FACULTY OF SEXUAL & REPRODUCTIVE HEALTHCARE

ROYAL COLLEGE OF OBSTETRICIANS & GYNAECOLOGISTS

Faculty of Sexual & Reproductive Healthcare Clinical Guidance

Quick Starting Contraception

Clinical Effectiveness Unit

September 2010

ISSN 1755-103X

ABBREVIATIONS USED

CEU	Clinical Effectiveness Unit
CHC	combined hormonal contraception
CI	confidence interval
COC	combined oral contraception
Cu-IUD	copper-bearing intrauterine device
CVR	combined vaginal ring
DMPA	depot medroxyprogesterone acetate
EC	emergency contraception
FSRH	Faculty of Sexual and Reproductive Healthcare
GMC	General Medical Council
LNG-IUS	levonorgestrel-releasing intrauterine system
NMC	Nursing and Midwifery Council
OR	odds ratio
PGD	patient group direction
POEC	progestogen-only emergency contraception
POP	progestogen-only pill
SPC	Summary of Product Characteristics
UPA	ulipristal acetate
UPSI	unprotected sexual intercourse

GRADING OF RECOMMENDATIONS

A	Evidence based on randomised controlled trials
B	Evidence based on other robust experimental or observational studies
C	Evidence is limited but the advice relies on expert opinion and has the endorsement of respected authorities
✓	Good Practice Point where no evidence exists but where best practice is based on the clinical experience of the multidisciplinary group

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

First published in 2010

CONTENTS

SUMMARY OF KEY RECOMMENDATIONS

✓ If a health professional is reasonably sure that a woman is not pregnant or at risk of pregnancy from recent unprotected sexual intercourse (UPSI), contraception can be started immediately unless the woman prefers to wait until her next period. Such practice may be outside the product licence/device instructions.

✓ If a health professional is reasonably sure that a woman is not pregnant but her preferred contraceptive method is not available, combined hormonal contraception (CHC), the progestogen-only pill (POP) or progestogen-only injectable can be used as a bridging method.

✓ When starting intrauterine methods or co-cyprindiol (Dianette®, Clairette®) health professionals should take particular care to exclude pregnancy or risk of pregnancy from recent UPSI. If pregnancy cannot be excluded, the copper-bearing intrauterine device may only be started immediately if the criteria for use as emergency contraception (EC) are met; insertion of the levonorgestrel-releasing intrauterine system or initiation of co-cyprindiol should be delayed until pregnancy can be excluded.

✓ If pregnancy cannot be excluded (e.g. following administration of EC) but a woman is likely to continue to be at risk of pregnancy or has expressed a preference to start contraception without delay, immediate 'quick starting' of CHC, the POP or progestogen-only implant may be considered. The woman should be informed of the potential risks and the need to have a pregnancy test at the appropriate time (see recommendation below).

✓ Women requesting the progestogen-only injectable should ideally be offered a bridging method if pregnancy cannot be excluded, but immediate start is acceptable if other methods are not appropriate or acceptable.

✓ If contraception is quick started in a woman for whom pregnancy cannot be excluded, a pregnancy test should be advised no sooner than 3 weeks after the last episode of UPSI.

