suggests that effectiveness of combined oral contraception (COC) is not affected by body weight or BMI.**
D	**Limited evidence suggests a possible reduction in patch effectiveness in women weighing ≥90 kg.**
D	**Limited evidence suggests that effectiveness of the vaginal ring is not affected by body weight or BMI.**
D	**Combined hormonal contraception (CHC) use is UKMEC 2 for use by women with BMI ≥30–34 kg/m^2 and UKMEC 3 for women with BMI ≥35 kg/m^2.**

Clinical recommendation

B	**Women with obesity should be informed that:** ► **risk of thrombosis increases with increasing BMI.** ► **current CHC use is associated with increased risk of VTE.** ► **current CHC use is associated with a small increased risk of myocardial infarction and ischaemic stroke.** ► **if BMI is ≥35 kg/m^2 the risks associated with use of CHC generally outweigh the benefits.**

Emergency contraception (EC)

Key information

✓	**The available evidence suggests that effectiveness of the copper intrauterine device (Cu-IUD) is not affected by body weight or BMI.**
C	**1.5 mg levonorgestrel emergency contraception (LNG-EC) appears to be less effective in women with BMI >26 kg/m^2 or weight >70 kg.**
C	**Ulipristal acetate EC (UPA-EC) may be less effective in women with BMI >30 kg/m^2 or weight >85 kg.**

Clinical recommendations

C	**Women should be informed that the Cu-IUD is the most effective method of EC.**
C	**Women should be informed that BMI >26 kg/m^2 or weight >70 kg may reduce the effectiveness of oral EC, particularly of LNG-EC.**
✓	**Consider UPA-EC and, if this is not suitable, double-dose (3 mg) LNG-EC if BMI >26 kg/m^2 or weight >70 kg. The effectiveness of double-dose LNG-EC is unknown.**
✓	**Double-dose UPA-EC is not recommended for women of any body weight or BMI.**

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Contraception and weight management treatment

Weight-loss medication and contraception

Clinical recommendation

✓	**Women should be advised that it is possible that medications that induce diarrhoea and/or vomiting (e.g. orlistat, laxatives) could reduce the effectiveness of POP, COC and oral EC.**

Weight-loss surgery and contraception

Key information

D	**Non-oral contraceptives have been studied in only small numbers of women following bariatric surgery but appear to be safe and effective.**
D	**For women with BMI ≥35 kg/m^2, risks associated with CHC use generally outweigh the benefits.**

Clinical recommendations

✓	**Women receiving counselling regarding bariatric surgery should have a discussion about contraception and have a plan for contraception in place prior to surgery.**
D	**Women should be advised that the effectiveness of oral contraception (OC), including oral EC, could be reduced by bariatric surgery and OC should be avoided in favour of non-oral methods of contraception.**
D	**Women should be advised to stop CHC and to switch to an alternative effective contraceptive method at least 4 weeks prior to planned major surgery (e.g. bariatric surgery) or an expected period of limited mobility.**

Approach to issues of weight in contraceptive consultations

Clinical recommendation

✓	**When providing contraception to women with raised BMI, healthcare providers, after asking permission, should raise the subject of weight, enquire about whether BMI is of concern, and signpost to appropriate support for weight management if wanted.**

Resources

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

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Resource 1: UK Medical Eligibility Criteria for Contraceptive Use (UKMEC) categories based on body mass index[1]

Method	BMI (kg/m^2)	UKMEC category* (BMI alone)	UKMEC category if obesity is one of multiple risk factors for cardiovascular disease	History of bariatric surgery
Combined hormonal contraception (COC, vaginal ring, patch)	≥30–34	2	3	2
	≥35	3		3
Progestogen-only pill	≥30–34	1	2	1*
	≥35			
Progestogen-only implant	≥30–34	1	2	1
	≥35			
Progestogen-only injectable (DMPA or NET-EN)	≥30–34	1	3	1
	≥35			
Copper intrauterine device	≥30–34	1	1	1
	≥35			
Levonorgestrel-releasing intrauterine system	≥30–34	1	2	1
	≥35			

BMI, body mass index; COC, combined oral contraceptive; DMPA, depot medroxyprogesterone acetate; NET-EN, norethisterone enanthate.

*It is important to note that UKMEC categories for contraceptive use after bariatric surgery relate to safety of use rather than effectiveness. Safety considerations after bariatric surgery relate to ongoing high BMI. In Section 6.2 (Weight-loss surgery and contraception) of this guidance, the CEU advises the following: Women should be advised that the effectiveness of oral contraception (OC), including oral emergency contraception, could be reduced by bariatric surgery and OC should be avoided in favour of non-oral methods of contraception.

FSRH Guideline (April 2019) Overweight, Obesity and Contraception (Revision due by April 2024)

1 Purpose and scope

This new guideline brings together evidence and expert opinion on the provision of contraception to women who are overweight and women with obesity. This guidance is most relevant to women of reproductive age who require contraception and have a body mass index (BMI) of 25 kg/m^2 or higher. The guidance is intended for use by health professionals who provide contraceptive advice or contraceptive supplies for women in community and hospital settings.

Recommendations are based on available evidence and the consensus opinion of experts and the guideline development group (GDG). They should be used to guide clinical practice but are not intended to serve alone as a standard of medical care or to replace clinical judgement in the management of individual cases. A key to the grading of recommendations, based on levels of evidence, is provided on page iv of this document. Details of the methods used by the Faculty of Sexual & Reproductive Healthcare (FSRH) Clinical Effectiveness Unit (CEU) in developing this guidance are outlined in **Appendix 1**.

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This guideline focuses on contraceptive choices for women who are overweight and women with obesity, reviews the current evidence regarding the interrelationship between contraception and weight (i.e. the effects of weight on contraceptive effectiveness and safety, and the effects of contraceptive use on weight gain) and touches on other potential considerations relating to contraception in women with raised BMI, such as contraception after bariatric surgery and during use of weight-loss medication.

For information on contraceptive choices for women who are overweight or women with obesity who have particular lifestyle risk factors, medical conditions, concomitant medication, or a history of bariatric surgery, health professionals should also refer to the UK Medical Eligibility Criteria for Contraceptive Use (UKMEC),[1] British National Formulary,[2] Stockley's Drug Interactions[3] and the electronic Medicine Compendium.[4]

2 Definitions of overweight and obesity

Overweight and obesity are defined based on BMI, which is an indirect measure of body fat. The degree of adiposity associated with a given level of BMI varies by age, sex, and racial and ethnic group, but BMI has been shown to correlate well to more direct assessments of body fat.[5,6] BMI is calculated by dividing weight in kilograms (kg) by height in meters squared (m^2). Although BMI is not a perfect indicator of body fat, it is relatively reliable, inexpensive and easy to perform in a clinical setting. This document uses BMI in order to correspond with the UKMEC. BMI categories are defined by the World Health Organization (WHO).[7] Normal weight is classified as BMI 18.5–24.9 kg/m^2, overweight as BMI ≥25 kg/m^2, and obesity as BMI ≥30 kg/m^2, with morbid obesity beginning at 40 kg/m^2 (see **Table 1**).

For the purpose of this document, the term 'women with raised BMI' will be used to refer to women who are overweight and women with obesity. The terms 'women who are overweight' and 'women with obesity' will be used when specificity is required. The terms 'BMI' and 'weight' will both be used in this document, but specified where appropriate.

Table 1: Definition of weight categories and body mass index

Weight category	Body mass index (BMI) (kg/m^2)
Underweight	<18.5
Normal weight	18.5–24.9
Overweight	25–29.9
Obese	30–34.9
	35–39.9
Morbidly obese*	≥40

*Sometimes referred to as severely obese.

3 Why is this guideline focusing on contraception and raised BMI needed?

The increasing prevalence of obesity is a worldwide health concern. In a systematic analysis of epidemiological studies from 199 countries, 1.46 billion adults worldwide are estimated to be overweight, and of these 502 million are obese.[8,9] Currently, it is estimated that over half of the women in the UK are overweight or obese, ranging from 53% of women in Wales to 61% of women in Scotland.[10,11] Levels of obesity are expected to continue rising in the UK and globally.[12] It is

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estimated that seven out of ten people in the UK will be overweight or obese by 2020.[9] A 2018 report from Public Health England states that "rates of obesity are increasing among women of reproductive age and an increasing number of women who become pregnant are obese – 19% of women of reproductive age in England are obese, 3.6% are severely obese, and of these obese women 5.3% will become pregnant each year".[13]

Guidance to support the safe and effective use of contraception by women of reproductive age with chronic medical conditions, such as obesity, is paramount for several reasons.

First, ensuring that women with raised BMI can safely and effectively use contraception is critical to their attainment of sexual and reproductive rights to decide when, whether and how many children to have.[14]

Second, safe and effective pregnancy prevention and planning is critical since women with obesity, particularly those with comorbidities, are at significantly higher risk of pregnancy-related complications,[13,15–17] making pregnancy planning and pre-pregnancy optimisation of weight especially important. Women with obesity who become pregnant face an increased risk of gestational hypertension, diabetes, pre-eclampsia, caesarean delivery, postpartum haemorrhage, and fetal complications such as growth restriction, macrosomia, neural tube defects, and stillbirth.[15–17] Maternal obesity impacts the long-term health of offspring, with increased rates of chronic health conditions like obesity and diabetes.[18–20]

Third, links between obesity and adverse health issues such as cardiovascular disease (CVD) and metabolic disorders are well established[21,22] and important when considering certain types of contraception. In addition, some contraceptive methods may offer non-contraceptive benefits to women with raised BMI.

Finally, healthcare practitioners (HCPs) providing contraception care are well-placed to raise the topic of weight and signpost women to appropriate support, because issues of weight are relevant to contraceptive decision-making.

It is a clinical and public health necessity for HCPs to understand the effectiveness and safety of contraception in women with raised BMI in order to assist them in making informed choices. Therefore, evidence-based guidance to inform the provision of contraceptive care for women with raised BMI in the UK is needed.

4 An overview of data on fertility, sexual activity, contraceptive use and unintended pregnancy among women with raised BMI

Understanding the evidence on fertility, sexual activity, contraceptive use and unintended pregnancy among women with raised BMI is essential to providing them with good contraceptive care.

Fertility

While women with obesity may experience reduced fecundity and fertility because of anovulation,[23–25] polycystic ovary syndrome and insulin resistance,[26] the majority of women with obesity may continue to ovulate on a regular basis and should therefore view themselves as having the potential to become pregnant.

Sexual activity and use of contraception

Despite common misconceptions, the available evidence[27–29] shows that the weight of adult women is not associated with their sexual behaviour, though most of the studies on this topic are limited by

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self-report of responses to very personal questions and could be subject to misreporting. However, data from the US indicates that adolescent girls with obesity are more likely to have an older partner, more likely to have more than three sexual partners in 1 year, and less likely to use condoms than girls who are not obese.[30] It is important to note that these differences were only seen among Caucasian girls but not African-American girls. Other large-scale analyses report similar findings.[31]

Although there are no published data on contraceptive use among women of differing weight or BMI categories from the UK, data on adult and adolescent women are available from several surveys in the US and Europe. In some US studies, the use of any contraceptive method by women with raised BMI does not differ from women who are normal weight.[32,33] Other studies have found degree of obesity to be associated with contraceptive use: women with BMI ≥35 kg/m^2 were more likely to not be using contraception compared with normal-weight women.[34] French surveys[29] have shown that women with obesity are significantly less likely to use contraception compared to normal-weight women;[35,36] the reasons for this, whether related to patient, provider or systems issues, are unclear.

Preventing unintended pregnancy

Findings as to whether BMI affects the likelihood of unintended pregnancy vary across studies. While recognising that this is a limitation of the available literature, some studies which have addressed this in the US have found no association between unintended pregnancy and BMI,[27] whereas others have found increased risk of unintended pregnancy associated with increasing BMI; women with BMI ≥40 kg/m^2 had significantly greater odds of mistimed or unwanted pregnancy compared with normal-weight women.[34] A French study found that women with obesity under 30 years of age were four times more likely to report a prior unintended pregnancy or abortion than normal-weight women, but this association was not present for older women.[29]

Overall, adult women with obesity appear to be at a similar or higher risk of unintended pregnancy as compared to women of normal weight. For younger women, associations between obesity and riskier sexual behaviours may place them at greater risk of unintended pregnancy than their normal BMI counterparts. It is therefore imperative that women with higher BMI, like all women, have access to effective, safe contraception, and are supported to use contraception successfully if they so desire.

5 Suitability of contraceptive methods for women who are overweight or women with obesity

Method by method, this section will review the current evidence and provide recommendations regarding four key clinical questions related to each contraceptive method and weight:

a) ***Question 1: Does raised BMI affect contraceptive effectiveness?***
b) ***Question 2: What is the safety of contraceptive use by women with raised BMI?***
c) ***Question 3: Does contraceptive use lead to weight gain among women with raised BMI?***
d) ***Question 4: Are there non-contraceptive health benefits of contraceptive use to women with raised BMI?***

Question 1: Effectiveness

Contraceptive effectiveness relies on several factors, including the user's contraceptive adherence and sexual behaviour, and the inherent efficacy of the contraceptive method. Methods that require consistent and correct use by individual users have wide ranging effectiveness that can vary according

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to age, socioeconomic status, and users' motivation to prevent or delay pregnancy. Estimates of the rates of unplanned pregnancy in the first year of use of the various contraceptive methods in the general population of users are presented in **Table 2.**[37] For each contraceptive method, we review the current evidence and provide recommendations regarding the effect of increased weight and obesity on contraceptive effectiveness.

