

FSRH Guideline

Quick Starting Contraception

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NICE has accredited the process used by the Faculty of Sexual & Reproductive Healthcare to produce its *Quick Starting Contraception* guidance. More information on accreditation can be viewed at www.nice.org.uk/accreditation.

Abbreviations Used

aOR	adjusted odds ratio
CEU	Clinical Effectiveness Unit
CHC	combined hormonal contraception/contraceptive
CI	confidence interval
COC	combined oral contraception/contraceptive
Cu-IUD	copper intrauterine device
DMPA	depot medroxyprogesterone acetate
EC	emergency contraception
FSRH	Faculty of Sexual & Reproductive Healthcare
GDG	guideline development group
HC	hormonal contraception
hCG	human chorionic gonadotrophin
HCP	healthcare practitioner
HR	hazard ratio
HSUP	high-sensitivity urine pregnancy test
IMP	progestogen-only implant
IU	international unit
IUC	intrauterine contraception
LARC	long-acting reversible contraception/contraceptive
LNG	levonorgestrel
LNG-EC	levonorgestrel (for emergency contraception)
LNG-IUS	levonorgestrel intrauterine system
NET	norethisterone
NMC	Nursing and Midwifery Council
NTD	neural tube defect
OC	oral contraception/contraceptive
OR	odds ratio
POP	progestogen-only pill
RCT	randomised controlled trial
SPC	Summary of Product Characteristics
SRH	sexual and reproductive healthcare
UKMEC	UK Medical Eligibility for Contraceptive Use
UPA-EC	ulipristal acetate (for emergency contraception)
UPSI	unprotected sexual intercourse (no contraception used or contraception used incorrectly)

Grading of Recommendations

Please refer to [Appendix 1](#) for a full explanation of the classification of evidence level and grading of recommendations.

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

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Executive Summary of Recommendations

Quick starting if pregnancy can be excluded



Healthcare practitioners (HCPs) can offer quick start of any method of contraception at any time in the menstrual cycle if it is reasonably certain that a woman is not pregnant or at risk of pregnancy from recent unprotected sexual intercourse (UPSI).

Quick starting if pregnancy cannot be excluded

Women who have a negative high-sensitivity urine pregnancy test (HSUP) [able to detect human chorionic gonadotrophin (hCG) levels around 20 mIU/ml] but are at risk of pregnancy from recent UPSI should be advised that:



Pregnancy cannot be excluded by an HSUP until ≥ 21 days after the last UPSI.



Emergency contraception (EC) may be indicated.



Combined hormonal contraception (CHC), progestogen-only pill (POP) and progestogen-only implant (IMP) can be quick started if they prefer not to delay starting contraception. Depot medroxyprogesterone acetate (DMPA) may be considered if other methods are not suitable or acceptable.



The levonorgestrel intrauterine system should not generally be quick started unless pregnancy can be reasonably excluded.



CHC containing cyproterone acetate should not be quick started unless pregnancy can be reasonably excluded.



A copper intrauterine device can be quick started only if the indications for use as EC are met.



After levonorgestrel EC (LNG-EC) administration, CHC, POP, IMP (and DMPA) can be quick started immediately.



After ulipristal acetate EC (UPA-EC) administration, they should wait 5 days before quick starting suitable hormonal contraception [CHC, POP, IMP (and DMPA)].



Additional contraceptive precautions (barrier or abstinence) are required until the quick started contraceptive method becomes effective.



A follow-up HSUP is required no sooner than 21 days after the last UPSI.

Use of bridging contraception



If a woman's choice of contraceptive method is not available or is not appropriate at the time of presentation, she should be offered a bridging method of contraception that can be quick started.

Pregnancy diagnosed after quick starting contraception



The guideline development group advises that women should be informed that contraceptive hormones are not thought to cause harm to the fetus and they should not be advised to terminate pregnancy on the grounds of exposure.

Women using CHC, POP, IMP or DMPA

Women who wish to continue the pregnancy



If a pregnancy is diagnosed after starting contraception and the woman wishes to continue the pregnancy, the woman should be advised that the method should usually be removed or stopped.

Women who choose not to continue the pregnancy

If a pregnancy is diagnosed after starting CHC, POP, IMP or DMPA and the woman chooses therapeutic abortion:



A woman using IMP or DMPA can be advised to continue her method of contraception with no additional contraceptive precautions after abortion.



A woman using CHC or POP can be advised to stop her method of contraception and restart contraception immediately after abortion with no additional contraceptive precautions.

B

A woman using DMPA should be advised that there may be a slightly higher risk of continuing pregnancy (failed abortion) if DMPA is administered at the time of mifepristone administration.

Women using IUC



HCPs should advise women whose intrauterine pregnancy is less than 12 weeks' gestation that intrauterine contraception (IUC) should be removed, as long as the threads are visible or it can be easily removed from the endocervical canal. This is regardless of whether the woman decides to continue with the pregnancy.

B

HCPs should explain to women who have an intrauterine pregnancy with an IUC *in situ* that the risk of adverse pregnancy outcomes is greater than that for pregnancies without an IUC *in situ*.

B

HCPs should advise women who have an intrauterine pregnancy with an IUC *in situ* that removal of the IUC in the first trimester could improve pregnancy outcomes, but is associated with a small risk of miscarriage.

FSRH Guidance (April 2017)

Quick Starting Contraception

(Revision due by April 2022)

1 Introduction

1.1 Purpose and Scope

This guideline is intended for use by health professionals providing contraception in any setting within the UK. The recommendations included should be used to guide clinical practice but are not intended to serve alone as a standard of medical care or to replace clinical judgement in the management of individual cases. Details of the methods used by the Clinical Effectiveness Unit (CEU) in developing this guidance are outlined in [Appendix 1](#).

1.2 Summary of Guidance and Changes from Previous Guideline

If contraception is started at the beginning of a normal, natural menstrual period, there is no risk that the woman is already pregnant and potential exposure of a very early pregnancy to contraceptive hormones is avoided. The contraceptive method is immediately effective if started at this time. However, women present to services requesting contraception at all times of the cycle. There are significant likely benefits to initiation of contraception at the time that a woman requests it rather than waiting for the start of her next menstrual cycle. Delaying initiation of contraception creates a window of time during which a woman may become pregnant, change her mind regarding contraception, or forget instructions regarding her chosen contraceptive method.

Commencement of a contraceptive method at a time other than the start of the menstrual cycle is termed 'quick starting'. With all quick started hormonal contraception (HC), additional contraceptive precautions (condoms or abstinence) are required until the quick started method becomes effective.

All methods of contraception can be quick started at any time if it is reasonably certain that there is no risk that the woman could be pregnant. Criteria for reasonably excluding pregnancy are outlined in [Section 5](#).

Quick start of combined hormonal contraception (CHC), the progestogen-only pill (POP), the subdermal progestogen-only implant (IMP) and the progestogen-only injection (DMPA, depot medroxyprogesterone acetate) can also be considered if a high-sensitivity urine pregnancy test (HSUP) is negative, but there is a potential risk of very early pregnancy from recent unprotected sexual intercourse (UPSI). Women who choose to quick start contraception when very early pregnancy cannot be excluded can be reassured that the vast majority of the available evidence suggests no adverse impact of fetal exposure to contraceptive hormones on pregnancy outcomes or risk of fetal abnormality. This updated guideline provides a more thorough review of the available evidence regarding fetal exposure to HC than the previous guideline.

The requirement for emergency contraception (EC) should be assessed if there has been recent UPSI. If EC is indicated, the copper intrauterine device (Cu-IUD) should be considered first, as it is the most effective method of EC and provides ongoing contraception. After levonorgestrel EC (LNG-EC), HC can be quick started immediately. However, after ulipristal acetate EC (UPA-EC), HC should not be started for 120 hours. This is a change to previous Faculty of Sexual & Reproductive Healthcare (FSRH) quick starting guidance.