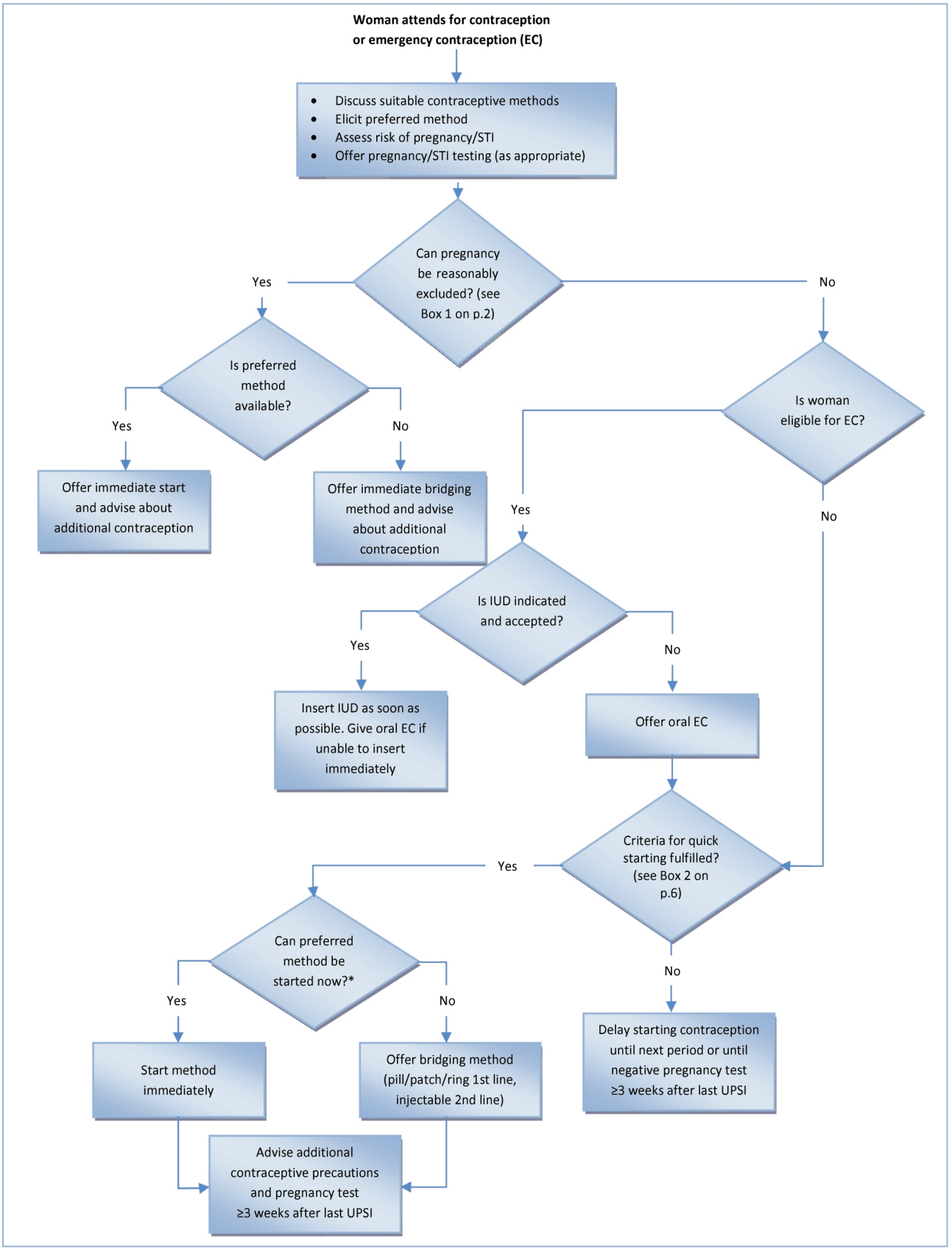
✓ If pregnancy cannot be excluded and the woman's preferred method is not available or appropriate, CHC or POP may be used as bridging methods; the progestogen-only injectable should only be considered as a bridging method if other methods are not appropriate or acceptable.

C If starting hormonal contraception immediately after progestogen-only emergency contraception, condoms or avoidance of sex should be advised for 7 days (2 days for POP, 9 days for Qlaira®).

✓ If starting hormonal contraception immediately after ulipristal acetate EC, the Clinical Effectiveness Unit recommends condoms or avoidance of sex for 14 days (9 days if starting POP, 16 days for Qlaira) (outside product licence).

✓ If pregnancy is diagnosed after starting contraception and the woman wishes to continue with the pregnancy, the method should usually be stopped or removed. Intrauterine contraceptives should not be removed if pregnancy is diagnosed after 12 weeks' gestation.

DECISION-MAKING ALGORITHM FOR QUICK STARTING CONTRACEPTION



*If requesting intrauterine method or co-cyprindiol always delay start until pregnancy excluded.
EC, emergency contraception; IUD, intrauterine device; STI, sexually transmitted infection; UPSI, unprotected sexual intercourse.