Question 2: Safety

The UKMEC 2016 provides guidance to inform safety of use of the various contraceptive methods in women with obesity.[1] Women who have obesity, compared to those with a normal BMI, are at increased risk for other diseases and health conditions, and these comorbidities also need be considered when providing contraception. Relevant comorbidities include: venous thromboembolism (VTE), hypertension, dyslipidaemias, type 2 diabetes, CVD, stroke, and some cancers (endometrial, breast).[38–42]

Table 2: Percentage of women experiencing an unintended pregnancy within the first year of use with typical use and perfect use (modified from Trussell)[37]

Method	Typical use (%) (estimated)	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*	9	0.3
Progestogen-only pill	9	0.3
Progestogen-only injectable	**6**	**0.2**
Copper intrauterine device	**0.8**	**0.6**
Levonorgestrel intrauterine system	**0.2**	**0.2**
Progestogen-only implant	**0.05**	**0.05**
Female sterilisation	0.5	0.5
Vasectomy	0.15	0.1

Long-acting reversible contraception/contraceptive methods in bold type.
*Includes combined oral contraception, transdermal patch and vaginal ring.

The primary safety concerns for women with obesity using contraception are cardiovascular risks from exogenous estrogen, including VTE, acute myocardial infarction (MI) and ischaemic stroke. Safety information and guidance with respect to risk of venous and arterial thrombosis is included in this guideline. The risk of VTE rises as BMI increases over 30 kg/m^2 and rises further with BMI ≥35 kg/m^2.[43,44] Baseline risk for VTE in obese women is two-fold higher than VTE risk in normal-weight women.[45,46] Detailed guidance on contraceptive use related to other comorbidities associated with obesity is outside the remit of this document, but these health conditions do need to be considered by HCPs when caring for women who are overweight and women with obesity. HCPs are advised to use the UKMEC for specific information to inform clinical decision-making in this regard.

Unless specifically stated, the UKMEC does not consider multiple conditions simultaneously. Assessing an individual woman's eligibility for use of a contraceptive method in the presence of multiple factors requires clinical judgment based on the evidence and **guidance available**.

There is very limited safety information regarding the use of hormonal and non-hormonal contraception in women with obesity who have other comorbidities, and very little safety information exists regarding the use of contraception in women with a BMI ≥40 kg/m^2.

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Overview of UKMEC guidance

See **Resource 1** at the start of this guideline which presents a table of UK Medical Eligibility Criteria for Contraceptive Use (UKMEC) based on BMI.[1]

For women with obesity (BMI categories of ≥30–34 kg/m^2 and ≥35 kg/m^2) **without coexistent medical conditions,** the UKMEC categorises all progestogen-only contraceptives and intrauterine contraception as UKMEC 1, which means that there are no restrictions on the use of these methods.[1]

For women with obesity (BMI categories of ≥30–34 kg/m^2 and ≥35 kg/m^2) of all ages, **all estrogen-containing contraception (i.e. combined hormonal contraception (CHC), including combined oral contraception (COC)** containing both ethinylestradiol (EE) and estradiol**, patch and ring)** are categorised as UKMEC 2 or 3, depending on BMI. These categorisations are primarily because of increased risk of VTE.

For women with raised BMI **with other risk factors for CVD in addition to obesity** (e.g. smoking, diabetes, hypertension and dyslipidaemias), while the copper intrauterine device (Cu-IUD) remains UKMEC 1 and the levonorgestrel-releasing intrauterine system (LNG-IUS), contraceptive implants and the progestogen-only pill (POP) are UKMEC 2, progestogen-only injectables (depot medroxyprogesterone acetate (DMPA) and norethisterone enanthate (NET-EN)) and CHC are classed as UKMEC 3.

It is important to note that UKMEC categories for contraceptive use after bariatric surgery relate to safety of use rather than effectiveness. Safety considerations after bariatric surgery relate to ongoing high BMI.

Question 3: Weight gain

Weight gain is a major concern for many women, for personal and health reasons, and may be so particularly for women with raised BMI. Worries about side effects of contraception in general, and weight gain specifically, are often cited as a reason why women do not initiate or do not continue to use contraception.[47,48] Studies of oral contraceptive (OC) users have found that a perceived weight gain is one of the leading reasons for discontinuation.[49] Many women will discontinue their contraception because of perceived side effects such as weight gain even though they are still at risk for an unintended pregnancy. Contraception is one of few medications that women commonly use for many years throughout their lives, and it is, thus, unsurprising that contraception is sometimes blamed by women and HCPs for a woman's weight gain. However, adolescents naturally continue to lay down adipose tissue through the late teens (a time when contraception is often initiated), even though adult height may have been reached already, and adult women tend to gain weight over time during the reproductive years regardless of contraceptive use, most likely due to a combination of genetics, environment and lifestyle factors.[50–52] Furthermore, women's perceptions of weight gain while using contraception have been shown to be incongruent with their actual weight.[53]

It is important to note that the majority of studies researching contraception and its potential impact on weight have used a population of women that are no more than 130% of ideal body weight. Thus, few or no women with obesity are included in these studies. There is some suggestion that the effect of contraception on weight may vary depending on a woman's weight at the time of contraceptive method initiation, but this has not been definitively studied.

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This guideline will provide evidence and information where available relating to weight gain for women with raised BMI using contraception. For further information, see the current FSRH statement ***Weight and Contraception***.[54]

Question 4: Health benefits

Pregnancy prevention is the primary benefit of contraceptive use for women of any weight desiring to avoid a pregnancy. An unplanned pregnancy in a woman with obesity carries greater risk than in women of normal BMI.[15–17] Pregnancy prevention aside, there is little specific evidence relating to other health benefits of contraceptive methods in women who are overweight or women with obesity in particular. This guideline will include information on benefits specific to women with raised BMI where available.

Method-by-method effectiveness, safety, effect on weight and health benefits

5.1 Intrauterine contraception (IUC)

Key information

C	**Intrauterine contraception (IUC) is a highly effective method of contraception and available evidence suggests that its effectiveness is not affected by body weight or BMI.**
D	**The available evidence suggests that IUC is a safe contraceptive option for women who are overweight and women with obesity.**

There are limited data relating to intrauterine contraception (IUC) use by women with raised BMI. For more information on effectiveness, safety, weight gain and benefits in the general population, refer to the FSRH guideline ***Intrauterine Contraception***.[55]

5.1.1 IUC effectiveness

The mechanisms of action of IUC are based on local effects and do not rely on systemic drug levels; therefore, a woman's weight would not be expected to affect contraceptive effectiveness of the Cu-IUD or LNG-IUS.[56–58]

There is no evidence of impaired contraceptive effectiveness in IUC users with obesity, either with the Cu-IUD or the LNG-IUS. A prospective cohort study reported no statistically significant difference in contraceptive failure rate during the first 2 to 3 years of use among IUC users (Cu-IUD or 52 mg LNG-IUS) who were of normal BMI (n=1584), overweight BMI (n=1149) or obese BMI (n=1467).[59] The overall IUC failure rate of less than one pregnancy per 100 woman-years did not vary by BMI; five women of normal weight, no women who were overweight, and seven women with obesity became pregnant. The initial efficacy trial of a lower dose 13.5 mg LNG-IUS included women weighing 38–155 kg (mean 68.7 kg) with BMIs from 16 to 55 kg/m^2 (mean 25.3 kg/m^2) and did not report lower efficacy for obese study participants.[60] The conclusions that can be drawn from these studies are limited by the low failure rate of IUC; there are too few pregnancies to determine statistically significant differences between weight groups.

Evidence level 2+

5.1.2 IUC safety

Cu-IUD

No studies have specifically evaluated the safety of the Cu-IUD in women with raised BMI. There are no theoretical reasons why the Cu-IUD would pose health risks to women with raised BMI. According to the UKMEC, obesity does not restrict the use of the Cu-IUD (UKMEC 1).[1]

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LNG-IUS

According to the UKMEC, obesity alone does not restrict the use of the LNG-IUS (UKMEC 1).[1] Even when obesity is in the context of other risk factors for CVD (e.g. smoking, diabetes and hypertension), use of the LNG-IUS is UKMEC 2.

No studies have directly assessed whether women with raised BMI who use LNG-IUS are at increased risk of VTE and other adverse cardiovascular outcomes, as compared to their normal-weight counterparts. Data presented here are therefore not specific to women with raised BMI.

Those few studies that have looked at different progestogen-only contraceptives generally suggest that there is little or no increased risk of VTE,[61–63] no statistically significant increased risk of MI[64] and no statistically significant increased risk of stroke[65] associated with use of POP, implants or the LNG-IUS. Data, however, are not available in relation to BMI or body weight. A Danish national registry-based cohort study[61] sought to assess the incidence of VTE in current users of non-oral hormonal contraception; the study included all Danish non-pregnant women aged 15–49 years (n=1 626 158), with no history of thrombosis, and followed them from 2001 to 2010. The risk of confirmed VTE was not increased with use of hormone-releasing intrauterine devices (IUDs) (adjusted relative risk (aRR) 0.57; 95% CI 0.41–0.81). A subanalysis of a case-control study on risk factors for venous thrombosis among women aged 18–50 years, which included 29 LNG-IUS users (3 cases and 26 controls), found that use of an LNG-IUS was not associated with an increased risk of VTE compared to non-use of hormonal contraception (odds ratio (OR) 0.3; 95% CI 0.1–1.1).[63] A meta-analysis of eight observational studies also showed no association between VTE risk and use of an LNG-IUS (aRR 0.61; 95% CI 0.24–1.53).[62]

Evidence level 2+

Very little research has been conducted to assess the effect of progestogen-only contraception on cardiovascular risk factors (e.g. lipid and carbohydrate metabolism) in women with raised BMI or in relation to BMI/weight. Studies looking at this in healthy, non-obese progestogen-only users or progestogen-only users of normal weight have been reassuring with no clinically meaningful changes observed.[53–61]

Evidence level 2+

5.1.3 Weight gain with IUC

There is no specific evidence relating to weight gain with IUC use by women with raised BMI. In the general population, there are no significant differences in weight gain when hormonal and non-hormonal intrauterine methods are compared and no evidence to support a causal association between IUC use and weight gain.

5.1.4 Health benefits of IUC

Obesity is associated with increased risk of endometrial hyperplasia and cancer.[74] Although not directly studied in women with obesity, studies of women in the general population suggest that use of the LNG-IUS or Cu-IUD is associated with reduced risk of endometrial hyperplasia and cancer.[75–79] The mechanism by which the Cu-IUD could reduce endometrial cancer risk has not been defined.

5.1.5 Practical considerations with IUC

IUC insertion for women with raised BMI is appropriate, safe and feasible. IUC is a highly effective and safe contraceptive option for women who are overweight and women with obesity. In practice, IUC insertion may be more challenging in women with obesity than in normal-weight women in

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terms of assessment of uterine position and gaining access to the uterus;[80] however, raised BMI is not a significant factor in failed IUC insertions or expulsions,[57] and insertion difficulties should not be presumed in women with raised BMI. Some practicalities may need to be considered in order to maximise the chances of insertion success. For example, having a supportive gynaecology couch and a range of speculum sizes is important. In addition, availability of a large blood pressure cuff for measuring blood pressure is necessary.

5.2 Progestogen-only implants (IMP)

Key information

C	**The etonogestrel (ENG) implant is a highly effective method of contraception and available evidence suggests that its effectiveness is not affected by body weight or BMI.**
✓	**The licensed duration of ENG implant use of 3 years applies to women of all weight categories.**
C	**The available evidence suggests that the ENG implant is a safe contraceptive option for women who are overweight and women with obesity.**

The single-rod etonogestrel (ENG) implant (Nexplanon®) is the only implant currently available in the UK, and is the method referred to as the 'implant' or 'IMP' throughout this document.

There are limited data relating to IMP use in women who are overweight or women with obesity. For more information on implant effectiveness, safety, weight gain and benefits in the general population, refer to the FSRH guideline ***Progestogen-only Implants***.[81]

5.2.1 Implant effectiveness

The implant is a highly effective method of contraception, and true contraceptive failures are very rare (see **Table 2**). However, the manufacturer-sponsored clinical trials which determined this excluded women who were >130% of their ideal body weight, meaning that no or few obese women were included.[82] Body composition could affect implant metabolism because of the increased volume of distribution, effects on plasma protein binding and altered plasma clearance in individuals with obesity.[83]

Though no studies have been specifically designed to answer the question of how obesity may impact implant effectiveness, currently available evidence suggests that both the ENG and levonorgestrel (LNG) contraceptive implants do remain highly effective in women with raised BMI. However, sufficient data on women with BMI ≥40 kg/m^2 are still lacking.