A pregnancy test is indicated 21 days after the last episode of UPSI. Pregnancy testing 28 days after quick starting contraception will also identify pregnancies resulting from UPSI that took place during the time before the contraception became effective. Recommendations are given in [Section 7](#) regarding stopping or removing contraceptive methods if pregnancy is diagnosed after quick starting contraception, whether the woman decides to continue with the pregnancy or proceed to termination of pregnancy.

2 What is Meant by 'Quick Starting' Contraception?

2.1 Quick Starting Contraception

Quick starting is the term used to describe immediate initiation of a contraceptive method at the time a woman requests it rather than waiting for the start of the next natural menstrual period. If a hormonal method of contraception is quick started, it may not be immediately effective and additional contraceptive precautions (barrier or abstinence) are often required until the new method becomes effective. Barrier methods of contraception may be started at any time.

Quick starting contraception includes:

- ▶ Starting contraception at a time other than the beginning of the menstrual cycle, **but it is reasonably certain that there is no risk of pregnancy** (see [Section 5.1](#) for suitable methods).
- ▶ Starting contraception at a time other than the beginning of the menstrual cycle **and there is a potential risk of very early pregnancy from recent UPSI** (but it is too early to exclude pregnancy using an HSUP) (see [Section 5.2](#) for suitable methods). Quick starting in this situation is appropriate if a woman considers it likely that she will continue to be at risk of pregnancy or if she wishes to avoid delaying commencement of contraception.

Quick starting is outside the product licence for many contraceptive methods, but use as described in this guideline is supported by the FSRH.

If a woman prefers to delay starting contraception or if she is concerned about potential risks associated with quick starting, she can wait until the beginning of her next period or until the risk of pregnancy has been excluded. Pregnancy can be reasonably excluded if an HSUP [able to detect human chorionic gonadotropin (hCG) levels around 20 mIU/ml] is negative 21 days or more after the last UPSI.

2.2 Bridging Contraception

If a woman's first choice of contraception is not suitable for quick starting because there is a risk of pregnancy or it is not available at the time of initial consultation, a suitable bridging method of contraception can be quick started to provide contraceptive cover until her preferred method can be commenced.

3 What are the Potential Advantages of Quick Starting Contraception?

Quick starting contraception, as opposed to waiting for the next menstrual period, could reduce a woman's risk of unintended pregnancy by facilitating immediate initiation of effective contraception. Quick starting could:

- ▶ Reduce the time during which a woman is at risk of pregnancy. Women who have taken EC or who have irregular cycles could have an even longer wait until onset of their next menstrual period.
- ▶ Prevent a woman from forgetting information on correct usage of her contraception.
- ▶ Avoid waning enthusiasm for the method and use of a less reliable alternative method.
- ▶ Avoid costs of, and barriers to, returning for contraception (e.g. transport, time, childcare).
- ▶ Reduce health care costs by reducing the number of appointments needed.

3.1 Avoidance of Unintended Pregnancy

A 2012 Cochrane review¹ found no clear evidence that quick starting contraception affects pregnancy rates. However, few studies were identified and none of the studies included in the review were powered to detect differences in pregnancy rates between conventional starting and quick starting.

A small Scottish study² randomised 168 women who attended pharmacies for oral EC to receive either a month's supply of POP to quick start, rapid access to a family planning clinic for contraceptive advice or standard care. At follow-up 6–8 weeks later, 56% of the POP group, 52% of the rapid access group and 16% of the standard care group were using effective contraception. The relative probability of a woman using an effective method of contraception versus barrier/no method, after use of EC, was 3.13 [95% confidence interval (CI) 1.90–5.13] in the POP group and 2.57 (95% CI 1.55–4.27) in the rapid access group. Further large, robust studies would be required to assess the impact of these interventions on later use of contraception and on pregnancy rates.

It is possible that the effect of quick starting contraception on pregnancy rates could depend on the contraceptive method. Five randomised controlled trials (RCTs) that examined quick starting CHC versus traditionally starting CHC found no significant difference in pregnancy rates.^{3–7} One RCT⁸ that compared quick starting DMPA with quick starting CHC as a bridging method to DMPA found that women in the bridging group were more likely to become pregnant [odds ratio (OR) 3.95, 95% CI 1.16–13.38] than women who quick started DMPA. However, this study lost nearly one-third of its participants to follow up. The Cochrane review¹ concluded that further studies that compare quick and traditional starting of the same method of contraception need to be conducted.

3.2 Adherence and Continuation

Women who quick start a hormonal method of contraception generally find quick starting acceptable or helpful.^{5,8,9} However, there is no strong evidence that quick starting improves long-term continuation rates.^{1,10}

RCTs that examined continuation rates found that women who quick started contraception were more likely to still be using their contraceptive method at 2 months compared with women who started contraception at the beginning of their next menstrual period.^{5,10,11} However, in the longer

term, rates of contraceptive continuation were similar whether women had quick started or not. These studies included CHC and DMPA; no studies were identified that considered continuation rates of the POP, IMP, Cu-IUD or levonorgestrel intrauterine system (LNG-IUS). It is possible that women might be more likely to continue a long-acting reversible method of contraception (LARC) that is started at the time of an initial consultation than a user-dependent method of contraception. The continuation rates merely assessed the percentages of women who continued their chosen contraceptive method; it is possible that women who did not continue that method may have switched to another form of contraception while still being categorised by the study authors as having discontinued contraception.

4 What are the Potential Disadvantages of Quick Starting Contraception and are these Significant?

When quick starting contraception there will sometimes be a small risk that the woman is already pregnant or that EC will fail and she will conceive from recent UPSI. Diagnosis of pregnancy may be delayed if amenorrhoea is assumed to be due to the contraceptive method or if bleeding associated with the contraception is mistaken for a period. There are also theoretical concerns that HC could be harmful to the fetus.

4.1 Fetal Exposure to Contraception: Pregnancy Outcomes and Risk of Fetal Abnormality

Almost all the available evidence suggests no adverse impact of fetal exposure to contraceptive hormones on pregnancy outcomes or risk of fetal abnormality. Even though the typical use failure rate of oral contraceptives (OCs) is estimated at around 9% and significant numbers of early pregnancies are therefore inadvertently exposed to contraceptive hormones, relatively few studies consider pregnancy outcomes after exposure to contraceptive hormones and these are limited by their observational nature, potential confounding factors, and/or very small sample sizes.

4.1.1 Oral contraception

Fetal demise

Analysis of the Danish National Birth Cohort,¹² which recruited nearly 92 000 women between 1996 and 2002, found no evidence that OC use during pregnancy was associated with an increased risk of fetal death. Among 945 pregnancies during which COC was taken and 157 pregnancies exposed to POP there was not a significantly increased risk of fetal death [hazard ratio (HR) 1.01, 95% CI 0.71–1.45 for COC and HR 1.37, 95% CI 0.65–2.89 for POP].

Previous studies have also shown no significant association between OC use during pregnancy and fetal death.¹³⁻¹⁶ However, these were small studies with heterogeneity in findings and wide confidence intervals, potentially reflecting chance instead of correlation.

There is no apparent association between OC exposure during pregnancy and fetal loss.

Preterm birth and small for gestational age

A 2016 large Norwegian population-based cohort study¹⁷ including 1062 pregnancies exposed to COC and 359 exposed to POP found no association between hormonal exposure and infants being small for gestational age (weight <3rd centile). The study reported no association between hormonal exposure *in utero* and preterm birth (defined as delivery <37 weeks) for COC containing drospirenone or LNG. However, among the 75 women who had used a COC containing

norethisterone (NET) and the 146 who had used a NET POP during the first 12 weeks of pregnancy, delivery before 37 weeks was significantly more common than in pregnancies that were not exposed to hormonal contraception [adjusted OR (aOR) for exposure to NET COC 3.33 (95% CI 1.69–6.57) and aOR for exposure to NET POP 2.02 (95% CI 1.09–3.75)]. These data are limited by the small exposure group.