SUMMARY OF ADDITIONAL CONTRACEPTIVE REQUIREMENTS WHEN STARTING CONTRACEPTION[1–6]

Method	Circumstances (day of menstrual cycle[a]/method of emergency contraception)	Requirements for additional contraception (condoms/ avoidance of sex)
Combined oral contraceptive pills (except Qlaira®)	Days 1–5	Not required
	Day 6 onwards/Quick starting after POEC	7 days
	Quick starting after UPA EC	14 days
Qlaira combined oral contraceptive pill[b]	Day 1	Not required
	Day 2 onwards/Quick starting after POEC	9 days
	Quick starting after UPA EC	16 days
Combined vaginal ring[b]/transdermal patch[b]	Day 1	Not required
	Day 2 onwards/Quick starting after POEC	7 days
	Quick starting after UPA EC	14 days
Progestogen-only pill (traditional/desogestrel)	Days 1–5	Not required
	Day 6 onwards/Quick starting after POEC	2 days
	Quick starting after UPA EC	9 days
Progestogen-only implant	Days 1–5	Not required
	Day 6 onwards/Quick starting after POEC	7 days
	Quick starting after UPA EC	14 days
Progestogen-only injectable	Days 1–5	Not required
	Day 6 onwards/Quick starting after POEC[c]	7 days
	Quick starting after UPA EC[c]	14 days
Levonorgestrel-releasing intrauterine system	Days 1–7	Not required
	Day 8 onwards[c]	7 days
Copper-bearing intrauterine device	Any start day[c]	Not required

[a]Day 1 defined as first day of menstrual bleeding; does not apply to withdrawal or unscheduled bleeding in women already established on hormonal contraception.
[b]Recommendations according to Summary of Product Characteristics; currently no Faculty guidance on these methods.
[c]See text for restrictions on quick starting these methods.
EC, emergency contraception; POEC, progestogen-only emergency contraception; UPA, ulipristal acetate.

Faculty of Sexual and Reproductive Healthcare
Clinical Effectiveness Unit

A unit funded by the FSRH and supported by NHS Greater Glasgow & Clyde to provide guidance on evidence-based practice

FSRH Guidance (September 2010) Quick Starting Contraception

(Update due by September 2015)

1 Purpose and Scope

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

2 Background

The appropriate time to start contraception depends on the contraceptive method and may also depend on medical and social factors. Traditionally, initiation of hormonal and intrauterine methods of contraception has been delayed until the onset of the next menstrual period in order to avoid inadvertent use during pregnancy. Starting early in the cycle also avoids the need for additional contraception. The manufacturers' Summaries of Product Characteristics (SPCs) vary in their advice on contraceptive start dates and the need for additional contraception. Faculty of Sexual and Reproductive Healthcare (FSRH) guidance advises that some methods may be started up to Day 5 or Day 7 [levonorgestrel-releasing intrauterine system (LNG-IUS)] of the menstrual cycle without the need for additional contraceptive precautions (see Summary on page iv for advice on additional contraception).[1–6] Such practice may be outside the terms of the product licence.

There is a theoretical concern that women with a short menstrual cycle may ovulate very early in their cycle, putting them at risk of pregnancy if starting contraception as late as Day 5 or Day 7 (LNG-IUS). There is no strong evidence to support or refute the risk but some sources of patient information (e.g. FPA) advise additional contraception for women in this situation if they have a cycle shorter than 23 days.

Faculty guidance on postnatal sexual and reproductive health includes recommendations on starting contraceptive methods after childbirth.[7] Advice on starting methods after miscarriage or abortion and on switching from one contraceptive method to another can be found in the Faculty's method-specific guidance.[1–5]

3 What is Meant by 'Quick Starting' and 'Bridging' Contraception?

The term 'quick starting' has been adopted to describe starting contraception at the time a woman requests contraception, rather than waiting for the next menstrual cycle. Condoms and barrier methods can be started at any time but quick starting is outside the terms of the product licence for hormonal contraceptives and the LNG-IUS and is not in line with the instructions for some copper-bearing intrauterine devices (Cu-IUDs).