Taken together, recent pharmacokinetic and clinical outcomes data are reassuring that the implant is a highly effective contraceptive option for women of all BMIs. Available evidence is detailed below.

Pharmacokinetic studies

Some pharmacokinetic studies have shown an inverse relationship between body weight and ENG serum levels,[84,85] raising concerns about the effectiveness of the method in women with raised BMI, and the duration for which the method is effective in women with high BMI.

Evidence level 2-

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In one small pharmacokinetic study[85] of the ENG implant in the first 6 months of use, consistently lower serum concentrations of ENG were observed amongst those women with a BMI >30 kg/m^2 (n=13), compared with those with a BMI <25 kg/m^2 (n=4), although the difference was not statistically significant. In the group with a BMI >30 kg/m^2 (weight range 90–164 kg), projected serum levels at 1, 2 and 3 years of implant use were estimated to be 133,102 and 98 pg/mL, respectively.

In a pharmacokinetic study comparing 52 women (10 normal weight, 19 overweight, 23 with obesity) using the implant for at least 1 year,[86] ENG levels were comparable across BMI categories and no participant fell below the suggested threshold for ovulation of 90 pg/mL.[86]

It is important to note that the absolute ENG serum level required for suppression of ovulation has not been defined and may be lower than the usually suggested 90 pg/mL.[87]

Evidence level 2+

A recent study of 237 implant users (where participant BMIs ranged from 16.6 to 53.2 kg/m^2; 29% (n=27) normal weight, 25% (n=23) overweight, 46% (n=42) obese or morbidly obese) showed no difference in median ENG levels between women of different BMI categories at 3 and 4 years of use.[88] However, at those longer durations of use (3 and 4 years) some ENG levels among women who were overweight or who had obesity fell below 90 pg/mL (no data on how many women that included), although no pregnancies occurred. This cohort was also evaluated up to 5 years of implant use. A statistical difference in median ENG levels was noted at the end of 4 years of use, with women who were overweight having the highest serum ENG (195.9 (range 25.0–450.5) pg/mL) when compared to normal-weight women (178.9 (range 87.0–463.7) pg/mL) and women with obesity (137.9 (range 66.0–470.5) pg/mL) women (p=0.04). The clinical relevance of this is unclear given the nonlinear trend.[89]

While some pharmacokinetic data show that women with raised BMI using the implant may have lower serum ENG concentrations, clinical data do not suggest these women are experiencing more unintended pregnancies.

Studies considering contraceptive failure

A combined analysis[90] of clinical trial and postmarketing surveillance data on 923 women and 1849 woman-years of implant use, stratified by body weight and duration of use, provides some data on contraceptive failure rates in women with raised BMI weighing up to 149 kg (134 women had a body weight of more than 70 kg; 79 of these women used the implant for 2 years or more and 11 for more than 3 years). The distribution of body weight among women with contraceptive method failure was similar to that of the general population of ENG implant users, though the numbers of users with obesity was small. Other studies[82] that have included women weighing >70 kg (n=162 had BMI >26 kg/m^2) have similarly not reported any pregnancies in this weight range, although none of these studies were designed specifically to compare women of differing weights. Findings of these studies are limited by the small number of women weighing >100 kg included, and the limited data in women weighing >70 kg for up to 3 years of implant use.

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Evidence level 2+

Two more recent analyses have included larger proportions of women with raised BMI and looked at extended implant use. A secondary analysis of 1168 implant users in the US Contraceptive CHOICE project showed that pregnancy rates in users of the ENG implant are extremely low and similar in women who were overweight and had obesity compared with normal-weight women over 4 years of implant use.[59] In this cohort, 28% of women were overweight and 35% had obesity. Cumulative failure rates over 3 years were 0.00 per 100 woman-years for normal-weight and overweight women, and 0.23 per 100 woman-years for women with obesity. This study also assessed contraceptive failure by body weight; those women weighing >70 kg were not significantly more likely to experience implant failure compared to those weighing ≤70 kg (aRR 1.34; 95% CI 0.53–3.43), but the precision of this estimate was limited by the fact that pregnancy was a rare event and the small number of women in this weight group.

In a study of prolonged ENG implant use (up to 5 years), 237 women continued ENG implant use beyond 3 years, of whom 25% were overweight and 46% had obesity.[88] No pregnancies occurred during the period of prolonged use, leading to an estimated failure rate of 0 (97.5% one-sided CI 0–1.61) over all BMIs. Serum ENG evaluation showed that median levels remain above the suggested ovulation threshold of 90 pg/mL for women in all BMI classes at 4 and 5 years. Some women with BMI ≥25 kg/m^2 experienced serum ENG levels below 90 pg/mL; however, the researchers did not specify how many women this included.

Overall these clinical outcomes data from recent prospective studies with appreciable numbers of women with raised BMI are reassuring that contraceptive failure is extremely rare with the ENG implant in women in all weight groups, even if use is extended beyond the licensed 3 years.

The Summary of Product Characteristics (SPC) for the ENG progestogen-only implant[91] advises that "the clinical experience in heavier women in the third year of use is limited". It therefore states that "it cannot be excluded that the contraceptive effect may be lower than for women of normal weight". It advises that health professionals may therefore consider earlier replacement of the implant in 'heavier' women. The SPC[91] does not specify a definition of heavier weight or after what duration of use replacement may need to be considered. The FSRH advises that there is no direct evidence to support a need for earlier implant replacement, and recent data assessing continued use in women with raised BMI beyond 3 years are very reassuring. Therefore, the GDG recommends that the ENG implant can be considered to provide very effective contraception for 3 years for women in all weight/BMI categories.

5.2.2 Implant safety

According to the UKMEC, obesity alone does not restrict the use of IMP (UKMEC 1).[1] Even when obesity coexists with other risk factors for CVD (e.g. smoking, diabetes and hypertension), use of IMP is UKMEC 2.

No studies have directly assessed cardiovascular risk in women who are overweight or have obesity and use IMP. Data presented here are, thus, not specific to women with raised BMI. Studies looking at cardiovascular risk factors (e.g. lipids and carbohydrate metabolism) in healthy, non-obese implant users have been reassuring.[56–58,60,61]

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Those studies that have looked at different progestogen-only contraceptives generally suggest that there is no increased risk of VTE,[61,62] no statistically significant increased risk of MI,[64] and no statistically significant increased risk of stroke associated with use.[65] However, data are not available in relation to BMI or body weight, more research is required in high-risk women, and few studies have included the ENG implant.

Evidence level 2+

A Danish national registry-based cohort study[61] sought to assess the incidence of VTE in current users of non-oral hormonal contraception as well as different OC formulations. The study included all Danish non-pregnant women aged 15–49 years (n=1 626 158), with no history of thrombosis, and followed them from 2001 to 2010. Five confirmed venous thrombosis events were observed during the use of ENG implants, corresponding to an incidence rate of 1.7 per 10 000 exposure years and a non-significant aRR of 1.40 (95% CI 0.58–3.38) compared with non-users of hormonal contraception.

Evidence level 2++

5.2.3 Weight gain with implants

In the general population of all implant users, there is no evidence of a causal association between implant use and weight gain. There is no specific evidence relating to weight gain with IMP use by women who are overweight or women with obesity.

5.2.4 Health benefits of implants

The main non-contraceptive benefit of IMP is that it may help alleviate dysmenorrhoea and ovulatory pain that are not associated with any identifiable pathological condition.[92–94] While there is theoretically no reason why this would not be the case for women who are overweight or with obesity, this has not been specifically studied in women of different weight categories.

5.2.5 Practical considerations with implants

There are no data to suggest placement or removal of IMP is problematic in women who are overweight or women with obesity. Correct subdermal placement of the implant is important in women of all BMIs. Insertion or removal difficulties should not be presumed in women with raised BMI. Removal of appropriately placed implants (i.e. subdermal placement) should not be affected by BMI, including in the case of weight gain after insertion.

5.3 Progestogen-only injectable

Key information

C	**The available evidence suggests that effectiveness of DMPA is not affected by body weight or BMI.**
B	**From the limited evidence available it is not possible to confirm or exclude a causal association between DMPA use and VTE.**
D	**Whilst obesity alone does not restrict the use of DMPA (UKMEC 1), DMPA use becomes a UKMEC 3 when obesity is one of multiple risk factors for CVD (e.g. smoking, diabetes and hypertension).**
B	**DMPA use appears to be associated with some weight gain, particularly in women under 18 years of age with a body mass index (BMI) ≥30 kg/m^2.**

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Clinical recommendation

✓

For women with obesity:

- **If using intramuscular DMPA or NET-EN injectable, consider use of a longer-length needle or deltoid administration to ensure the muscle layer is reached.**
- **Consider use of subcutaneous DMPA.**

Three progestogen-only injectable contraceptives are available in the UK: depot medroxyprogesterone acetate (DMPA), intramuscular (DMPA-IM) and subcutaneous (DMPA-SC) progestogen-only injectables which are administered every 13 weeks, and intramuscular norethisterone enanthate (NET-EN) injectable which is administered every 8 weeks.

There are limited data relating to progestogen-only injectable use in women who are overweight or women with obesity. For more information on effectiveness, safety, weight gain and benefits in the general population, refer to the FSRH guideline ***Progestogen-only Injectable Contraception***.[95]

5.3.1 DMPA effectiveness

There is limited evidence regarding the effect of weight on the contraceptive effectiveness of progestogen-only injectable contraception, and no studies have specifically compared DMPA-IM or NET-EN failure rates in women with obesity versus women of normal weight.[58] Overall, the available evidence (summarised below) indicates that the contraceptive effectiveness of DMPA is not affected by weight or BMI.

Evidence level 2+

A study of the pharmacokinetics of DMPA-SC in women with BMI ≥30 kg/m^2 versus women with normal BMI observed that median medroxyprogesterone levels remained above the level needed to prevent ovulation. This study of 15 women (five per group) of normal weight, BMI ≥30 to <40 kg/m^2 and BMI ≥40 kg/m^2 found that medroxyprogesterone levels were lower in women with BMI ≥30 kg/m^2, and especially those with BMI ≥40 kg/m^2, compared to normal-weight women, although high enough to successfully suppress ovulation. In one woman with BMI ≥40 kg/m^2, levels dipped below the therapeutic level for the first 2 months of treatment and then rose.[96] One multicentre study of DMPA-IM in 846 women (over 389.5 woman-years) reported a pregnancy rate of 0.7/100 woman-years across all women, and baseline body weight was not related to contraceptive failure. However, less than 5% of this population weighed >80 kg.[97] An analysis of the contraceptive efficacy of DMPA-SC from two large phase III efficacy studies that included substantial numbers of women with obesity (n=601, BMIs ranging from 14.7 to 57.7 kg/m^2; 18% with BMI >30 kg/m^2 in the trial sites in the Americas) reported no pregnancies in 16 023 woman-cycles of DMPA-SC use.[98]

5.3.2 DMPA safety

According to the UKMEC, obesity alone does not restrict the use of progestogen-only injectable contraception (UKMEC1).[1] However, when obesity is one of multiple risk factors for CVD (e.g. smoking, diabetes and hypertension), use of progestogen-only injectable contraception becomes a UKMEC 3 (the theoretical or proven risks usually outweigh the advantages of using the method).[1] The UKMEC notes that for women using NET-EN, the UKMEC categories are considered the same as for DMPA.

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Studies relating effect of progestogen-only injectable use to risk of adverse cardiovascular events

No studies have specifically assessed whether women with raised BMI using progestogen-only injectable contraception are at increased risk of VTE and other cardiovascular outcomes, as compared to their normal-weight counterparts. Data presented here are therefore not specific to women with raised BMI.

Evidence level 2++

One case-control study found a non-statistically significant increased risk of venous thrombosis in the small number of DMPA users compared to non-users of any type of hormonal contraceptive (11 cases and 34 controls); aOR for VTE 2.19 (95% CI 0.66–7.26).[99] A larger case-control study,[63] which included 446 cases and 1146 controls, found that DMPA use was associated with a 3.6-fold (95% CI 1.8–7.1) increased VTE risk compared with non-users of hormonal contraceptives. A meta-analysis of five case-control and three retrospective cohorts reported an increased risk of VTE associated with progestogen-only injectable use (VTE RR for users of an injectable progestogen versus non-users 2.67 (95% CI 1.29–5.53)).[62] Only two studies, with a total of 31 VTE events, could be used to compute this value because no other studies reported the results separately for the subgroup of progestogen-only injectable users. More research is required before a causal relationship between progestogen-only injectable use and VTE can be confirmed or excluded. An international hospital-based case-control study[99] comparing progestogen-only injectable users and non-users reported that current use did not affect risk of combined CVD, risk of stroke, or MI.