One previous Thai cohort study of 601 pregnancies in which OC was continued after conception of unplanned pregnancies observed among the liveborn infants a greater risk of low birth weight associated with OC exposure [exposed verses unexposed liveborns from planned pregnancies aOR 1.5 (95% CI 2.2–2.0)].¹⁸ The authors do however comment that there may be significant confounding factors including the fact that the exposed pregnancies were unplanned and the unexposed pregnancies were planned.

The very limited evidence is inadequate to determine whether exposure to OC during early pregnancy could be associated with low birth weight or with delivery before 37 weeks.

Fetal abnormalities

The most recent and largest prospective cohort study¹⁹ of 880 694 live births in Denmark included 22 013 infants with major birth defects. The study found no increase in risk of major birth defects associated with OC exposure after conception (OR 0.95, 95% CI 0.84–1.08) compared with an unexposed control group. This study had several limitations. Information regarding use of contraception was taken from prescription records; it is unknown whether women took OC up to the date of their most recently filled prescription. The number of exposed cases of some congenital abnormalities was small. Residual confounding was possible, and the analysis lacked information on folate. Similarly, a large case-control study²⁰ in the USA with 9 986 cases of congenital abnormality, including 32 different major birth defects, reported no association between OC use and overall risk of birth defects. The findings of these studies were consistent with the conclusions of earlier case-control studies^{21,22} and a meta-analysis of 12 prospective observational studies,²³ which did not find any significant association between *in utero* exposure to HC and risk of birth defects.

The available evidence suggests no association between OC exposure during pregnancy and overall risk of birth defects.

Specific birth defects

Some studies have suggested a potential association between maternal OC use and risk of certain specific congenital abnormalities. The recent Danish prospective cohort study¹⁹ found no association between maternal use of OC in pregnancy and any specific group of birth defects. While the large case-control study in the USA mentioned above²⁰ reported no association between OC use in pregnancy and overall risk of birth defects, it did find an increased risk for two specific birth defects associated with OC use in the first trimester: hypoplastic left heart syndrome (OR 2.3, 95% CI 1.3–4.3) and gastroschisis (OR 1.8, 95% CI 1.3–2.7). Numbers of exposed cases were small and there are potential confounding factors. The authors cautioned that their findings could be attributable to chance. The Danish cohort study¹⁹ found no significant association for either of these specific abnormalities.

Congenital heart disease

Other than the possible association with hypoplastic left heart syndrome described above, the large case-control study in the USA²⁰ which included 3 521 cases of congenital cardiac abnormality (171 were exposed to OC during pregnancy) found no association between OC exposure during pregnancy and congenital heart disease. The Danish cohort study¹⁹ found no association of OC use in pregnancy with cardiac abnormalities, including hypoplastic left heart syndrome, and a 1990 meta-analysis²³ of 12 prospective studies found no association with congenital heart disease.

Neural tube defects

Neither of the two large, recent observational studies^{19,20} that considered the risk of a wide range of congenital abnormalities reported any difference in risk of neural tube defects (NTD) between pregnancies that were exposed to OC and those that were not exposed (although Charlton *et al.*¹⁹ reported “nervous system abnormalities” as a group). This is consistent with the findings of four smaller case-control studies,²⁴⁻²⁷ although the numbers of cases that were exposed to OC during pregnancy are small.

In contrast, a retrospective cohort study¹⁶ of Welsh births between 1974 and 1976 including 37 infants with NTD suggested a greater incidence of NTD if OC had been used during pregnancy or in the 3 months prior to conception (reported as a statistically significant difference, 0.63% OC users versus 0.25% non-users). Data for OC use during pregnancy alone are not available. It is not clear whether results were adjusted for confounding factors and the use or non-use of folic acid is not documented. A case-control study in China²⁸ including 97 exposed NTD cases reported an increased risk of NTD associated with OC use between 1 month prior to conception and 2 months after conception (OR 2.06, CI 1.16–3.68). The data do not distinguish between use prior to and during pregnancy. The population studied has a very high incidence of NTD and the study also suggested significant associations between NTD and various other factors.

The evidence overall does not support a causal association between use of OC in early pregnancy and an increased risk of NTD.

Limb reduction defects

Neither of the two large, recent observational studies^{19,20} that considered the risk of a wide range of congenital abnormalities reported any difference in risk of limb defects between pregnancies exposed to OC and pregnancies that were not. One of these studies included 37 exposed cases and the other 26 exposed cases. A meta-analysis of 12 prospective studies²³ found no association between OC exposure in early pregnancy and limb defects.

While some earlier retrospective observational studies^{29,30} also found no association, other studies^{31,32} suggested that the risk of limb reduction defects could be greater in pregnancies exposed to OC. These earlier studies have significant shortcomings.

The evidence overall does not support a causal association between use of OC in early pregnancy and increased risk of limb reduction defects.

Urogenital abnormalities

Neither of the two large, recent observational studies^{19,20} that considered the risk of a wide range of congenital abnormalities reported any difference in risk of urinary tract or genital abnormalities, including between pregnancies exposed to OC and pregnancies that were not. A 1995

meta-analysis³³ of 14 observational studies found no association between OC exposure in pregnancy and fetal genital abnormality (exposure versus no exposure, OR 0.98, 95% CI 0.24–3.94). A case-control study³⁴ including 118 cases of congenital urinary tract abnormality reported a significant association with use around the time of conception, but numbers of exposed cases were very small and there may have been significant confounding factors.

Considering hypospadias specifically, the 2010 case-control study²⁰ mentioned above, a 2009 Danish case-control study³⁵ including 1 683 male infants with hypospadias and a 2005 USA case control study³⁶ including 502 male infants with hypospadias observed no association with OC exposure.

The available evidence suggests no association between OC exposure during pregnancy and any specific birth defect.

4.1.2 Depot medroxyprogesterone acetate

There is very little evidence in the literature relating to fetal exposure to DMPA.

A 1991 case control study¹³ of 1431 pregnancies in Thailand exposed to DMPA found an increased risk for neonatal death (OR 1.8, 95% CI 1.1–3.0) and infant death (OR 2.0, 95% CI 1.3–3.2) compared with control pregnancies that were not exposed to DMPA. When the analysis was adjusted for low birth weight, the risk was reduced; the authors suggested that low birth weight may act as an intermediate factor of DMPA-associated mortality. There was an apparent correlation between shorter injection-to-conception intervals when maternal blood levels of the drug were higher, and an increased risk of mortality. The OR for neonatal mortality was 2.5 (95% CI 1.1–5.7) for intervals of ≤ 4 weeks, 2.1 (95% CI 1.0–4.6) for 5–8 weeks and 0.9 (95% CI 0.4–2.4) for > 9 weeks. Again, adjustment for low birth weight reduced these risks.

The authors of the same study¹⁸ reported an increased risk of low birth weight in 1 573 unplanned pregnancies exposed to DMPA compared to planned unexposed pregnancies (OR 1.5, 95% CI 1.2–1.9). In another study,³⁷ the authors also considered growth and pubertal development in 1 207 Thai children who had been exposed to DMPA *in utero* and reported no significant effect compared to non-exposed individuals. It is important to note that there is significant risk of confounding in all of these studies.

A prospective cohort study³⁸ published in 1990 found no difference in health, growth or sexual development between 172 teenagers who had been exposed to MPA (used for contraception or for maintenance of pregnancy) *in utero* and non-exposed controls.