Box 1 Criteria for excluding pregnancy (adapted from *UK Selected Practice Recommendations for Contraceptive Use*)[8]

Health professionals 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 last normal menses
- She has been correctly and consistently using a reliable method of contraception
- She is within the first 7 days of the onset of a normal menstrual period
- She is within 4 weeks postpartum for non-lactating women
- She is within the first 7 days post-abortion or miscarriage
- She is fully or nearly fully breastfeeding, amenorrhoeic, and less than 6 months postpartum

A pregnancy test, if available, adds weight to the exclusion of pregnancy, but only if ≥3 weeks since the last episode of unprotected sexual intercourse.

NB. Health professionals should also consider if a woman is **at risk of becoming pregnant** as a result of unprotected sexual intercourse within the last 7 days.

Although not specifically referred to as quick starting, previous Faculty guidance has advised that contraceptive methods can be started at any point in the menstrual cycle if a practitioner is reasonably certain that the woman is not currently pregnant (Box 1)[8] or at risk of pregnancy. As sperm may be viable in the female reproductive tract for up to 7 days, health professionals should consider if a woman is at risk of becoming pregnant as a result of unprotected sexual intercourse (UPSI) within the last 7 days. Although there are few days in the menstrual cycle when women are not potentially at risk of pregnancy,[9] the probability of pregnancy from a single act of intercourse in the first 3 days of the cycle appears to be negligible.[10]

For the purposes of excluding pregnancy, the CEU would advise that hormonal, intrauterine and barrier methods can be considered reliable providing they have been used consistently and correctly on every incidence of intercourse. This should be assessed on an individual basis.

Quick starting may also mean starting a method immediately after the administration of emergency contraception (EC). In this situation there is a possibility of EC failure and pregnancy, therefore such practice would always be outside the licence of hormonal contraceptives. Faculty guidance on emergency contraception has advised that the decision to start a contraceptive method immediately after progestogen-only emergency contraception (POEC) should be considered on an individual basis.[11]

A Cu-IUD may only be inserted after UPSI if either of the following criteria for use as an emergency contraceptive is fulfilled:[5]

- At any time in the cycle if within 120 hours (5 days) of the first episode of UPSI.
- Up to 5 days after the earliest expected date of ovulation (e.g. up to and including Day 19 in a regular 28-day cycle) irrespective of time since UPSI or number of episodes.

A method that has been quick started may be continued as an ongoing method of contraception or it may be used as a temporary 'bridging' method until pregnancy can be excluded and a longer-acting method initiated.

Currently, within the UK, local health services vary in the extent to which quick starting after EC is included in clinical protocols and in the range of methods for which quick starting is approved.

4 What are the Potential Benefits of Quick Starting Contraception?

Starting contraception immediately, rather than waiting for the next menses, may theoretically reduce the time a woman is at risk of pregnancy; prevent her forgetting information on correct use of the method; prevent waning enthusiasm for the method and use of a less reliable alternative method; avoid patient costs and barriers to returning for contraception (e.g. transport, time, childcare) and reduce health care costs by reducing the number of appointments.

Women who have taken EC or who have irregular cycles may have an even longer wait for their next menses. It has been shown that there is a two- to three-fold higher risk of pregnancy in women who go on to have other episodes of sex in the same cycle that EC has been given compared to those who abstain.[12]

The quick start method might, therefore, be expected to reduce unintended pregnancy rates by improving initiation and continuation of contraceptives compared to conventional start methods.[13,14] Several studies that have addressed this hypothesis are discussed below.

4.1 Unintended pregnancies

A Cochrane review has found limited evidence that immediate ('quick') start of hormonal contraception reduces unintended pregnancies or improves continuation rates.[15] None of the studies included in the review were powered to detect contraceptive efficacy. Whilst there is currently a paucity of evidence demonstrating effectiveness, there are data to suggest women find quick starting acceptable.