Studies relating to effect of progestogen-only injectable use on cardiometabolic markers

A prospective, non-randomised study[100] of 14 women examined the effects of DMPA-IM or DMPA-SC on coagulation and inflammatory factors indicative of increased risk of thrombosis. Following four injections (i.e. 12 months of DMPA use), coagulation and inflammatory factors were not adversely affected by DMPA use, with concentration of D-dimer significantly reduced from baseline.[100] The study was limited by very small numbers and no control group, making the findings difficult to interpret. However, the findings were not suggestive of DMPA having a negative effect on possible markers of thrombosis.

A prospective study[101] examining the short-term effects of DMPA-SC on androgenic markers (testosterone, androstenedione, dehydroepiandrosterone sulphate, 3α-androstanediol glucuronide and sex hormone-binding globulin) in women of differing BMIs (five normal-weight, five obese and five morbidly obese women) reported significant decreases in levels from baseline administration of DMPA-SC to week 26 among all three BMI groups and no differences between the groups at any time points. A Cochrane Review[102] examined data from 31 randomised controlled trials (RCTs) to assess whether hormonal contraceptive use affected carbohydrate metabolism in healthy women and women who were at risk for diabetes due to being overweight. There were few data available for progestogen-only injectables, and one study showed a higher mean fasting glucose, glucose 2-hour response, and fasting insulin level amongst DMPA users compared to those using NET-EN. Overall the review suggested that there was little evidence on which to base conclusions about the impact of hormonal contraceptives in women with diabetes. Among women without diabetes, there did not appear to be any major differences in terms of carbohydrate metabolism. No studies were identified comparing DMPA-IM and DMPA-SC with regard to cardiovascular parameters.

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5.3.3 Weight gain with DMPA

Evidence level 2++

The data on progestogen-only injectable use and weight gain specifically in women who are overweight or women with obesity mainly derive from studies of adolescents. Overall, the available evidence (summarised below) indicates that use of DMPA is associated with some weight gain.

BMI prior to DMPA use in adolescents (aged <18 years) may predict weight gain with DMPA use, with higher initial BMI being predictive of increased weight gain, but evidence is insufficient to draw definitive conclusions.[103–106] A systematic review of adverse events after contraceptive initiation among users of all ages and BMIs examined whether early weight gain among DMPA users was associated with later weight gain.[107] Women who gained more than 5% of their baseline body weight in the first 6 months of DMPA use were more likely to experience continued weight gain.[108,109]

Significantly greater weight gain has been observed in the general population of new adolescent users of progestogen-only injectables compared to OC users, non-hormonal contraception users and discontinuers of any of the methods studied.[103,110] A longitudinal study recruited 15–19-year-old initiators of DMPA (n=115), NET-EN (n=115), COCs (n=116) and non-users of contraception (n=144), and followed them for 4–5 years with 6-monthly assessments.[103] Adolescents using DMPA or NET-EN throughout, or switching between the two, had gained an average of 6.2 kg compared to average increases of 2.3 kg in the COC group, 2.8 kg in non-users and 2.8 kg among discontinued users of any method (p=0.02). There was no difference in weight gain between adolescents classified as normal weight or overweight/obese at baseline in any of the four study groups.

Among young women with raised BMI, an observational study on weight gain with DMPA has reported that adolescents with raised BMI gain significantly more weight when using DMPA than when using oral contraception or no contraception.[110] This prospective study of predominately black adolescents in the US of varying weight showed that those with a BMI >30 kg/m^2 had significantly increased weight gain over 18 months after initiating DMPA compared with obese adolescents initiating OC or using no hormonal contraception.[110] At 18 months, mean weight gain was 9.4, 0.2 and 3.1 kg, respectively, for adolescents with obesity receiving DMPA, OC and no hormonal contraception (p<0.001).[110] Weight gain over 18 months in adolescents with obesity using DMPA was also greater than weight gain among non-obese DMPA and OC users and non-obese users of no hormonal contraception.

5.3.4 Health benefits of DMPA

DMPA can be used as a treatment for the management of heavy menstrual bleeding (HMB), dysmenorrhea and for pain associated with endometriosis.[111,112] DMPA may confer some protection against ovarian and endometrial cancers.[95,113–116] While there is no reason to expect this would not be the case for women with raised BMI, the health benefits associated with DMPA have not been specifically studied in women of different weight categories.

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5.3.5 Practical considerations with DMPA

The SPC for DMPA-IM[117] states that it should be administered by deep intramuscular injection into muscle tissue, preferably the gluteus maximus but other muscle such as the deltoid (upper arm) may be used. Traditionally the dorsogluteal site (upper outer quadrant of the buttock) has been used. The ventrogluteal site (lateral thigh) has been investigated as an alternative site because the risk of sciatic nerve injury is reduced[118,119] and the fat layer is thinner than in the dorsogluteal area. However, in women who are classified as overweight or obese it may be difficult to ensure intramuscular administration in either the dorsogluteal or ventrogluteal region. A retrospective study[120] of 100 adult women reported that using standard-length 'green' 21-gauge needles (40 mm) into the ventrogluteal site resulted in 12% of injections being subcutaneous rather than intramuscular, and that in the dorsogluteal site 43% of injections failed to reach the muscle. For standard-length 'blue' 23-gauge needles (25 mm) the proportions were higher (26% and 72%, respectively). If there are concerns about the ability to administer an intramuscular injection due to body weight then the deltoid muscle in the upper arm may be considered as an alternative site[117] or DMPA-SC could be a suitable alternative.

5.4 Progestogen-only pill (POP)

Key information

D	**The available evidence suggests that effectiveness of POP is not affected by body weight or BMI.**
D	**The available evidence suggests that POP is a safe contraceptive option for women who are overweight and women with obesity.**

Clinical recommendation

✓	**Double-dose POP for contraception is not recommended for women who are overweight or women with obesity.**

There are limited data relating to POP use in women with raised BMI. For more information on effectiveness, safety, weight gain and benefits in the general population, refer to the FSRH guideline ***Progestogen-only Pills***.[121]

5.4.1 POP effectiveness

There is very limited evidence on POP effectiveness in women who are overweight or women with obesity. The available data (summarised below) have not shown reduced POP effectiveness in women with higher weight and/or BMI.

One UK observational cohort study found no association between body weight and contraceptive failure in traditional POP users;[122] however, this study had significant limitations, including no report of the number of women with obesity or who were overweight, lack of statistical power, and measurement of weight only at recruitment (from 1968–1974). Data from an exploratory *in vitro* study of 16 women[123] found that a single tablet of LNG 30 µg (n=8) or NET 350 µg (n=8) prevented sperm migration in cervical mucus 12 hours after ingestion, including in the three women who had a BMI >35 kg/m^2.[123] As this study only examined the impact of a single POP dose, further evidence is required before conclusions can be drawn about the impact of weight or BMI on the cervical mucus effect of POPs.

Evidence level 2-

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No studies have examined the comparative effectiveness of the desogestrel (DSG) pill in women of differing weights or BMIs. One 12-month study[124] of 71 women examining inhibition of ovulation with use of the DSG pill compared to an LNG pill reported that ovulation was suppressed in all but one of 59 DSG cycles. The weight range of the women in the DSG group was 46–78 kg, suggesting that the DSG pill is effective in women up to this weight. Some 16/57 LNG cycles were ovulatory, and women in this group weighed between 50 and 91 kg. However, no analysis was carried out by weight.

The SPCs for POPs[125–127] do not advise dose adjustments based on weight or BMI.

5.4.2 POP safety

According to the UKMEC, obesity alone does not restrict the use of POP (UKMEC 1 indicating no restrictions on use).[1] Even when obesity is in the context of other risk factors for CVD (e.g. smoking, diabetes and hypertension), use of POP is UKMEC 2.

No studies have directly assessed whether women with raised BMI who use POP are at increased risk of VTE and other cardiovascular outcomes, as compared to their normal-weight counterparts. Data presented here are therefore not specific to women with raised BMI but do not suggest a likely association between POP use and increased risk of CVD.

Those few studies that have looked at different progestogen-only contraceptives generally suggest that there is little or no increased risk of VTE,[61,62] no statistically significant increased risk of MI,[64] and no statistically significant increased risk of stroke[65] with POP, implants or LNG-IUS. Data, however, are not available in relation to BMI or body weight. A Danish national registry-based cohort study[61] sought to assess the incidence of VTE in current users of non-oral hormonal contraception as well as different OC formulations. The study included all Danish non-pregnant women aged 15–49 years (n=1 626 158), with no history of thrombosis, and followed them from 2001 to 2010. The risk of confirmed VTE was not increased with use of hormone-releasing IUDs (aRR 0.57; 95% CI 0.41–0.81) or progestogen-only subcutaneous implants (aRR 1.40; 95% CI 0.58–3.38) compared with non-users of hormonal contraception. This study did not include POPs.

Evidence level 2+

Very little research has been conducted to assess the effect of progestogen-only contraception on cardiovascular risk factors (e.g. lipid and carbohydrate metabolism) in women with raised BMI or in relation to BMI/weight. Studies looking at this in healthy, non-obese POP users have been reassuring, with no clinically meaningful changes observed.[66–73]

Evidence level 2+

5.4.3 Weight gain with POP

In the general population there is no evidence suggesting a causal association between POP use and weight gain. There is no specific evidence relating to weight gain with POP use by women with raised BMI.

5.4.4 Health benefits of POP

The main non-contraceptive benefits of POP are that they may help alleviate HMB and dysmenorrhoea with possible alleviation of premenstrual syndrome symptoms for the DSG-containing POP.[128–130] While there is theoretically no reason this would not be the case for women with raised BMI, this has not been specifically studied in women of different weight categories.

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5.5 Combined hormonal contraception (CHC)

Key information

C	**Most evidence suggests that effectiveness of COC is not affected by body weight or BMI.**
D	**Limited evidence suggests a possible reduction in patch effectiveness in women weighing ≥90 kg.**
D	**Limited evidence suggests that effectiveness of the vaginal ring is not affected by body weight or BMI.**
D	**CHC use is UKMEC 2 for use by women with BMI ≥30–34 kg/m^2 and UKMEC 3 for women with BMI ≥ 35kg/m^2.**

Clinical recommendation

C	**Women with obesity should be informed that:** ► **risk of thrombosis increases with increasing BMI.** ► **current CHC use is associated with increased risk of VTE.** ► **current CHC use is associated with a small increased risk of MI and ischaemic stroke.** ► **if BMI is ≥35 kg/m^2 the risks associated with use of CHC generally outweigh the benefits.**

Note that UKMEC recommendations relate to safety of use rather than to effectiveness of contraceptive methods. Use of CHC is UKMEC 3 for use by women with BMI ≥35 kg/m^2. Use of CHC is UKMEC 2 for use by women with BMI ≥30–34 kg/m^2.

There are limited data relating to CHC use in women who are overweight or women with obesity. For more information on effectiveness, safety, weight gain and benefits in the general population, refer to the FSRH guideline ***Combined Hormonal Contraception***.[131]

5.5.1 CHC effectiveness

Combined oral contraceptive pill (COC)

The findings of studies of COC effectiveness in relation to increased body weight/BMI vary. In general, evidence relating to the effect of increased body weight/BMI on effectiveness of COC is limited to observational studies in which height, weight and pregnancy are often self-reported, and potential confounding factors such as contraceptive adherence and frequency of sexual intercourse are unknown. Most studies include relatively few women in the highest weight/BMI categories, and are unable to elucidate possible differences in weight-related effectiveness by type of progestogen.

Evidence level 2+

A 2017 systematic review[132] reported that 10 of the 14 studies of COC identified did not report a difference in COC effectiveness by body weight or BMI. In the remaining four studies, the magnitude of the reported increase in COC failure among overweight women and women with obesity compared to normal-weight women was very small.[133–136] Potential differences between different COC formulations could not be distinguished. The studies included used a variety of measures and thresholds to examine associations between obesity and contraceptive effectiveness, making interpretation across studies difficult. All included studies were of fair to poor quality. Most of the studies reporting an association between higher BMI and COC failure are significantly limited by lack of data on pill adherence as well as self-reported weight recorded at a time distant from the time of contraceptive failure.

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A total of four fair to poor quality studies identified an increased risk of contraceptive failure with COC in women with obesity compared to women without obesity. Two studies of low quality suggested that women with raised BMI using COC could experience up to a two-fold risk of contraceptive failure compared to their normal-weight counterparts. However, these studies relied on self-assessment of height and weight, recalled an average of 76.5 months after last COC use, and reported dichotomous outcomes using cut-off points that included a range of raised BMIs.[133,134] Another study, a recent pooled analysis of the original data from seven phase III trials submitted to the US Food and Drug Administration (FDA), noted a small but statistically higher COC failure rate among women with obesity: women with a BMI ≥30 kg/m^2 had a slightly increased risk of contraceptive failure compared to those with a BMI <30 kg/m^2 (adjusted hazard ratio (aHR) 1.44; 95% CI 1.06–1.95). The magnitude of the difference reported (Pearl Index of 3.14 in users with obesity vs 2.53 in users with normal weight) is unlikely to be clinically important.[135] This study may be biased due to limited control for confounding variables, no information about pill compliance, and pooling of data where women were exposed to COC containing different progestogens. In addition, one study found an association between women with more extreme obesity (BMI ≥35 kg/m^2) and decreased COC effectiveness (aHR 1.5; 95% CI 1.3–1.8).[136]

By contrast, all 10 remaining studies in this systematic review did not show an association between increased BMI/weight and COC effectiveness. Four large, population-based studies did not demonstrate an association with more detailed analyses of weight and BMI classes.[122,137–139] Further, four observational studies that incorporated more rigorous methods for capturing measures of height and weight, validated pregnancy status and included measures of contraceptive adherence also did not report any increased risk for COC failure.[140–143] Two lower-quality case-control studies limited by small numbers and lack of information on contraceptive adherence also found no association between BMI and COC failure.[144,145]

In addition, a 2016 Cochrane Review[58] concluded that in general, the evidence identified in that review did not indicate an association between increasing body weight or BMI and effectiveness of COC.