The guideline development group (GDG) recommend that there is no strong evidence that fetal exposure to DMPA is associated with adverse pregnancy outcomes or fetal abnormality.

4.1.3 Progestogen-only implant

A few individual cases³⁹⁻⁴¹ of pregnancy with etonogestrel implants *in situ* are described in the literature; in the two cases where information is available, the pregnancies continued to term with no apparent adverse pregnancy or fetal outcomes.^{39,40} A review⁴² of the toxicology of progestogens in contraceptive implants, based on published data and data submitted to the United States Food and Drug Administration, showed no significant or unusual toxicity. The authors found that fetal

development studies demonstrated overall safety, and concluded that these progestogens have a similar safety profile to oral contraceptives.

The Summary of Product Characteristics (SPC) for Nexplanon[®],⁴³ the only currently available implant on the market in the UK, says that while the device should be removed if pregnancy occurs, there is no clear evidence to suggest that the implant has any teratogenic effect. It further states that pharmacovigilance data indicate that etonogestrel- and desogestrel-containing products pose no risk to the fetus; Nexplanon contains etonogestrel, a desogestrel metabolite.

4.1.4 Intrauterine contraception

A systematic review⁴⁴ of observational studies found that women who conceived with an IUD *in situ* were at a greater risk of adverse pregnancy outcomes such as spontaneous abortion and preterm delivery compared with women who conceived without an IUD *in situ*. See [Section 7.2](#).

Considering fetal exposure to the LNG-IUS, the SPCs for Mirena[®] and Jaydess[®] state the theoretical possibility that adverse effects (particularly virilisation) could occur as a result of the local exposure to LNG. The SPCs^{45,46} conclude, however, that there is currently no evidence that an LNG-IUS remaining *in situ* during pregnancy is associated with birth defects. However, there are very limited clinical data regarding the outcomes of pregnancies conceived with an LNG-IUS *in situ* due to their high contraceptive efficacy. One case report and review⁴⁷ of the evidence on the risk of adverse effects of fetal exposure to LNG-IUS reported a low frequency of congenital abnormalities. This study is limited, however, by the very small numbers: in the 35 pregnancies studied, there were two cases of congenital abnormalities (6%).

4.2 Ectopic Pregnancy

4.2.1 Hormonal contraception

The absolute risk of ectopic pregnancy is reduced by all contraceptive methods. Evidence is lacking relating to the effect of contraceptive hormones started around the time of conception on ectopic pregnancy risk.

4.2.2 Intrauterine contraception

The risk of any pregnancy, including ectopic pregnancy, during use of intrauterine contraception (IUC) and after insertion of a Cu-IUD for EC is very low. However, should a pregnancy occur with IUC *in situ*, the likelihood of it being ectopic is greater than if a pregnancy were to occur without IUC *in situ*. The UK incidence of ectopic pregnancy is estimated at 1.1% of all pregnancies.⁴⁸ An early prospective study from the UK¹⁶ reported that among 90 pregnancies in women using IUDs, 8.9% were ectopic. In a cross-sectional study⁴⁹ of LNG-IUS users (17 360 users, totalling 58 600 woman-years) there were 64 pregnancies reported with a 52 mg LNG-IUS *in situ*. The risk of pregnancy was therefore low (6-year cumulative pregnancy rate of 0.5 per 100 users); however, roughly half of the 64 pregnancies (53%) were ectopic. In the EURAS-IUD study,⁵⁰ 52 mg LNG-IUS users appeared to experience fewer ectopic pregnancies than Cu-IUD users, but when pregnancy did occur, 5/13 (38.6%) were ectopic compared with 10/56 (17.9%) in Cu-IUD users.

4.3 Bleeding Patterns

There is no evidence that bleeding patterns are significantly different with quick start versus conventional start of HC. A systematic review¹ including four RCTs that reported bleeding data

found that women who quick started HC had bleeding patterns similar to women who conventionally started contraception. Observational studies that considered bleeding patterns have also found no significant difference.⁵¹⁻⁵³ It is worth noting that all of the aforementioned studies except one – which listed an unspecified formulation of ‘oral contraceptive pills’ – studied CHC and not progestogen-only methods.

4.4 Timing of Intrauterine Insertion

Contrary to traditionally held beliefs, there is no evidence that the cervix dilates or softens during menstrual periods or that insertion of IUC is easier at this time.

5 When and How to Quick Start Contraception

Current FSRH guidance support commencement of CHC, POP, IMP and DMPA on Days 1–5 and the LNG-IUS on Days 1–7 of a natural menstrual cycle without any requirement for additional contraception. This is outside the product licence for some methods. FSRH guidance regarding starting contraception following pregnancy – including miscarriage, abortion and ectopic pregnancy – can be found in FSRH Guideline *Contraception After Pregnancy*.⁵⁴

5.1 Quick Starting if Pregnancy Can be Excluded



Healthcare practitioners (HCPs) can offer quick start of any method of contraception at any time in the menstrual cycle if it is reasonably certain that a woman is not pregnant or at risk of pregnancy from recent UPSI.

All methods of contraception can be started at any time in the menstrual cycle if a healthcare practitioner (HCP) is reasonably certain that the woman is not currently pregnant (see [Box 1](#)) or at risk of pregnancy.

Box 1: Criteria for reasonably excluding pregnancy

Healthcare practitioners can be **reasonably certain** that a woman is **not currently pregnant** if any one or more of the following criteria are met **and** there are no symptoms or signs of pregnancy:

- ▶ She has not had intercourse since the start of her last normal (natural) menstrual period, since childbirth, abortion, miscarriage, ectopic pregnancy or uterine evacuation for gestational trophoblastic disease.
- ▶ She has been correctly and consistently using a reliable method of contraception. (For the purposes of being reasonably certain that a woman is not currently pregnant, barrier methods of contraception can be considered reliable providing that they have been used consistently and correctly for every episode of intercourse.)
- ▶ She is within the first 5 days of the onset of a normal (natural) menstrual period.
- ▶ She is less than 21 days postpartum (non-breastfeeding women).
- ▶ She is fully breastfeeding, amenorrhoeic AND less than 6 months postpartum.
- ▶ She is within the first 5 days after abortion, miscarriage, ectopic pregnancy or uterine evacuation for gestational trophoblastic disease.
- ▶ She has not had intercourse for >21 days AND has a negative high-sensitivity urine pregnancy test (able to detect hCG levels around 20 mIU/ml).

Table 1: Percentage of women experiencing an unintended pregnancy within the first year of use with typical use and perfect use (modified from Trussell *et al.*⁵⁶)

Method	Typical use (%)	Perfect use (%)
No method	85	85
Fertility awareness-based methods	24	0.4–5
Female diaphragm	12	6
Male condom	18	2
Combined hormonal contraception*	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.

*Includes combined oral contraception, transdermal patch and vaginal ring.

If a woman asks to start contraception immediately and pregnancy can be reasonably excluded, she can be offered her choice of all methods of contraception to which she has no medical contraindications [see *UK Medical Eligibility Criteria for Contraceptive Use (UKMEC)*].⁵⁵ Women should be given information about all methods for which they are medically eligible and supported to decide which might best suit their needs. [Table 1](#) compares the effectiveness of currently available methods, with the most effective LARC methods highlighted. If a woman's preferred method is not available at the time of presentation, she can be offered quick start of CHC, POP or DMPA as a bridging method.

Some women may, however, prefer to wait and start contraception at the beginning of the next menstrual period.

Unless HC is started at the beginning of a natural menstrual cycle, additional contraceptive precautions (barrier or abstinence) are required until the new method becomes effective (see [Table 2](#)). A follow-up pregnancy test no sooner than 21 days after the last episode of UPSI is advised (this includes UPSI resulting from failure to use additional contraceptive precautions during the time until contraception becomes effective).