It is possible that effectiveness may vary depending on method type. Two studies investigating immediate start of combined oral contraception (COC) versus conventional start did not demonstrate any significant difference in pregnancy rates.[16,17] Another study showed no difference in pregnancy rates when comparing quick starting the combined vaginal ring (CVR) and COC.[18] However in a study that compared immediate start of the progestogen-only injectable depot medroxyprogesterone acetate (DMPA) with immediate start of a short-acting hormonal method (combined pill, transdermal patch or CVR) as a bridging method to DMPA, women in the DMPA group were less likely to become pregnant than women in the bridge group [odds ratio (OR) 0.36; 95% confidence interval (CI) 0.16–0.84).[19] The Cochrane review[15] concluded that more trials examining immediate versus conventional start of the same hormonal contraceptive method are required.

4.2 Adherence and continuation

In clinical studies women quick started onto a hormonal method of contraception generally found it acceptable or helpful.[16,19–21] However, there is no strong evidence to suggest that quick starting improves method discontinuation rates.[15]

Short-term benefits have been noted in studies comparing immediate start of COC with conventional start.[14] In a randomised trial, those who were quick started were more likely to start their second pack of pills (OR 1.5; 95% CI 1.0–2.1). However at 3 and 6 months, continuation rates were comparable between the two groups.[16] This study involved mainly socially deprived young Latino women and therefore these findings may not translate to other groups of women. Another randomised study comparing immediate start of the contraceptive patch with conventional start did not show any benefits in terms of continuation rates after follow-up over three cycles.[21] A retrospective study of women receiving DMPA injections found that there was no difference in continuation rates in those who had immediate injections compared with conventional starters, although continuation rates were low in both groups.[22] No evidence was found in relation to other methods.

5 What are the Potential Disadvantages of Quick Starting Contraception?

When quick starting contraception there is a small risk that the woman is already pregnant or that EC will fail. Diagnosis of pregnancy may be delayed if amenorrhoea is assumed to be due to the contraceptive method or if bleeding is mistaken for a period. There are also theoretical concerns that hormonal contraception may be harmful to the fetus.

5.1 Effects of fetal exposure to steroid hormones

Inadvertent fetal exposure to contraceptive hormones is common, with a USA study estimating that approximately 70 000 fetuses are exposed to oral contraceptives annually.[23] Most of the data on fetal outcomes relate to COC. The CEU found no studies that specifically assessed exposure through quick starting contraception. Studies are often limited by their observational nature, potential confounding factors and small sample size. Reassuringly there have been no consistent findings of specific fetal abnormalities. Animal studies have shown that very high doses of progestogens may cause masculinisation of female fetuses. A very small number of cases of clitoral enlargement have been reported in humans[24] but there have been no reports of serious abnormalities.

The SPC for Depo-Provera®[25] mentions that infants born from accidental pregnancies that occur 1–2 months after injection may be at increased risk of low birth weight and neonatal death. This is based on reports[26,27] of an observational study of Thai DMPA users in which the

authors acknowledge the difficulties of adjusting for confounding variables such as differences in antenatal care, socioeconomic status, and smoking and alcohol use among DMPA users and controls. Longer-term follow-up of the same group of children showed no evidence of any adverse effects on their growth or pubertal development.[28] Other observational data have not shown any adverse effects on physical, intellectual, sexual or social development of children exposed to DMPA *in utero* and followed to adolescence.[27]

Co-cyprindiol (ethinylestradiol and cyproterone acetate; Dianette®, Clairette®) is indicated primarily for acne or hirsutism but it is also contraceptive and concerns have been raised about fetal exposure to cyproterone acetate. The SPC for Dianette[29] advises that pregnancy must be excluded before treatment is begun, and states that animal studies have revealed that feminisation of male fetuses may occur if cyproterone acetate is administered during the phase of embryogenesis at which differentiation of the external genitalia occurs. Although the results of these tests are not necessarily relevant to man, the possibility must be considered that administration of Dianette to women after the 45th day of pregnancy could cause feminisation of male fetuses.[29]