There is limited evidence that ovarian activity in the hormone-free interval (HFI) could be more pronounced in obese women.[146,147] In one study, hormone profiles at the end of a 7-day HFI in 10 women with normal BMI and 10 women with obesity noted estradiol levels consistent with dominant follicles and progesterone levels consistent with ovulation in more women with obesity than women with normal BMI.[146] A further study of women with obesity using 20 µg EE COC in a 21/7 regimen noted a reduction in ovarian activity when the woman changed to either a 30 µg EE COC as a 21/7 regimen or a 20 µg EE COC taken continuously.[147]

Overall, most high-quality studies suggest that COCs are as effective at preventing pregnancy in women with obesity as among non-obese women, but could potentially be less forgiving of imperfect use because the pharmacokinetics of steroid hormones appear to be altered in obese OC pill users compared with normal-weight users. However, ovulation is still suppressed in most OC pill users with obesity.[148–150]

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Combined transdermal patch (patch)

The patch currently available in the UK, Evra®, is an EE/norelgestromin (NGMN) patch.[151] Data on the patch in the context of obesity are limited.

The limited evidence identified[132,135,152] suggests that increasing body weight and BMI may be associated with increasing contraceptive failure rates of the EE/NGMN patch. Two studies have reported on contraceptive patch effectiveness and weight.[135,152]

Evidence level 2-

A pooled analysis of phase III clinical trials between 2000 and 2012 submitted to the US FDA included one trial of an EE/NGMN patch (n=1523), with the same dosing as Evra.[135] This study found that when adjusted for age and race, women with obesity (n=152) using the patch were at increased risk for contraceptive failure compared to women without obesity (aHR 8.8; 95% CI 2.54–30.5). Another pooled analysis of three multicentre, open-label studies of the EE/NGMN contraceptive patch (n=3319) reported that contraceptive failure was low and uniformly distributed across the range of body weights <90 kg, but suggested that the patch may be less effective in the subgroup of women weighing ≥90 kg. In total, 15 pregnancies were diagnosed during 6–13 cycles of follow-up. Five pregnancies occurred among women weighing ≥90 kg; women of this weight comprised less than 3% of the study population. Ten pregnancies were diagnosed among women weighing <90 kg.[152] Thus, women weighing ≥90 kg reported proportionally more pregnancies compared to those of lesser weight. While results by BMI were not provided, the researchers noted a statistically significant association between baseline body weight and pregnancy. However, the pregnancy rates on the EE/NGMN patch were still low in both of these studies across all weight categories.

The SPC for the Evra patch[151] states that contraceptive effectiveness could be decreased in women weighing ≥90 kg. As there are no new data to refute the manufacturer's statement, the GDG recommends that additional precautions for pregnancy prevention or an alternative method of contraception should be advised for women weighing ≥90 kg.

Combined vaginal ring (ring)

The combined vaginal ring contains EE and ENG.[153] Data on the ring in the context of obesity are limited. Most large trials assessing the effectiveness of the EE/ENG vaginal ring have been conducted in women without obesity.

Evidence level 2-

One study directly assessed contraceptive failure by weight among women using the combined vaginal ring.[154] This study of 128 pregnancies that resulted from a combined group of COC, patch or ring users concluded that 3-year failure rates among women using these methods were not different across BMI categories. However, the methodology used and the possible effect of non-adherence to the methods could have masked an actual effect of BMI on contraceptive failure in this study.[155] The only study to specifically assess contraceptive failure of the EE/ENG vaginal ring in women with obesity versus women without obesity was a secondary analysis of phase III efficacy trials, but it included too few obese women to provide a precise answer. In this study, the pregnancy rate for women in the highest decile of weight (>75 kg/167 lbs) was 1.2%, with no pregnancies reported in the highest weight women (85–123 kg).[156]

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Two pharmacokinetic analyses of the EE/ENG vaginal ring provide some indication that ring effectiveness could be similar in obese and non-obese women. In one analysis of 20 normal-weight women, while women with obesity had lower EE levels during ring use, ENG levels were similar, and follicular development was minimal in both groups. The researchers concluded that the findings predict that ring effectiveness will be similar in women with a BMI up to 39.9 kg/m^2 [157]. In another pharmacokinetic analysis comparing 20 women with a normal BMI and 20 women with obesity, a single ring used for 6 weeks demonstrated therapeutic serum levels of EE and ENG among women with normal and obese BMI.[158] Although reassuring, these studies were conducted over only one cycle in small groups of women.

This limited evidence suggests that the effectiveness of the ring is not affected by weight.

5.5.2 CHC safety

UKMEC recommendations relate to safety of use. CHC is UKMEC 3 for use by women with BMI ≥35 kg/m^2. Use of CHC is UKMEC 2 for use by women with BMI ≥30–34 kg/m^2.

These UKMEC 2 and 3 classifications, which indicate safety concerns for obese women using CHC, are related to cardiovascular risks from exogenous estrogen, including VTE, acute MI and stroke. They are based primarily on evidence that obesity and CHC use are both independent risk factors for thrombosis.

Venous thromboembolism (VTE)

Evidence level 2+

Independent of CHC use, the risk of VTE rises as BMI increases over 30 kg/m^2 and rises further with BMI >35 kg/m^2.[43,44] Baseline VTE risk in obese women is two-fold higher than VTE risk in normal-weight women.[45,46] VTE risk also increases significantly with age, irrespective of BMI.[159] CHC is associated with an increased risk of VTE, with use of CHC increasing VTE risk three-fold (in non-obese CHC users).[160–163] Some research has suggested that there may be additional additive increased VTE risk in women who have raised BMI *and* use CHC.[45,164–166]

Among normal-weight women, evidence from observational studies suggests that current COC use is associated with a 3–3.5-fold increase in VTE risk compared with non-use.[161–163] And, while data are conflicting, with some studies finding no increased risk of VTE in users of the contraceptive patch or ring when compared to COC users,[167,168] other studies have reported a significant two-fold greater VTE risk among patch and ring users compared to COC users.[61,169]

Evidence level 2++

A recent systematic review[170] investigated whether CHC use modifies the risk of VTE in obese women, and also evaluated evidence for a dose–response relationship between BMI and VTE. No studies regarding the contraceptive patch or vaginal ring met the inclusion criteria in this review. Data from one pooled analysis,[171] one cohort study[172] and eight case-control studies[45,164,166,173–179] showed that obese COC users consistently had VTE risk five to eight times that of obese non-users and approximately 10 times that of non-obese non-users. A single study[180] of 129 cerebral venous thrombosis (CVT) cases suggested that COC users with BMI ≥25 kg/m^2 were at higher risk for CVT compared with normal-weight non-users (BMI <25 kg/m^2), and that increasing BMI was associated with increasing CVT risk, but due to the small sample size, estimates of this association were imprecise.

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Both COC use and higher BMI increase risk for VTE, and the greatest relative risks in this body of data were for those women with both risk factors. These studies are all limited by small numbers in BMI and COC-using subgroups, lack of information on the type/formulation of OC, and no adjustment for lifestyle factors or genetics. Data around BMI were frequently self-reported, and OC use was often based on prescriptions given, not actual use. Confidence intervals were often wide, particularly for the higher BMI groups (e.g. ≥35 kg/m^2) because of the small numbers of OC users in those categories.

Based on the available data it is not possible to estimate absolute risk of VTE among women with both of these VTE risk factors: CHC and obesity. However, the absolute risk of VTE in healthy women of reproductive age is small (2 events per 10 000 women per year),[181] as is the absolute risk of VTE associated with use of CHC (5–12 events per 10 000 women per year).[181] The additional risk of VTE in the context of obesity in addition to CHC use is still likely to be less than the VTE risk that pregnancy/postpartum poses in a woman with obesity.[181,182] However, women with obesity should be advised about effective methods of contraception that are not associated with increased risk of VTE.

There are no published studies focusing on VTE risk in contraceptive patch or ring users with obesity.

Other cardiovascular outcomes

Evidence level 2+

The 2016 systematic review[170] also investigated whether CHC use modifies the risk of other cardiovascular outcomes in obese women. No studies on the contraceptive patch or vaginal ring were identified that met the inclusion criteria in this review. This review included one pooled analysis[183] and one case-control study[184] of MI and one pooled analysis[185] and one case-control study[186] of stroke. The pooled analyses of case-control data found no increased risk for MI or stroke for COC users overall or stratified by BMI,[183,185] whereas the other case-control studies that were included in the systematic review found significantly increased risk of MI[184] and ischaemic stroke[186] for obese COC users compared to normal-weight non-users, with the highest risk estimates for high-BMI COC users. These studies were of fair quality with diagnostic criteria for MI and stroke and adjustment for confounders, but with self-reported weight and height and inadequately systematic inclusion of MI and stroke fatalities, which could have led to bias. These studies all also considered a BMI of 27.3 kg/m^2 as the threshold for obesity, which is below the WHO definition of 30 kg/m^2, and could have led to an underestimation of the strength of the association between these cardiovascular outcomes and obesity.

5.5.3 Weight gain with CHC

In the general population there is no evidence that use of CHC causes weight gain. There is no specific evidence relating to weight gain with CHC use by women who are overweight or women with obesity.

5.5.4 Health benefits of CHC

Many non-contraceptive benefits are associated with CHC, including reduction of HMB and pain, alleviation of premenstrual symptoms, and management of symptoms associated with polycystic ovary syndrome. There is also a reduced risk of endometrial, ovarian and colorectal cancer.[187–195]

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The only evidence relating to these benefits in women with raised BMI is from one large US prospective cohort study[190] that found a significant 34% reduction in endometrial cancer risk associated with ≥10 years OC use compared to never-use or use for less than a year; the greatest risk reduction was observed amongst smokers, women who rarely exercised and women with obese BMIs.

5.6 Barrier methods of contraception

5.6.1 Barrier method effectiveness

No studies have evaluated the effectiveness of barrier methods in women with obesity versus women without obesity or assessed weight-related effectiveness. Condoms (male and female), the diaphragm, cervical cap and contraceptive sponge are the most common forms of barrier contraception, and theoretically should be equally effective in women of all weights; however, there are no studies which make this direct comparison.

Following a large change in weight or childbirth, the GDG suggests good practice would be to check if a woman's diaphragm still fits. A small magnetic resonance imaging (MRI) study has shown that following simulated intercourse, the single-size SILCS diaphragm remained in position covering the cervix in women with varying parity and BMI (n=2, BMI <25 kg/m^2; n=2, BMI 25–30 kg/m$^{2;}$ n=2, BMI >30 kg/m^2).[196]

Barrier methods are prone to user-related contraceptive failure due to non-adherence or incorrect use. This is reflected in their relatively higher contraceptive failure rates when compared to other contraceptive methods (see **Table 2**).

5.6.2 Barrier method safety

No studies have specifically evaluated the safety of barrier methods of contraception in women with raised BMI. There are no theoretical reasons for barrier methods of contraception to pose health risks to such women.

5.7 Fertility awareness methods

There is no evidence relating to fertility awareness methods (FAM) and BMI. When counselling a woman with raised BMI who has irregular menstruation and is considering FAM, HCPs should discuss how irregular bleeding patterns affect fertility awareness.

5.8 Emergency contraception (EC)

Key information

✓	**The available evidence suggests that effectiveness of the Cu-IUD is not affected by body weight or BMI.**
C	**1.5 mg levonorgestrel emergency contraception (LNG-EC) appears to be less effective in women with BMI >26 kg/m^2 or weight >70 kg.**
C	**Ulipristal acetate emergency contraception (UPA-EC) may be less effective in women with BMI >30 kg/m^2 or weight >85 kg.**

Clinical recommendations

C	**Women should be informed that the Cu-IUD is the most effective method of EC.**
C	**Women should be informed that BMI >26 kg/m^2 or weight >70 kg may reduce the effectiveness of oral EC, particularly of LNG-EC.**

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✓ **Consider UPA-EC and, if this is not suitable, double-dose (3 mg) LNG-EC if BMI >26 kg/m^2 or weight >70 kg. The effectiveness of double-dose LNG-EC is unknown.**

✓ **Double-dose UPA-EC is not recommended for women of any body weight or BMI.**

Evidence summary

There is limited evidence available on the effectiveness of oral emergency contraception (EC) for women with obesity. No studies of oral EC were specifically designed to analyse whether weight affected pregnancy rates. Five meta-analyses[197–201] were limited by small numbers of pregnancies, small numbers of women in overweight/obese subgroups, and, thus, wide confidence intervals around estimates.