Advice regarding switching from one method of contraception to another is given in the FSRH guidelines relating to individual contraceptive methods and is summarised in the 2016 FSRH Guidance *Starting or Switching Methods of Contraception*.⁵⁷

Table 2: Additional contraceptive requirements (condoms/abstinence) when starting contraception excluding after ulipristal acetate emergency contraception administration

Method	Day of menstrual cycle*	Days of additional contraception required
Combined oral contraception	1–5	0
	6 onwards	7
Zoely® COC	1	0
	2 onwards	7
Qlaira® COC	1	0
	2 onwards	9
Combined transdermal patch and vaginal ring	1–5	0
	6 onwards	7
Progestogen-only pill (traditional/desogestrel)	1–5	0
	6 onwards	2
Progestogen-only injectable and implant	1-5	0
	6 onwards	7
Levonorgestrel intrauterine system	1–7	0
	8 onwards	7
Copper intrauterine device	Any start day	0

*Day 1 is defined as the first day of natural menstrual bleeding; it does not apply to withdrawal or unscheduled bleeding in women already established on hormonal contraception. Healthcare practitioners must consider on an individual basis whether a bleed following oral emergency contraception constitutes a natural menstrual bleed. Criteria may include whether the bleeding occurred close to the time of expected menstruation and whether the bleed was characteristic of the woman's usual menstrual bleeding.

5.2 Quick Starting if Pregnancy Cannot be Excluded

Women who have a negative HSUP (able to detect hCG levels around 20 mIU/ml) but are at risk of pregnancy from recent UPSI should be advised that:

✓	Pregnancy cannot be excluded by an HSUP until ≥ 21 days after the last UPSI.
✓	EC may be indicated.
✓	CHC, POP and IMP can be quick started if they prefer not to delay starting contraception. DMPA may be considered if other methods are not suitable or acceptable.
✓	LNG-IUS should not generally be quick started unless pregnancy can be reasonably excluded.
✓	CHC containing cyproterone acetate should not be quick started unless pregnancy can be reasonably excluded.
✓	A Cu-IUD can be quick started only if the indications for use as EC are met.
D	After LNG-EC administration, CHC, POP, IMP (and DMPA) can be quick started immediately.
D	After UPA-EC administration, they should wait 5 days before quick starting suitable hormonal contraception [CHC, POP, IMP (and DMPA)].
✓	Additional contraceptive precautions (barrier or abstinence) are required until the quick started contraceptive method becomes effective.
✓	A follow-up HSUP is required no sooner than 21 days after the last UPSI.

Quick start of some methods of contraception may be considered if there is a potential risk of very early pregnancy as a result of recent UPSI but an HSUP is still negative. (Pregnancy cannot be excluded by an HSUP until ≥ 21 days after the last UPSI.)

Quick starting in this situation is indicated if a woman is likely to continue to be at risk of pregnancy from further UPSI or has expressed a preference to begin contraception as soon as possible. The woman should be advised on what is known about the use of HC during very early pregnancy. Additional contraception (barrier or abstinence) is required until contraception becomes effective and follow-up pregnancy testing is essential.

The requirement for EC should be assessed first and EC should be offered if appropriate. After oral EC, a woman is at risk of pregnancy if she has UPSI later in the cycle. Ongoing contraception after EC is therefore extremely important to avoid unintended pregnancy. Suitable HC can be quick started immediately after LNG-EC and 5 days after UPA-EC. If EC is not indicated or is not accepted, suitable HC can be quick started immediately.

5.2.1 Requirement for EC

The Cu-IUD should be offered if a woman has had UPSI only within the last 5 days or if she is within 5 days of her earliest estimated date of ovulation.⁵⁸ A Cu-IUD inserted for EC is immediately effective for ongoing contraception. The Cu-IUD offers reliable contraception for its licensed duration. If inserted when a woman is aged over 40 years, a Cu-IUD will be effective for contraception until after the menopause.⁵⁹

If a Cu-IUD is unsuitable or is declined and a woman has had UPSI within the last 5 days, oral EC should be offered. It is extremely important that providers of EC explain to women that oral EC provides no ongoing protection from pregnancy. The main mechanism of action of oral EC is to delay ovulation, but when ovulation is delayed until later in the cycle, there is a risk of pregnancy if a woman has further UPSI. Studies have demonstrated a higher pregnancy rate after EC amongst women who have further UPSI in the same cycle than amongst women who do not have further UPSI.⁶⁰

EC providers should offer information regarding ongoing contraception and should provide quick start contraception if that is the woman's preference (see [Section 5.2.2](#) and [Section 5.2.3](#) on quick starting after LNG-EC and after UPA-EC, respectively). A bridging method of contraception can be quick started if the woman's preferred method cannot be commenced until pregnancy has been excluded. If an EC provider cannot themselves offer a woman her contraceptive method of choice, they must be able to give advice as to how she can access local contraceptive services.

5.2.2 Quick starting after LNG-EC

If LNG-EC is taken, suitable HC (see [Section 5.2.5](#) for suitable methods) can be quick started immediately.⁵⁸ The woman should be advised to use additional contraceptive precautions (barrier or abstinence) until contraception becomes effective.

Evidence level 4

Table 3: Time to contraceptive effectiveness when starting 120 hours after ulipristal acetate for emergency contraception (UPA-EC)⁵⁸

Contraceptive method (start >120 hours after UPA-EC)	Requirement for additional contraception after starting method (days)
Combined oral contraceptive pill (except Qlaira®)	7
Qlaira combined oral contraceptive pill	9
Combined vaginal ring/transdermal patch	7
Progestogen-only pill (traditional/desogestrel)	2
Progestogen-only implant or injectable	7

5.2.3 Quick starting after UPA-EC

If UPA-EC is taken, its effectiveness for EC could be reduced if progestogen is taken in the following 5 days.^{58,61} Quick start of suitable HC should therefore be delayed for 5 days (120 hours) after UPA-EC. This ensures that the UPA-EC is as effective as possible in preventing pregnancy resulting from the episode(s) of UPSI for which it was taken. Importantly, there is a risk of pregnancy if there is further UPSI before ongoing contraception is started and becomes effective. The woman should be advised to use additional contraception (barrier or abstinence) during the 5 days waiting and then until the chosen contraception becomes effective.

Evidence level 1-

Data from Brache *et al.*⁶¹ and Cameron *et al.*⁶² suggest that the effectiveness of the desogestrel POP and of COC is not affected when they are started after UPA-EC.

Extrapolating from these data, the CEU advises that CHC, IMP and DMPA commenced 5 days after administration of UPA-EC will be effective 7 days after starting and POP 2 days after starting (see [Table 3](#)).⁵⁸

Evidence level 4

5.2.4 Quick starting if pregnancy cannot be excluded but there is no requirement for EC

If EC is not indicated or is not accepted, suitable HC (see [Section 5.2.5](#)) can be quick started immediately. The woman should be advised to use additional contraception (barrier or abstinence) until contraception becomes effective (see [Table 2](#)).

5.2.5 Contraceptive methods that can be quick started if risk of pregnancy cannot be reasonably excluded

If pregnancy cannot be reasonably excluded and a woman is likely to continue to be at risk of pregnancy or has expressed a preference to begin contraception as soon as possible, the CEU supports quick starting CHC (excluding co-cyprindiol), the POP or IMP. Women requesting DMPA should ideally be offered CHC or POP as a quick starting or bridging method as the injectable cannot be removed or stopped if pregnancy is diagnosed and evidence relating to fetal exposure to DMPA is limited. If these alternative methods are not acceptable to a woman, immediate start of DMPA can be considered providing that the lack of evidence regarding use in early pregnancy is explained (see [Section 4.1.2](#)).