Pregnancies conceived with a Cu-IUD *in situ* do not appear to be associated with congenital abnormalities but may be associated with an increased risk of miscarriage.[30] In theory the risks associated with the LNG-IUS may be higher than with other methods due to direct *in utero* exposure to progestogen. For this reason, the SPC for the Mirena® LNG-IUS indicates that teratogenicity (especially virilisation) cannot be completely excluded, but that in cases where pregnancies have continued with the LNG-IUS there is no evidence of birth defects to date.[6]

5.2 Bleeding patterns

It has been suggested that quick starting contraception may be associated with more disruption to a woman's usual bleeding pattern than when initiating contraception at the beginning of the menstrual cycle. However, studies comparing quick start and conventional start of the COC and CVR have demonstrated no significant difference in bleeding patterns.[14,17,18]

5.3 Insertion of intrauterine contraceptives

Contrary to previously held beliefs that the cervical canal is wider during menses and that this is the optimal time to insert an intrauterine method, there is no evidence that the cervix dilates during menses or that insertion of an intrauterine contraceptive is easier at this time.

6 What are the Ethico-legal Issues to Consider When Quick Starting Contraception?

It is illegal to knowingly insert an IUD in a woman who is pregnant. It is outside the terms of the product licences of all hormonal contraceptives for a health professional to supply hormonal contraception without being reasonably sure that the woman is not pregnant. The General Medical Council (GMC)[31] advises that when prescribing a licensed medication for use outside the terms of the product licence:

- A clinician must be satisfied that there is sufficient evidence and/or experience of using the medicine to demonstrate its safety and efficacy.
- A clinician must make a clear, accurate and legible record of all medicines prescribed and, where you are not following *common practice*, the reasons for prescribing the medicine.
- Where *current practice* supports the use of a medicine in this way it may not be necessary to draw attention to the licence when seeking consent.

In a joint statement the Clinical Standards and Clinical Effectiveness Committees of the FSRH have agreed that CEU guidance on use of contraceptives is guidance on "*common practice*" and "*current practice*" in the use of these medicines and devices.[32] Therefore, it is recommended that it may not be necessary for health professionals to document every occasion when a contraceptive preparation is prescribed outside the product licence if such use falls within current guidance issued by the CEU.

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 better

serves the patient/client's needs, and there is a sufficient evidence base. The patient/client should understand the reasons why such medicines are not licensed for this proposed use and this should be documented accordingly.[33] The NMC also states it is acceptable for medicines 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 direction clearly describes the status of the product.[34]

7 What are the CEU's Recommendations on Quick Starting Contraception?

Quick starting contraception is likely to be an acceptable option for women requesting contraception, and may offer some benefits, with no strong evidence of adverse effects. Where appropriate, immediate start of the method of choice or a bridging method may be offered to women as an alternative to waiting until the next menstrual period. If a woman prefers to delay starting contraception or if she is concerned about potential risks she may wait until her next period or until risk of pregnancy has been excluded.

7.1 Pregnancy excluded

If pregnancy has been reasonably excluded the CEU would support immediate initiation of any contraceptive method at any time in the cycle (see Summary on page iv for advice on additional contraception). Combined hormonal contraception (CHC), the progestogen-only pill (POP) and the progestogen-only injectable can be offered as bridging methods if the woman's preferred method is not available at the time of presentation.

7.2 Pregnancy cannot be excluded

If there is a risk of pregnancy due to recent UPSI then the need for EC should be assessed. The benefits and risks of quick starting contraception should be weighed up for each individual. The CEU would support same-day initiation of CHC (excluding co-cyprindiol), the POP or progestogen-only implant for either of the following reasons:

- The woman is likely to continue to be at risk of pregnancy.
- The woman has expressed a preference to begin contraception as soon as possible.

When pregnancy cannot be excluded, women requesting the progestogen-only injectable should ideally be offered a bridging method as the injectable cannot be removed or stopped immediately if pregnancy is diagnosed. If other methods are not appropriate or acceptable (e.g. due to difficulties using the method correctly) immediate start of the progestogen-only injectable can be considered providing the potential risks are explained.