5.8.1 Cu-IUD

The Cu-IUD is the most effective method of EC and effectiveness of the Cu-IUD is not known to be affected by weight or BMI. Women overweight or with obesity desiring EC should be counselled on the effectiveness of all methods, including the Cu-IUD, which remains the most effective option for EC regardless of weight.[202]

Evidence level 2+

5.8.2 Oral EC

Some studies have suggested that both levonorgestrel EC (LNG-EC) and ulipristal acetate EC (UPA-EC) could be less effective in women who are overweight or obese compared to women with normal or underweight BMI.[203] The reported negative effect of obesity on effectiveness of LNG-EC is greater than that on effectiveness of UPA-EC.[204] However, the European Medicines Agency concluded in 2014 that the available evidence was limited and not robust enough to support with certainty a conclusion that oral EC is less effective in women with higher body weight or BMI.[205]

Evidence level 2+

UPA-EC

A 2012 meta-analysis[197] suggests that UPA-EC is less effective for women with a BMI >30 kg/m^2 than for women with a BMI <30 kg/m^2 (pregnancy OR for women with obesity vs women without obesity 2.1 (95% CI 1.0–4.3; p=0.04); pregnancy OR for women weighing >85 kg vs women weighing <85 kg 2.2 (95% CI 1.1–4.6; p=0.03)). A 2011 meta-analysis[198] reports a non-significantly greater pregnancy risk for women with obesity (BMI >30 kg/m^2) using UPA-EC than for women with BMI <25 kg/m^2 (OR 2.62; 95% CI 0.89–7.00). The findings have limitations: none of the trials from which the data were taken[206–208] were designed primarily to consider the effect of weight or BMI; weight and height were self-reported by women and may be inaccurate; numbers of pregnancies amongst women with obesity were small and confidence intervals are wide. Despite these limitations, the data suggest that UPA-EC could potentially be less effective for women weighing >85 kg or with a BMI >30 kg/m^2 than for women weighing <85 kg or with BMI <30 kg/m^2. A recently published pharmacokinetic study[209] comparing serum UPA concentrations in 16 obese-BMI women and 16 normal-BMI women after taking UPA 30 mg found no significant difference between the two groups. This contrasts with the findings for LNG-EC (see below). There is no evidence that an increased dose of UPA-EC is more effective than the standard 30 mg dose in these women, as this has not yet been tested. Double-dosing of UPA-EC is not currently recommended.

Evidence level 2+

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LNG-EC

A pooled analysis[199] of data from the LNG-EC comparator arms of two RCTs carried out comparing UPA-EC with LNG-EC[206,208] demonstrates a sharp increase in pregnancy rates with LNG-EC for women weighing >70 kg or with BMI >26 kg/m^2. Considering the same data, women with raised BMI who took LNG-EC were at four times greater risk of pregnancy than women with BMI <25 kg/m^2 who took LNG-EC (OR 4.41; 95% CI 2.05–9.44; p=0.0002).[198] These studies considered women from the UK and US; they were not designed primarily to assess the effect of weight or BMI on the effectiveness of oral EC, weights were sometimes self-reported, and the number of pregnancies amongst women with raised BMI were small.

Evidence level 2+

One analysis of pooled data from three RCTs conducted by WHO concluded that there is no apparent effect of BMI or body weight on the effectiveness of LNG-EC.[200] A second analysis of pooled data from these same three RCTs and a fourth WHO RCT suggested a greater risk of pregnancy after LNG-EC amongst women with a BMI >30 kg/m^2 than women with a BMI <25 kg/m^2. Again, the data were taken from studies that were not primarily designed to consider effect of weight or BMI on effectiveness of oral EC, weights were self-reported and the number of women included in the studies who had a BMI >30 kg/m^2 was small. A total of only six pregnancies occurred in women with obesity, all at the same Nigerian study site, and all of whom took oral EC after the expected date of ovulation.[201]

Evidence level 2+

A study[210] of the pharmacokinetics of LNG-EC in five women with obesity and five women without obesity demonstrates that obesity adversely impacts maximum serum concentrations of LNG. The authors postulate that this may explain a reduction in effectiveness of LNG-EC in women with obesity. In this study, doubling the dose of LNG-EC appears to correct the obesity-related pharmacokinetic changes without observed adverse effects. However, it is concluded that "additional research is needed to determine if this also improves EC effectiveness in obese women". Another pharmacokinetic study comparing 16 women with obese-BMI and 16 with normal-BMI also demonstrated a significant difference in drug levels.[209] The study concludes that after a single dose of LNG-EC, obese-BMI women are exposed to lower concentrations of LNG when compared to normal-BMI women. In a recent pharmacokinetic study, 1.5 mg LNG was given to 10 women with normal BMI and 16 women with obesity. All women studied were of reproductive age and ovulatory. Total serum LNG was measured over 0 to 96 hours; women with obesity were exposed to significantly lower total and bioavailable (free plus albumin-bound) LNG than women with normal BMI.[211] The authors concluded that this lower LNG exposure could play a role in the purported reduced efficacy of LNG-EC in women with obesity. These pharmacokinetic findings contrast with those for UPA-EC (see above).

Evidence level 2-

The evidence presented above suggests that LNG-EC could be less effective in women weighing >70 kg or with a BMI >26 kg/m^2. If a Cu-IUD is not indicated or not acceptable, such women can be offered UPA-EC. If UPA-EC is not suitable, a double-dose (3 mg) of LNG-EC can be used. Studies testing the effectiveness of double-dose LNG-EC are in progress, but its effectiveness is unknown. However, 3 mg LNG-EC is well tolerated and pharmacokinetic data[210] suggest its potential ability to prevent unintended pregnancy more effectively than 1.5 mg LNG-EC in women weighing >70 kg or with a BMI >26 kg/m^2.

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5.9 Female surgical sterilisation

5.9.1 Effectiveness and safety

There is very limited evidence relating to sterilisation in women with obesity compared with women who are not obese. The available data suggest that women who are obese undergoing sterilisation may be at an increased risk of complications and/or technical failure of laparoscopic sterilisation,[80,212] but that hysteroscopic sterilisation is unaffected by weight/BMI. Hysteroscopic tubal occlusion (Essure®) is effective and may be a safer surgical sterilisation procedure than laparoscopic sterilisation for obese women because it can be performed under local anaesthesia and does not require entrance into the abdominal cavity, with its attendant morbidity. Essure had offered this alternative approach; however, it is no longer available in the UK, Europe or the US. Laparoscopic tubal sterilisation procedures are also effective, but are associated with longer operating times and more anaesthetic and surgical complications in women with obesity compared with women who are not obese.[212–221]

6 Contraception and weight management treatment

6.1 Weight-loss medication and contraception

Clinical recommendation

✓ **Women should be advised that it is possible that medications that induce diarrhoea and/or vomiting (e.g. orlistat, laxatives) could reduce the effectiveness of POP, COC and oral EC.**

It is recommended that people with raised BMI lose weight, which may be assisted by taking anti-obesity medications, in addition to dietary advice, and behavioural and exercise components. Current guidelines for the pharmacological management of obesity in the UK and available on the National Health Service (NHS) include the medication orlistat (Xenical/Alli®) which has been approved for long-term weight reduction. Naltrexone/bupropion (Mysimba®) and liraglutide (Saxenda®) may also be used.

Data on the safe and effective use of contraception with concomitant use of weight-loss medication are extremely limited. Two studies on contraception and orlistat, two studies on contraception and liraglutide, and no studies on contraception and naltrexone/bupropion were identified. There are no known drug interactions between contraceptive hormones and these weight-loss medications. Refer to the FSRH Guideline ***Drug Interactions with Hormonal Contraception*** for further guidance.[222]

6.1.1 Orlistat

According to the National Institute for Health and Care Excellence (NICE),[223] orlistat may be prescribed as part of an overall plan for managing obesity in adults who meet one of the following criteria: BMI ≥28 kg/m^2 with associated risk factors or BMI ≥30 kg/m^2, or to maintain or reduce weight before surgery for people who have been recommended bariatric surgery as a first-line option.

Orlistat 120 mg, an oral medication only available on prescription in the UK, is a gastrointestinal lipase inhibitor that acts by inhibiting the absorption of dietary fats, and is primarily metabolised within the gastrointestinal wall.[224,225] A lower dose (60 mg) of orlistat is available over the counter. Orlistat is not recommended for use in pregnancy and breastfeeding[224,226] so effective contraception with orlistat use is important.

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There is almost no evidence on orlistat and OC. Based on its mechanism of action, orlistat could theoretically reduce the absorption of OC. One small pharmacokinetic study of poor quality, conducted by the makers of orlistat, concluded that orlistat has no effect on pharmacokinetics and/or pharmacodynamics of COC.[227] In this study[227] of normal-weight women, two groups of 10 women "on a stable regimen with OCs", received either 120 mg orlistat three times daily or placebo three times daily on days 1–23 of the first cycle. Then, separated by a placebo washout period on days 24–28, women received the alternative treatment on days 1–23 of the second cycle. In both cycles, serum luteinising hormone was measured on days 12–16 and progesterone on days 12, 16 and 19–23. No changes in the ovulation-suppressing action of the COC were reported.

In seven double-blind, placebo-controlled clinical trials of orlistat,[225] gastrointestinal symptoms, including diarrhoea and vomiting, were the most commonly observed (defined as >5% or an incidence in the orlistat group that is at least twice that of placebo) treatment-emergent adverse events associated with orlistat use. This could potentially have implications for the concomitant use of OCs and orlistat.

A secondary analysis[228] of 319 women from two RCTs of women aged 18–40 years who were overweight or had obesity (BMI 27–42 kg/m^2) and infertile with PCOS reported on serious adverse events and side effects with concomitant orlistat and COC use. In one arm of that study, 43 women received concomitant orlistat and COC (20 EE/1 NET) for 16 weeks prior to clomifene treatment (the other arms received either orlistat or COC alone). No serious adverse events were reported in the 43 women using orlistat and COC concomitantly, but women using both were more likely to have diarrhoea/steatorrhoea than women using one or the other alone.

6.1.2 Liraglutide

Liraglutide (Saxenda®) is a long-acting glucagon-like peptide-1 receptor agonist. In a crossover RCT[229] of liraglutide versus placebo in 21 postmenopausal women (who had had an oophorectomy or at least 1 year of amenorrhoea) with BMI 18–30 kg/m^2 and we re given a single dose of COC (30 EE/15 LNG) to assess COC pharmacokinetics. No clinically relevant reduction in bioavailability of EE/LNG occurred, though more women reported gastrointestinal side effects while on both treatments than when on COC alone.

6.1.3 Naltrexone/buproprion

There were no studies identified on the use of naltrexone/buproprion with contraception.

6.1.4 Laxatives

Some individuals use and/or abuse laxatives in order to lose or manage weight. For more information on contraception for women who self-induce diarrhoea and/or vomiting, refer to the FSRH CEU Statement ***Contraception for Women with Eating Disorders***.[230]

6.2 Weight-loss surgery and contraception

Key information

C	**Non-oral contraceptives have been studied in only small numbers of women following bariatric surgery but appear to be safe and effective.**
C	**For women with BMI ≥35 kg/m^2, risks associated with CHC use generally outweigh the benefits.**

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Clinical recommendations

✓	**Women receiving counselling regarding bariatric surgery should have a discussion about contraception and have a plan for contraception in place prior to surgery.**
D	**Women should be advised that the effectiveness of OC, including oral EC, could be reduced by bariatric surgery, and OC should be avoided in favour of non-oral methods of contraception.**
D	**Women should be advised to stop CHC and to switch to an alternative effective contraceptive method at least 4 weeks prior to planned major surgery (e.g. bariatric surgery) or an expected period of limited mobility.**

6.2.1 Background

Bariatric surgery is provided to women with morbid obesity to obtain substantial weight loss and reduce obesity-related comorbidities.[231] Bariatric procedures have their effect on weight loss and comorbidity improvement through either a restrictive or a malabsorption mechanism, or a combination of both.[231] The NICE clinical guideline Obesity Prevention[232] recommends that surgery should be an obesity management option in certain circumstances. The most common procedure performed in the UK is the gastric bypass, with gastric sleeve and gastric banding performed less frequently.[233,234] Most procedures are performed laparoscopically.[235]

UKMEC 2016 identifies bariatric surgery in the past 2 years as a condition that exposes a woman to increased risk in the context of pregnancy.[1] Effective contraception is important, as pregnancy should be avoided during the period of intensive weight loss, from 12 to 18 months after surgery.[236,237] Pregnancy occurring after surgery may be associated with an increased risk of both maternal and child complications.[237–239] The weight loss that accompanies bariatric surgery can enhance fecundity in women who were subfertile because of anovulation.[237,240] Thus, contraception education, counselling and follow-up should be conducted prior to and at the time of bariatric surgery for all women with the potential to conceive.