Because of the increased risks of adverse pregnancy outcomes (see [Section 7.2](#)) IUC should not be quick started unless pregnancy has been reasonably excluded or a woman meets the criteria for use of the Cu-IUD for EC.⁵⁸

Although the COC co-cyprindiol has not been shown to be harmful to the human fetus, on the basis of animal studies the SPC for Dianette® states that feminisation of male fetuses could occur if cyproterone acetate is administered during the phase of embryogenesis at which differentiation of the external genitalia occurs.⁶³ The SPC advises that pregnancy must be excluded before starting co-cyprindiol. Other CHC methods should therefore be used for quick starting.

5.2.6 Use of bridging contraception



If a woman's choice of contraceptive method is not available or is not appropriate at the time of presentation, she should be offered a bridging method of contraception that can be quick started.

5.3 Follow-up after Quick Starting Contraception

Women who quick start contraception when pregnancy cannot be excluded must be informed that a pregnancy test must be taken 21 days after the last episode of UPSI. This includes any UPSI due to failure to use additional contraceptive precautions after starting the new method but before it becomes effective. Women should be made aware that bleeding during or soon after stopping HC is not the same as a natural period and is not a reliable indicator that a woman is not pregnant.

6 Ethical Issues to Consider

It is illegal to knowingly insert IUC in a woman who is pregnant.

It is outside the terms of the product licences of all HCs for a HCP to supply HC without being reasonably sure that the woman is not pregnant. However, the FSRH supports quick start of contraceptive methods as described in this guideline.

The FSRH *Service Standards for Medicines Management in Sexual and Reproductive Health Services*⁶⁴ [i.e. statement on the process for prescribing unlicensed medicines and for the use of medicines outside the manufacturer's license (off-label prescribing)] states:

- ▶ The purpose of using a medication outside its licence should be justifiable and in line with a recognised body of opinion.
- ▶ HCPs should be satisfied that they have sufficient information to administer an unlicensed or 'off label' drug safely.
- ▶ Patients must be given sufficient information about the medicines proposed to be prescribed to allow them to make an informed decision. In accordance with the General Medical Council (GMC), "where prescribing unlicensed medicines is supported by authoritative clinical guidelines, it may be sufficient to describe in general terms why the medicine is not licensed for the proposed use".⁶⁵
- ▶ Non-medical prescribers may prescribe a medicine outside the manufacturer's licence if done under current recognised guidance for use by a professional body, i.e. when a contraceptive preparation is used within current guidance from the Faculty's Clinical Effectiveness Committee.

The Nursing and Midwifery Council (NMC) advises that nurse or midwife independent prescribers may prescribe outside the product licence if they are satisfied that this would better serve the patient's needs and there is a sufficient evidence base to demonstrate safety and efficacy. The patient should understand why the medication is not licensed for the proposed use and this should

be documented accordingly.⁶⁵ The NMC also states that it is acceptable for medicines to be used outside the terms of the licence to be included in patient group directions (PGDs) when such use is justified by current best clinical practice and the PGD clearly describes the status of the product.⁶⁶

7 Pregnancy Diagnosed After Starting Contraception



The GDG advises that women should be informed that contraceptive hormones are not thought to cause harm to the fetus and they should not be advised to terminate pregnancy on the grounds of exposure.

See [Section 4](#).

7.1 Women using CHC, POP, IMP or DMPA

7.1.1 Women who wish to continue the pregnancy



If a pregnancy is diagnosed after starting contraception and the woman wishes to continue the pregnancy, the woman should be advised that the method should usually be removed or stopped.

7.1.2 Women who choose not to continue the pregnancy

If a pregnancy is diagnosed after starting CHC, POP, IMP or DMPA and the woman chooses therapeutic abortion:



A woman using IMP or DMPA can be advised to continue her method of contraception with no additional contraceptive precautions after abortion.



A woman using CHC or POP can be advised to stop her method of contraception and restart contraception immediately after abortion with no additional contraceptive precautions.

B

A woman using DMPA should be advised that there may be a slightly higher risk of continuing pregnancy (failed abortion) if DMPA is administered at the time of mifepristone administration.

If a woman chooses to terminate the pregnancy and is using IMP or DMPA, the GDG recommend that she may continue her method of contraception. If DMPA injection is due prior to the date of abortion, it should usually be delayed and given after abortion. If she is using CHC or POP, she should stop the contraceptive until the day of administration of mifepristone or surgical abortion and on that day restart either the same contraceptive method or a suitable alternative.

There has been theoretical concern that use of progestogen-only contraception at the same time as mifepristone (a progestogen receptor modulator) might reduce the efficacy of medical abortion due to competition at the progesterone receptor. Studies have not examined the effectiveness of medical abortion in women who are already using HC at the time of medical abortion. Two RCTs^{67,68} and a prospective observational study⁶⁹ found no significant difference in the effectiveness of medical abortion whether the progestogen-only implant was inserted at the time of administration of mifepristone or was delayed until abortion was complete.

Evidence level 1+

A recent RCT⁷⁰ in the USA randomised 461 women undergoing first-trimester medical abortion to receive intramuscular DMPA either at the time of administration of mifepristone or after completion of abortion. The study reports a significantly greater risk of ongoing pregnancy if DMPA is given at the time of mifepristone – the effect is however small.

Evidence level 1+

A retrospective chart review study⁷¹ of 51 women receiving DMPA on the same day as mifepristone found that the success rate of early medical abortion was not significantly different to that without the use of progestogen-only contraception reported in a published systematic review.⁷²

Evidence level 2-

The 2017 FSRH guideline *Contraception After Pregnancy*⁵⁴ recommends that women should be advised that there may be a slightly higher risk of continuing pregnancy (failed abortion) if DMPA is initiated at the time of mifepristone administration.⁷³

Evidence level 4

See FSRH Guideline *Contraception After Pregnancy*⁵⁴ for advice regarding initiation of contraception after abortion. No additional contraceptive precautions are required if contraception is initiated within 5 days of abortion.

7.2 Women using IUC

✓	HCPs should advise women whose intrauterine pregnancy is less than 12 weeks' gestation that IUC should be removed, as long as the threads are visible or it can be easily removed from the endocervical canal. This is regardless of whether the woman decides to continue with the pregnancy.
B	HCPs should explain to women who have an intrauterine pregnancy with IUC <i>in situ</i> that the risk of adverse pregnancy outcomes is greater than that for pregnancies without IUC <i>in situ</i>.
B	HCPs should advise women who have an intrauterine pregnancy with IUC <i>in situ</i> that removal of the IUC in the first trimester could improve pregnancy outcomes, but is associated with a small risk of miscarriage.

The FSRH guideline *Intrauterine Contraception*⁵⁹ recommends that if a woman is found to be pregnant with IUC *in situ*, the site of the pregnancy should be determined by ultrasound scan to exclude ectopic pregnancy.

A systematic review⁴⁴ of nine observational studies – eight of which studied Cu-IUD users and one which studied LNG-IUS users – concluded that compared to women who conceive without IUC *in situ*, those who conceive with IUC *in situ* are at greater risk of adverse pregnancy outcomes including miscarriage, preterm delivery and chorioamnionitis. The review⁴⁴ found that compared to women who had their device removed in early pregnancy, those whose IUC remained *in situ* during pregnancy were at higher risk for miscarriage, preterm delivery and septic abortion.

Evidence level 2++

The evidence relating to pregnancy and fetal outcomes with an LNG-IUS *in situ* is extremely limited. The SPC for the 52 mg LNG-IUS⁴⁵ states that teratogenicity cannot be completely excluded; however, to date there is no evidence of birth defects caused by Mirena use in cases where pregnancy continues to term with Mirena *in situ*.