The evidence regarding use of contraception after bariatric surgery, however, is very limited. Based on evidence from surveys conducted outside the UK, condoms and OC appear to be the most commonly utilised contraceptive methods after bariatric surgery in the US, whereas IUC is the predominant method used by women in Scandinavian countries.[241–243] Gaps in contraception education and low levels of postoperative use were reported in all studies.[241–243]

A US survey[244] of 574 bariatric surgeons reported that the majority provided a consistent message to patients to delay pregnancy after bariatric surgery, but far fewer provided appropriate referrals or were aware of whether patients initiated contraception. This supports the need for better communication between bariatric surgeons and women's HCPs. In a survey amongst members of the British Obesity and Metabolic Surgery Society, bariatric surgeon respondents reported that contraceptive information was rarely provided in bariatric surgical clinics, practitioners had low levels of confidence in discussing contraception, and the majority of respondents requested further training, guidance and communication with contraceptive practitioners.[245]

6.2.2 UKMEC information on bariatric surgery

The UKMEC[1] states that women with conditions that may pose a significant health risk during pregnancy (e.g. bariatric surgery within the past 2 years) should be advised to consider using the most effective long-acting reversible contraception (LARC) methods, which provide highly reliable

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and effective contraception (failure rate <1 pregnancy per 100 women in a year).[1] The sole use of barrier methods and user-dependent methods of contraception may not be the most appropriate choice for women who have undergone bariatric surgery in the past 2 years given the relatively high typical-use failure rates of these methods (see **Table 2**).

Table 3 outlines UKMEC recommendations relating to contraceptive use by women in different BMI categories following bariatric surgery. The UKMEC makes no distinctions based on type of bariatric surgery. UKMEC categories relate to the safety, and not effectiveness, of use. With the exception of CHC methods, all methods of hormonal and intrauterine contraception (i.e. Cu-IUD, LNG-IUS, IMP, DMPA and POP) are UKMEC 1 for use in women with a history of bariatric surgery for all BMI categories (i.e. BMI <30, ≥30–34 and ≥35 kg/m^2).

Table 3: UK Medical Eligibility Criteria for Contraceptive Use (UKMEC)[1] recommendations for contraceptive safety following bariatric surgery

	UKMEC category					
Condition	**Cu-IUD**	**LNG-IUS**	**IMP**	**DMPA**	**POP**	**CHC**
History of bariatric surgery						
a) With <30 kg/m^2 BMI	1	1	1	1	1	1
b) With ≥30–34 kg/m^2 BMI	1	1	1	1	1	2
c) With ≥35 kg/m^2 BMI	1	1	1	1	1	3

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

6.2.3 Effectiveness and safety of contraception after bariatric surgery

The evidence regarding effective and safe use of contraception after bariatric surgery is very limited. No RCTs or large prospective longitudinal studies have been conducted.

Individuals who undergo bariatric surgery require life-long calcium and vitamin D supplementation. Refer to **Section 6.2.3.5** below and method-specific guidance when considering osteoporosis risk factors and contraception.

6.2.3.1 OC after bariatric surgery

There are theoretical concerns that both malabsorptive (e.g. jejunoileal bypass, biliopancreatic diversion with/without duodenal switch and Roux-en-Y bypass (gastric bypass)) and restrictive bariatric (e.g. vertical banded gastroplasty, laparoscopic adjustable gastric band or laparoscopic sleeve gastrectomy) procedures could decrease the absorption of OC, including oral EC.[246,247] Thus, bariatric procedures have the potential to decrease OC effectiveness, and OC effectiveness could perhaps be further decreased by postoperative complications such as long-term diarrhoea and/or vomiting.

One pharmacokinetic study[248] reported lower serum progestogen levels 1–8 hours after administration of oral NET (3 mg) and LNG (0.25 mg) for women with BMI >40 kg/m^2 after jejunoileal bypass surgery (n=7) compared with healthy normal-weight women. The difference could, however, be attributable to body weight, and not bariatric procedure. A second pharmacokinetic study[249] reported higher serum progestogen levels after administration of a COC in 12 women with morbid obesity

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after bypass surgery than in six women with morbid obesity who had not had surgery. In a recent pharmacokinetic study of nine women using 75 μg DSG before and after Roux-en-Y bypass surgery (and serving as their own controls), ENG pharmacokinetic parameters measured on three occasions (8 weeks before surgery, and 12 and 52 weeks after surgery) did not show any clinically significant changes before and after surgery.[250]

Evidence level 2-

There are no quality clinical outcome studies comparing OC effectiveness before and after bariatric surgery. A 2010 systematic review[251] evaluating the safety and effectiveness of contraceptive use among women with a history of bariatric surgery identified five relevant studies, two of which were on jejunoileal bypass, a procedure no longer performed. No RCTs or large prospective studies were identified, and the included studies had significant limitations and were generally of poor quality. In one small prospective case series of 40 patients,[236] two of nine women who self-reported using COC after biliopancreatic bypass surgery (both with significant diarrhoea) became pregnant in the 2 years following surgery (at 9 and 24 months). Contraceptive use was self-reported at the end of the 2-year period. A second descriptive study[252] among 215 women reported no pregnancies among COC users (number unknown) in the 2 years after a gastric banding procedure.

Subsequent to the 2010 systematic review,[251] two other low-quality retrospective studies have partially addressed this question. In a chart review[241] of 1012 women presenting for bariatric surgery evaluation, only 27% of charts contained documentation of a contraceptive method (OC 48.5%, sterilisation 39%, IUD 6%, DMPA 3%, patch/ring 1.8%, barrier 1.4%, vasectomy 0.4%), and 16 pregnancies were identified in the first 18 months postoperatively, but method used was only documented in three pregnancies (two OCs, one condom). Another retrospective study[253] assessed outcomes after laparoscopic Roux-en-Y gastric bypass in 19 patients aged under 18 years between 2 and 10 years post-bypass. Data were self-reported. Two of 12 women became pregnant 6 and 8 years after surgery, and reported using OC.

There are very sparse, low-quality and conflicting data regarding the effectiveness of OC in women post-bariatric surgery. The evidence is too limited and of too poor quality to make a definite recommendation regarding the effectiveness of OC after bariatric surgery. Women who have had bariatric surgery should be advised of the potential reduced effectiveness of OC, including oral EC, and should consider using non-oral methods of contraception.

Practical considerations

The restrictions on eating, drinking and pill-taking following bariatric surgery may make it difficult for some women to comply with OC regimens. Women are advised to follow a specific diet for the first few weeks postoperatively that phases from a liquid diet slowly back into solid foods. There are restrictions on how much time is required between eating and drinking. Surgeons advise that medications are preferably taken in liquid, chewable or dissolved form. As the effectiveness of OC depends on consistent and correct use, it is theoretically possible that the effectiveness of OC could be reduced by the requirements of the postoperative period. This should be discussed with women who are considering using, or are already using, OC.

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6.2.3.2 Non-oral contraception after bariatric surgery

Some non-oral hormonal contraceptives (namely the contraceptive implant and LNG-IUS), which are unaffected by malabsorptive surgery, have been studied in small numbers of women who have undergone bariatric surgery; they appear to be effective based on very limited data.[254,255] There are no data available on use of the Cu-IUD or progestogen-only injectables after bariatric surgery but there are no theoretical reasons why their effectiveness would be affected.

Evidence level 2-

One study[254] presents three cases of women aged 19–24 years with an ENG implant inserted 1–2 months prior to Roux-en-Y gastric bypass. After surgery, serum ENG concentrations *decreased* with weight loss but remained above the minimum concentration that is considered to be required for contraceptive effect of the implant for at least 6 months following Roux-en-Y gastric bypass (average 170 pg/mL) and there were no pregnancies. However, no further follow-up data are available, and no assessment of follicular development or ovulation was made.

Evidence level 3

6.2.3.3 EC after bariatric surgery

Women presenting for EC who have had bariatric surgery should be offered a Cu-IUD, assuming the criteria for Cu-IUD use are met (see FSRH guideline ***Emergency Contraception***).[204] Where a Cu-IUD is not appropriate or acceptable, there is no evidence relating to which, if any, oral EC option would be most effective after bariatric surgery.

6.2.3.4 Safety of contraception after bariatric surgery

There is exceptionally limited evidence relating to the safety of contraception use following bariatric surgery.

Thrombotic risk and contraception after bariatric surgery

There are no RCTs or prospective studies, and no data on several of the contraceptive methods post-bariatric surgery.

It is established that the risk of complications such as VTE may be higher in women with obesity when using CHC and this must be considered during counselling on contraceptive methods, given that women may remain obese for some period after bariatric surgery or despite bariatric surgery.[23]

In a small (n=25) retrospective cohort study[255] of adolescent females who underwent bariatric surgery, 92% percent had LNG-IUS placement at time of surgery, and all but two were still using the method at 6 months. There were no known serious side effects or complications related to IUC use, but the numbers were very small. Two retrospective cohort studies reporting on very small numbers of patients with portomesenteric vein thrombosis (n=17 and n=5) after laparoscopic sleeve gastrectomy[256,257] reported OC use (unspecified type) in some patients with this complication (n=7 and n=1, respectively), but also no contraceptive use or contraceptive implant use in others. A 2018 systematic review and meta-analysis[258] on portomesenteric vein thrombosis after a bariatric procedure included 41 studies with a total of 110 patients. None of these studies were designed to look at contraceptive safety; all had very small numbers and no meaningful contraceptive comparison groups, and were conducted in a population at high risk for thrombotic events irrespective of contraceptive use, so these data are generally uninformative.

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DMPA injectable contraception after bariatric surgery

Bariatric surgery appears to be associated with reduced bone mineral density (BMD). An association between bariatric surgery and increased fracture risk has not, however, been established. Both obesity and bariatric surgery are associated with vitamin D deficiency, a risk factor for reduced calcium absorption and potential loss of BMD.

Use of DMPA for contraception is also associated with a small loss of BMD, which is usually recovered after discontinuation. There is no evidence relating specifically to risk of osteoporosis or fracture in women who have had bariatric surgery and *also* use DMPA.

When choosing a contraceptive method, women who have had bariatric surgery should be informed that bariatric surgery and DMPA use are both associated with reduced BMD but that the clinical significance of this for women who have had bariatric surgery *and* use DMPA is unknown. They should be made aware that other effective contraceptive methods are not associated with reduced BMD.

6.2.3.5 Other considerations after bariatric surgery

It has been suggested that because women experience significant weight loss after surgery, the resulting loose skin may affect contraceptive choices (e.g. difficulties in finding a suitable site for applying transdermal patches and making insertion of subdermal implants technically more difficult). There is, however, no evidence relating to these concerns.

6.2.4 Contraception before bariatric surgery

Irrespective of bariatric surgery, CHC use is UKMEC 3 (a condition where the theoretical or proven risks usually outweigh the advantages of using the method) for women with BMI ≥35 kg/m^2 and UKMEC 2 for women with BMI ≥30–34 kg/m^2, due to concerns about cardiovascular risks from exogenous estrogen, including VTE. Most women undergoing bariatric surgery should not be on a CHC method prior to surgery. However, some may be.

Women who are immobile or have restricted mobility for an extended period of time (e.g. due to surgery) are at increased risk for VTE. This risk may be further increased with use of CHC. Women using CHC who are planning to undergo bariatric surgery should discontinue use at least 1 month before surgery to reduce the risk of postoperative thromboembolism. With regard to the use of CHC by women undergoing surgery, the BNF[259] advises that "estrogen-containing contraceptives should preferably be discontinued (and adequate alternative contraceptive arrangements made) at least 4 weeks before major elective surgery. A non-oral progestogen-only contraceptive or the Cu-IUD should be offered as an alternative". In general, progestogen-only contraceptives are considered more appropriate in women with obesity than combined hormonal methods, especially in the context of surgery.[174,260]

Evidence level 2-

7 Approach to issues of weight in contraceptive consultations

Clinical recommendation

✓ **When providing contraception to women with raised BMI, HCPs, after asking permission, should raise the subject of weight, enquire about whether BMI is of concern, and signpost to appropriate support for weight management if wanted.**

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HCPs giving contraception care are well placed to raise the topic of weight and signpost women to appropriate support, because issues of weight are relevant to contraceptive decision-making. It is good practice to calculate and document BMI when providing contraception. Many HCPs feel concerned they may cause offense when discussing weight.

The GDG suggests that safe principles include:

- **Ask permission to discuss weight**
- **Use a respectful and non-judgemental approach**
- **Give context as to why weight is relevant to your discussion**
- **Be aware of stigmatising language**
- **Be sensitive to cultural issues (different cultures value weight in different ways)**
- **Use the 'third person' to convey factual information about risks to reduce chance of patients becoming defensive or feeling disempowered or burdened by their weight**
- **Offer supportive resources and referrals for weight management if appropriate.**

The following phrases could encourage a positive conversation when raising the topic of weight with contraception patients:

- **"I would like to talk to you about your weight. Is that OK?"**
- **"How do you feel about your weight?" or "Do you have any concerns about your weight? Is this something you would like more help with?" HCPs should be aware of local weight management support services in their locality or signpost to web-based resources such as NHS Choices.**
- **"We know that body weight can affect some of the contraceptive choices. Is it OK if I talk to you about your weight?"**
- **"We know that a higher BMI is linked to increased risk of…/may affect the safety of…/may alter the effectiveness of… Shall I explain more about this risk?"**

Practical considerations

Facilities providing contraceptive care should have weighing scales that can accurately measure high body weights.