A subsequent retrospective cohort study⁷³ compared pregnancy outcomes amongst 114 women who conceived with an Cu-IUD *in situ* and had it removed with those amongst 30 patients who continued the pregnancy with the Cu-IUD *in situ*. The relative risk of combined adverse pregnancy outcomes (miscarriage, intrauterine fetal death, intrauterine growth retardation, preterm birth and premature rupture of membranes) was 2.0 (95% CI 1.3–3.3) for retention of the Cu-IUD versus removal.

Evidence level 2+

The GDG recommends that IUC should be removed if a woman is less than 12 weeks' gestation, as long as the threads are visible or it can be easily removed from the endocervical canal. This is regardless of whether the woman decides to continue with the pregnancy. Women should be informed of the increased risks of second-trimester miscarriage, preterm delivery and infection if the IUC is left *in situ*. Removal in the first trimester is thought to reduce the overall risk of adverse outcomes but is associated with a small risk of miscarriage. After 12 weeks gestation, it is recommended that expert advice should be taken and the potential benefits and risks of removing or not removing IUC should be considered on an individual basis

Recommendations for Future Research

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

- ▶ Impact of quick starting contraception on unintended pregnancy rates
- ▶ Long-term health and development outcomes in offspring who were exposed to HC in early pregnancy
- ▶ Impact of quick starting effective contraception on long-term continuation rates
- ▶ Impact of quick starting LARC on long-term continuation rates of LARC
- ▶ Safety, feasibility and acceptability of quick starting LNG-IUS after oral EC
- ▶ Side effects (tolerability, bleeding patterns) associated with quick starting contraception at different times in the menstrual cycle or after switching methods, EC or pregnancy
- ▶ Acceptability and feasibility of quick starting (same day) IUC after medical abortion (including mid-trimester)
- ▶ Acceptability and feasibility of quick starting contraception at the time of medical management of ectopic pregnancy (using methotrexate)
- ▶ Acceptability and feasibility of quick starting contraception after medical or surgical management of miscarriage.

Useful Links

- ▶ [FSRH Guideline *Emergency Contraception*⁵⁸](#)
- ▶ [FSRH Guideline *Contraception After Pregnancy*⁵⁴](#)
- ▶ [FSRH Guidance *Switching or Starting Methods of Contraception*⁵⁷](#)

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Appendix 1 – FSRH Clinical Guideline Development Process

Who has developed the guideline?

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

Development of the guideline was led by the secretariat (CEU staff) and involved the intended users of the guidelines (contraception providers) and patient/service user representatives as part of a multidisciplinary group. The scope of the guideline was informed by a scoping survey conducted amongst members of the FSRH and amongst service users from three sexual and reproductive health services across the UK [Sandyford (Glasgow), Scotland; Brook (Liverpool & Wirral and Milton Keynes), England; Aneurin Bevan University Health Board (Gwent), Wales]. The first draft of the guideline was produced based on the final scope of the guideline agreed by the GDG. The first draft of the guideline (version 0.1) was reviewed by the GDG and a revised draft guideline (version 0.2) was produced in response to comments received, after which it was sent to international and UK-based external independent reviewers suggested by the GDG at the face-to-face meeting. A further revision generated a version of the draft guideline (version 0.3) which was placed on the FSRH website for public consultation between 8 February and 7 March 2017. The revised draft guideline (version 0.4) was sent to the GDG for final comments and to reach consensus on the recommendations (details of this process are given later).

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

Guideline Development Group (GDG)

Secretariat

- | | |
|-----------------------------|--|
| ▶ Dr Ailsa Gebbie | Director, Clinical Effectiveness Unit |
| ▶ Dr Sarah Hardman | Deputy Director, Clinical Effectiveness Unit |
| ▶ Mrs Valerie Warner | Researcher, Clinical Effectiveness Unit |

Multidisciplinary group

- | | |
|---------------------------|--|
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| ▶ Dr Lynne Gilbert | Associate Specialist in Sexual and Reproductive Healthcare (iCASH Cambridgeshire); Vice Chair Clinical Standards Committee, FSRH |

- ▶ **Dr Jennifer Heathcote** Associate Specialist (East Cheshire Centre for Sexual Health, Macclesfield)
- ▶ **Dr Diana Mansour** Consultant in Community Gynaecology and Reproductive Healthcare, Head of Clinical Service, Sexual Health (Newcastle upon Tyne); FSRH Vice-President Clinical Quality
- ▶ **Dr Anatole S Menon-Johansson** Clinical Lead for Sexual & Reproductive Health, (Guy's & St Thomas' NHS Foundation Trust, London)
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- ▶ **Professor James Trussell** Senior Research Demographer (Princeton University, Princeton, NJ, USA)
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Independent reviewers

- ▶ **Dr Sharon Cameron** Director, Clinical Effectiveness Unit
Consultant Gynaecologist (Chalmers Centre, NHS Lothian, Edinburgh)
- ▶ **Dr Alison Edelmann** Professor OB/GYN, Director Section of Family Planning and the Fellowship in Family Planning (Oregon Health & Science University, Portland, OR, USA)
- ▶ **Professor Kristina Gemzell-Danielsson** Chair (Division of Obstetrics and Gynecology, Department of Women's and Children's Health, Karolinska Institutet, and Karolinska University Hospital, Stockholm, Sweden)
- ▶ **Dr Raymond Li** Associate Professor in Obstetrics and Gynaecology (The University of Hong Kong and Honorary Medical Consultant, The Family Planning Association of Hong Kong, Hong Kong)
- ▶ **Dr Clare Spencer** GPwSI in Gynaecology and GP Partner (Meanwood Practice, Leeds)

Declaration of interests

Dr Baird received an honorarium from HRA Pharma for a presentation at their symposium at Current Choices 2013 entitled 'EC: is choice achievable?'. Dr Mansour has received financial support to attend pharmaceutical advisory board meetings, undertake research studies and speak at educational meetings and conferences along with travel grants from Aspen, Astellas, Bayer, Consilient Healthcare, HRA Pharma, Merck, Mithra, Pfizer and Vifor Pharma. Professor Gemzell-Danielsson serves on advisory boards and has been an invited speaker at scientific meetings for

Bayer AG, MSD/Merck, HRA Pharma, Exelgyn, Actavis, NaturalCycles and Gedeon Richter on an *ad hoc* basis. Her institution has conducted studies sponsored by HRA Pharma, Mithra, Bayer and MSD/Merck. None of the individuals involved had competing interests that prevented their active participation in the development of this guideline.

Public consultation contributors

The CEU 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 28 November 2016. The evidence identified up to this point was used to develop the first draft of the guideline. Any evidence published after this date was not considered for inclusion.

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

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

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.