Recommendations for future research

- **Sexual health and outcome data for women of different BMI groups in the UK (most data is from US/Europe)**
- **Impact of medical and surgical treatment for obesity on absorption of OC**
- **Acceptability to women of using the contraceptive consultation to discuss weight management**
- **Understanding of weight bias amongst HCPs giving contraceptive advice**

Considerations for implementation of this guideline

- **Appropriate equipment is required in general (e.g. weighing scales that can accommodate high body weights) and for certain methods of contraception (e.g. supportive gynaecology couches). If unavailable at certain facilities, HCPs should be aware of where they can refer women to that can accommodate their needs.**

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- **Bariatric and primary care colleagues may need to be educated on contraception for women undergoing/who have undergone bariatric surgery. Joined-up care would be an ideal approach.**
- **This guideline will require wide dissemination in order to raise awareness of the particular needs and support relating to contraception for women with raised BMI.**

Useful links

- **Public Health England – Adult Obesity: Applying All Our Health**
- **Royal College of General Practitioners – Top Ten Tips Raising the Topic of Weight**
- **US Department of Health and Human Services – Talking with Patients About Weight Loss: Tips for Primary Care Providers**
- **NHS Choices – Healthy Weight**
- **FSRH – Statement on Pre-conception Care**
- **Public Health England – Health Matters: Reproductive Health and Pregnancy Planning**

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Appendix

Appendix 1: FSRH Clinical Guideline Development Process

Who has developed the guideline?

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

Development of the guideline was led by the secretariat (CEU staff) and involved the intended users of the guidelines (contraception providers) and patient/service user representatives as part of a multidisciplinary group. The scope of the guideline was informed by a scoping survey conducted among FSRH members and among service users from two sexual and reproductive health services (Oxfordshire Sexual Health Services, Oxford/Banbury, England and Aneurin Bevan University Health Board, Newport/Blackwood, Wales) across the UK. The first draft of the guideline was produced based on the final scope of the guideline agreed by the GDG. The first draft of the guideline (version 0.1) was reviewed by the GDG in person and a revised draft guideline (version 0.2) was produced in response to comments received, after which it was sent to international and UK-based external independent reviewers suggested by the GDG at the face-to-face meeting. A further revision generated a version of the draft guideline (version 0.3) which was placed on the FSRH website for public consultation between 14 December 2018 and 21 January 2019. The revised draft guideline (version 0.4) was sent to the GDG for final comments and to reach consensus on the recommendations (details of this process are given later).

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

Guideline development group (GDG) secretariat

► Dr Chelsea Morroni	► Deputy Director, Clinical Effectiveness Unit
► Dr Sarah Hardman	► Co-Director, Clinical Effectiveness Unit
► Professor Sharon Cameron	► Co-Director, Clinical Effectiveness Unit
► Mrs Valerie Warner Findlay	► Researcher, Clinical Effectiveness Unit

Multidisciplinary group

► Patient Representative 1*	Patient Representative
► Ms Janet Dearden	Registered Nurse and Clinical Team Leader, Lancashire Care NHS Foundation Trust (Blackburn with Darwen); Nurse Representative, Clinical Effectiveness Committee, FSRH
► Professor Fiona Denison	Professor of Translational Obstetrics, University of Edinburgh MRC Centre for Reproductive Health, Queens Medical Research Institute (Edinburgh)
► Dr Rachel d'Souza	Consultant in Sexual and Reproductive Health, Margaret Pyke Centre (London)

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Multidisciplinary group	
► Dr Lucinda Farmer	Specialty Doctor, Unity Sexual Health (Bristol), Chair of General Training Committee, FSRH
► Dr Annabel Forsythe	Specialty Registrar, Community Sexual and Reproductive Healthcare, Oxfordshire Sexual Health Services (Oxford and Banbury)
► Ms Natika H Halil	Chief Executive of Family Planning Association (FPA)
► Dr Vivian Iguyovwe	Associate Specialist, Camberwell Sexual Health Centre (London); Clinical Standards Committee Member, FSRH
► Dr Susie Nickerson	General Practitioner Partner, Murrayfield Medical Centre (Edinburgh)
► Dr Michelle Olver	Specialty Registrar, Community Sexual and Reproductive Health, Aneurin Bevan University Health Board (Newport/Blackwood)
► Dr Amy Reimoser	Patient Representative; General Practitioner (West Sussex) and Specialty Doctor in Sexual and Reproductive Healthcare (Brighton)
► Professor Rebecca Reynolds	Professor of Metabolic Medicine and Deputy Director Centre for Cardiovascular Science, Queen's Medical Research Institute, University of Edinburgh (Edinburgh)

***Patient Representative has chosen to remain anonymous.**

The FSRH CEU wishes to acknowledge the contribution made by Ms Claire Nicol who worked on the literature review for the sections on contraceptive efficacy with raised BMI.

Independent reviewers

► Professor Jan Brynhildsen (Sweden)	Professor and Consultant of Obstetrics and Gynecology, Department of Clinical and Experimental Medicine (Linköping University)
► Professor Alison Edelman (USA)	Professor of Obstetrics and Gynecology (Oregon Health & Science University)
► Dr Louise Massey (UK)	Consultant in Sexual and Reproductive Health (Aneurin Bevan University Health Board)
► Dr Rachel Pryke (UK)	General Practitioner (Winyates Health Centre)
► Professor Carolyn Westhoff (USA)	Professor of Reproductive Health in the Department of Obstetrics and Gynecology, Professor of Population and Family Health and Epidemiology (Columbia University Medical Center)

Declaration of interests

None of the individuals involved had competing interests that prevented their active participation in the development of this guideline.

Patient involvement

Service users from two sexual and reproductive health services (Oxfordshire Sexual Health Services, Oxford/Banbury, England and Aneurin Bevan University Health Board, Newport/Blackwood, Wales) across the UK were involved in providing feedback on the scope of the

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guideline. Mrs Jolene West, lay representative, assisted the FSRH CEU with the content of the surveys given to service users.

Two patient representatives were involved consistently throughout the development process. They provided valuable feedback on multiple drafts of the guideline; their input informed and supported content and the development of recommendations.

Public consultation contributors

We would like to thank the contributors who provided their valuable feedback during the public consultation.

Guideline development methodology

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

Systematic review of evidence

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

Search date: The databases were initially searched up to 11 November 2017. The evidence identified up to this point was used to develop the first draft of the guideline. The searches were re-run up to 27 August 2018 to check additional evidence published since the initial search. Any evidence published after this date was not considered for inclusion.

Search strategy: The literature search was performed separately for the different subcategories covered in this clinical guideline.

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

Synthesis of evidence and making clinical recommendation

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

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

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

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

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Considerations when making recommendations

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

Reaching consensus on the recommendations

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

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

Updating this guideline

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

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Questions for continuing professional development

The following multiple choice questions (MCQ) have only one correct answer and have been developed for continuing professional development (CPD). The answers to the questions and information on claiming CPD points can be found in the 'members-only section' of the FSRH website (www.fsrh.org).

1 When considering oral emergency contraception (EC) in women with body mass index (BMI) >30 kg/m^2, which of the following statements is true?
   a) A double-dose of ulipristal acetate emergency contraception (UPA-EC) could be considered
   b) A double-dose of levonorgestrel emergency contraception (LNG-EC) could be considered
   c) UPA-EC is not recommended
   d) LNG-EC is not recommended

2 When considering contraception in a woman with BMI ≥30–34 kg/m^2, which of the following is UKMEC Category 3?
   a) Combined hormonal contraception (CHC) if there is a history of bariatric surgery
   b) Progestogen-only implant (IMP) if obesity is one of multiple risk factors for cardiovascular disease (CVD)
   c) Progestogen-only injectable (depot medroxyprogesterone acetate (DMPA)) if obesity is one of multiple risk factors for CVD
   d) Progestogen-only pill (POP) if there is a history of bariatric surgery

3 When considering contraceptive effectiveness, which of the following statements is true?
   a) The FSRH recommends that healthcare providers replace IMP earlier in women weighing >149 kg
   b) The FSRH recommends a shortened interval between doses of DMPA in women weighing >90 kg
   c) The FSRH advises that there may be a possible reduction in combined hormonal patch effectiveness in women weighing >90 kg
   d) The FSRH advises doubling the dose of POP in women weighing >149 kg

4 Which of the following statements is false? Obesity is associated with increased risk of…
   a) Diabetes
   b) Venous thromboembolism (VTE)
   c) Endometrial cancer
   d) Epilepsy

5 Which of the following statements regarding POP in women with obesity is true?
   a) There is evidence to support a dose of more than one pill per day
   b) POP may be used safely by women with additional risk factors for CVD
   c) Use of POP is UKMEC 3 after bariatric surgery
   d) Use of POP increases VTE risk and is therefore not recommended

6 Which of the following statements regarding CHC is true?
   a) CHC is not recommended in women with BMI ≥35 kg/m^2 due to increased risk of contraceptive failure
   b) CHC is safe in women with BMI ≥35 kg/m^2 as long as they have undergone bariatric surgery
   c) The combined patch or ring are regarded as safer options than combined oral contraception (COC) in women with BMI ≥35 kg/m^2
   d) Use of COC is UKMEC 2 for women with BMI 30–34 kg/m^2 who have no other risk factors for CVD

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7 Which of the following statements regarding use of DMPA by women with obesity is true?
   a) Benefits of use of DMPA generally outweigh risks for women with multiple risk factors for CVD
   b) The negative effect of DMPA on bone mineral density (BMD) is countered by the protective effect of higher BMI on BMD
   c) Teenagers who are overweight may be at increased risk of weight gain with DMPA use compared with teenagers who are not overweight
   d) Evidence suggests that effectiveness of DMPA may be reduced by increased BMI

8 Which of the following statements regarding use of IMP by women with obesity is true?
   a) IMP is safe and may be used where there are multiple risk factors for CVD
   b) Evidence supports a reduction in effectiveness and IMP should be replaced early
   c) Evidence suggests removal is likely to be more difficult if the arm circumference is >30 cm
   d) Inadvertent intramuscular insertion is more common in women with BMI >30 kg/m^2

9 Which of the following statements regarding VTE risk is true?
   a) The baseline risk of VTE in healthy women of reproductive age is in the range of 6–11 events per 10 000 women per year.
   b) The risk of VTE is 8–10-fold higher in women with obesity compared to women without obesity
   c) The VTE risk associated with CHC use is the same as that in the immediate postpartum period
   d) VTE risk increases significantly with age, irrespective of BMI

10 After bariatric surgery, which of the following statements is true?
   a) Use of DMPA is UKMEC 4 due to the increased risk of osteoporosis
   b) The combined vaginal ring could be more effective than COC
   c) Use of POP is UKMEC4 due to risk of malabsorption
   d) Use of COC is UKMEC 4 due to risk of VTE

Auditable outcomes

Auditable outcome	Target
Percentage of women with body mass index (BMI) ≥30 kg/m^2 requiring emergency contraception (EC) who (subject to eligibility): 1 Are advised that a copper intrauterine device is the most effective method of EC 2 Are advised that oral EC could be less effective because of their higher BMI	97%
Percentage of women taking weight-loss medication and using or requesting oral contraception (including oral EC) who are informed regarding a potential reduction in effectiveness associated with vomiting and/or diarrhoea	97%
Percentage of women who have undergone bariatric surgery (or are about to undergo bariatric surgery) who are informed regarding a potential reduction in effectiveness of oral contraception	97%

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Comments and feedback on published guideline

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

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

The Faculty of Sexual & Reproductive Healthcare (FSRH) is the largest UK professional membership organisation working in the field of sexual and reproductive health (SRH). We support healthcare professionals to deliver high-quality healthcare including access to contraception. We provide our 15 000 doctor and nurse members with NICE-accredited evidence-based clinical guidance, including the UKMEC, the gold standard in safe contraceptive prescription, as well as clinical and service standards.

The FSRH provides a range of qualifications and training courses in SRH, and we oversee the Community Sexual and Reproductive Healthcare (CSRH) Specialty Training Programme to train consultant leaders in this field. We deliver SRH-focused conferences and events, provide members with clinical advice and publish *BMJ Sexual & Reproductive Health* – a leading international journal. As a Faculty of the Royal College of Obstetricians and Gynaecologists (RCOG) in the UK, we work in close partnership with the College but are independently governed.

The FSRH provides an important voice for UK SRH professionals. We believe it is a human right for women and men to have access to the full range of contraceptive methods and SRH services throughout their lives. To help to achieve this we also work to influence policy and public opinion working with national and local governments, politicians, commissioners, policymakers, the media and patient groups. Our goal is to promote and maintain high standards of professional practice in SRH as a way towards realising our vision of holistic SRH care for all.

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