Estimating ovulation	(accurate OR accuracy) AND ovulation AND (perceive OR perception OR estimate OR estimation) ("last menstrual period") AND (ovulation OR ovulate OR ovulatory) [human]
Quick starting	Contracept* AND immediate AND start Contracept* AND quick AND (start or starting) Contracept* AND timing AND start (initiate OR initiating OR initiation) AND contracept* AND (immediate OR quick) ((quick OR immediate) AND start) AND contracept*
Bridging	contracept* AND bridging contracept* AND bridge
Hormonal exposure	((foetal OR fetal OR baby OR babies) AND exposure) AND ((hormonal OR hormones) AND contracept*)
Bleeding patterns	((time OR timing) AND start) AND contracept* AND bleed*
Emergency contraception	(emergency AND contracept*) AND failure
Lifespan of sperm	(spermatozoa OR sperm) AND (lifetime* OR survive OR survival) AND (ovulation OR mucus)
Intrauterine contraception	(pregnant OR pregnancy) AND (intrauterine AND (device OR system OR contracept*)) AND (in situ)
Ulipristal acetate	ulipristal AND (progestogen OR progesterone OR progestin) AND contracept* [filtered for humans]

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
<p>1++ High-quality systematic reviews or meta-analysis of randomised controlled trials (RCTs) or RCTs with a very low risk of bias.</p>	<p>A At least one systematic review, meta-analysis or RCT rated as 1++, and directly applicable to the target population; <i>or</i> 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.</p>
<p>1+ Well-conducted systematic reviews or meta-analysis of RCTs or RCTs with a low risk of bias.</p>	
<p>1- Systematic reviews or meta-analysis of RCTs or RCTs with a high risk of bias.</p>	
<p>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.</p>	<p>B A body of evidence including studies rated as 2++ directly applicable to the target population and demonstrating overall consistency of results; <i>or</i> Extrapolated evidence from studies rated as 1++ or 1+.</p>
<p>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.</p>	<p>C A body of evidence including studies rated as 2+ directly applicable to the target population and demonstrating overall consistency of results; <i>or</i> Extrapolated evidence from studies rated as 2++.</p>
<p>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.</p>	
<p>3 Non-analytical studies (e.g. case report, case series).</p>	<p>D Evidence level 3 or 4; <i>or</i> Extrapolated evidence from studies rated as 2+.</p>
<p>4 Expert opinions.</p>	<p>✓ Good Practice Points based on the clinical experience of the guideline development group.*</p>

*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.

Considerations when making recommendations

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

Reaching consensus on the recommendations

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

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

Updating this guideline

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

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), which is accessible to all Diplomates, Members, Associate Members and Fellows of the FSRH.

- 1 Which statement regarding quick starting contraception is false?**
 - a. It can reduce the time during which a woman is at risk of pregnancy.
 - b. Bleeding patterns are not significantly different than with traditional starting.
 - c. Insertion of a copper intrauterine device (Cu-IUD) is likely to be more difficult if it is not done during menstruation.
 - d. It can prevent a woman from forgetting information on correct usage of her chosen contraception.

- 2 A woman presents for contraception. Her periods are very irregular. She has had only one episode of unprotected sexual intercourse (UPSI) 23 days ago and has a negative high-sensitivity pregnancy test (HSUP). Which of the following is false?**
 - a. Quick starting any method of contraception to which she has no medical contraindications is appropriate.
 - b. If her preferred method is not available at the time of presentation, she can be offered quick start of combined oral contraception (COC) as a bridging method.
 - c. She should be advised that additional contraceptive precautions are required until the new method becomes effective.
 - d. An HSUP should be repeated in 21 days time.

- 3 Which of the following is a true criterion for reasonably excluding pregnancy if there are no symptoms or signs of pregnancy?**
 - a. The woman has been correctly and consistently using a reliable method of contraception.
 - b. The woman is within the first 8 days of a normal menstrual period.
 - c. The woman is less than 6 weeks postpartum (non-breastfeeding).
 - d. The woman is within the first 21 days after abortion, miscarriage, ectopic pregnancy or uterine evacuation for gestational trophoblastic disease.

- 4 Unless hormonal contraception (HC) is started at the beginning of the menstrual cycle, additional contraceptive precautions are required until the new method becomes effective. Which of the following is false?**
 - a. Combined oral contraception (COC) started on Day 6 of the menstrual cycle onwards requires 7 days of additional contraception.
 - b. A Cu-IUD started on Day 8 of the menstrual cycle onwards requires 7 days of additional contraception.
 - c. A levonorgestrel-releasing intrauterine system (LNG-IUS) started on Day 8 of the menstrual cycle onwards requires 7 days of additional contraception.
 - d. Qlaira® COC started on Day 2 of the menstrual cycle onwards requires 9 days of additional contraception.

- 5 A woman presents with risk of pregnancy from recent UPSI. She is likely to continue to be at risk of pregnancy from further UPSI and has expressed a preference to begin contraception as soon as possible. Which of the following is true?**
- There is no indication to do a pregnancy test on presentation.
 - A Cu-IUD cannot be quick started and can only be inserted after the next normal menstrual period.
 - Quick starting depot medroxyprogesterone acetate (DMPA) may be considered if other methods are not suitable or acceptable.
 - An LNG-IUS can be quick started.
- 6 A woman presents for emergency contraception (EC). Which of the following is false?**
- A Cu-IUD can be offered if a woman has had UPSI only within the last 5 days or if she is within 5 days of her earliest estimated date of ovulation, and this will be effective immediately for ongoing contraception.
 - After levonorgestrel EC, combined hormonal contraception (CHC), progestogen-only pill (POP), progestogen-only implant (IMP) and DMPA can be quick started immediately.
 - When quick starting HC after ulipristal acetate EC (UPA-EC), the usual requirements for additional contraception after starting the method apply.
 - After ulipristal acetate EC, CHC, POP, IMP and DMPA can be quick started immediately.
- 7 A woman is given UPA-EC. Quick start of suitable HC should be delayed:**
- For 5 days
 - Not at all
 - For 7 days
 - Until the next menstrual period.
- 8 When quick starting HC, which of the following advice is false?**
- The woman should be advised about what is known regarding the use of HC during very early pregnancy.
 - Quick starting HC is within the terms of product licences of all HC.
 - Additional contraception (barrier or abstinence) is required until the quick started contraception becomes effective.
 - Women who quick start contraception when pregnancy cannot be excluded must take a pregnancy test 21 days after the last episode of UPSI.

9 A woman is found to be pregnant after starting the POP. She chooses to have an abortion. Which of the following is true?

- a. She should be advised that the POP could have caused harm to the fetus so you would advise to terminate the pregnancy on grounds of exposure.
- b. She should continue the POP until the abortion.
- c. She should be advised that the use of contraceptive hormones can reduce the effectiveness of medical abortion and you would therefore recommend a surgical abortion.
- d. She should be advised to stop the POP and restart contraception immediately after the abortion with no additional contraceptive precautions.

10 A woman is found to be 6 weeks' pregnant with intrauterine contraception (IUC) *in situ*. Which of the following is false?

- a. She should be advised that since the pregnancy is less than 12 weeks' gestation, the IUC should be removed regardless of whether she decides to continue with the pregnancy.
- b. The location of the pregnancy should be determined by ultrasound scan because of the increased risk of ectopic pregnancy.
- c. She should be advised that there have been cases of birth defects caused by the LNG-IUS where the pregnancy continues to term with the IUS *in situ*.
- d. She should be advised that the removal of the IUC in the first trimester could improve overall pregnancy outcomes and lower the risk of miscarriage, preterm delivery and septic abortion, but is associated with a small risk of miscarriage.

Auditable Outcomes

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

Auditable outcome	Target
Percentage of women quick starting the levonorgestrel intrauterine system (LNG-IUS), combined hormonal contraception (CHC), progestogen-only pill (POP), progestogen-only implant (IMP) or depot medroxyprogesterone acetate (DMPA) who are advised to use additional contraceptive precautions until the method becomes effective.	97%
Percentage of women quick starting CHC, POP, IMP or DMPA when pregnancy cannot be excluded who are advised that a high-sensitivity urine pregnancy test is required no sooner than 21 days after the most recent episode of unprotected sexual intercourse.	97%
Percentage of women quick starting CHC, POP, IMP or DMPA after ulipristal acetate emergency contraception (UPA-EC) who are advised to delay commencing the method until 5 days after UPA is administered.	97%
Percentage of women who are unable to start their chosen method of contraception at presentation who are offered a bridging method of contraception that can be quick started.	97%

Comments and Feedback on Published Guideline

All comments on 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 and any necessary amendments made subsequently.

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