Because of the increased risk of miscarriage, intrauterine methods should not be quick started unless risk of pregnancy has been reasonably excluded or the criteria for use of the Cu-IUD as EC are met. The LNG-IUS is not effective as EC and it should never be quick started if there has been a risk of conception.[5] Although co-cyprindiol has not been shown to be harmful to human fetuses, it is not licensed for use primarily as a contraceptive and other CHC methods should be used for quick starting.

Health professionals should inform women of the need for additional contraceptive precautions (see Summary on page iv) and pregnancy testing. The timing of the pregnancy test should be no sooner than 3 weeks after the woman's last episode of UPSI (including any UPSI due to failure to use additional contraception). Women should be informed that bleeding during or soon after stopping hormonal contraception is not the same as a natural period and that even regular withdrawal bleeds on CHC may not be a reliable indicator that a woman is not pregnant.

7.3 Bridging

If a woman's method of choice cannot be started immediately, a short-acting method such as CHC (pill, patch or CVR) or POP can be started as a bridging method until pregnancy has been excluded and the preferred method initiated.

The progestogen-only injectable may be used as a bridging method in individual cases but, for the reasons discussed above, this method should be considered second line.

7.4 Quick starting after emergency contraception

When starting hormonal contraception after POEC (Levonelle 1500® or Levonelle One Step®) additional contraception should be advised until contraceptive efficacy is established (see Summary on page iv).

There are no data on quick starting hormonal contraception after use of the emergency contraceptive, ulipristal acetate (UPA) (ellaOne®). As UPA is a progesterone receptor modulator that blocks the action of progesterone, it may affect the contraceptive efficacy of hormonal methods.[35,36] However, no interaction studies have been carried out to date. Therefore, the CEU have taken a pragmatic approach in developing its recommendations and these may be amended if new evidence becomes available.

The half-life of UPA is 32.4 hours, which means that most of the drug is eliminated by 1 week and the interaction with hormonal contraception is likely to be clinically insignificant by this time. If a hormonal method is quick started the CEU advises use of additional contraceptive precautions for 1 week after taking UPA plus the time required for contraceptive efficacy to be established (see Summary on page iv).

There is also a theoretical concern that progestogen-containing contraceptives could antagonise the action of UPA if taken concurrently or started soon after administration of UPA. Although there is no evidence looking at this interaction, UPA has been approved for use following contraceptive failure. The SPC for ellaOne warns of a possible interaction if continuing hormonal contraception but it does not mention any contraindication to use following failure of hormonal contraception.[35]

Box 2 lists the key information recommended for women quick starting contraception. A decision-making algorithm for quick starting contraception is provided on page iii.

✓ If a health professional is reasonably sure that a woman is not pregnant or at risk of pregnancy from recent UPSI, contraception can be started immediately unless the woman prefers to wait until her next period. Such practice may be outside the product licence/device instructions.

✓ If a health professional is reasonably sure that a woman is not pregnant but her preferred contraceptive method is not available, CHC, the POP or the progestogen-only injectable can be used as a bridging method.

✓ When starting intrauterine methods or co-cyprindiol (Dianette®, Clairette®) health professionals should take particular care to exclude pregnancy or risk of pregnancy from recent UPSI. If pregnancy cannot be excluded, the Cu-IUD may only be started immediately if the criteria for use as EC are met; insertion of the LNG-IUS or initiation of co-cyprindiol should be delayed until pregnancy can be excluded.

✓ If pregnancy cannot be excluded (e.g. following administration of EC) but a woman is likely to continue to be at risk of pregnancy or has expressed a preference to start contraception without delay, immediate quick starting of CHC, the POP or progestogen-only implant may be considered. The woman should be informed of the potential risks and the need to have a pregnancy test at the appropriate time (see recommendation overleaf).

Box 2 Checklist for quick starting contraception

If risk of pregnancy cannot be reasonably excluded, the contraceptive provider should ensure that the woman is:

- Likely to continue to be at risk of pregnancy or that she has expressed a preference to begin contraception immediately
- Aware that there is a possibility of pregnancy
- Informed that there is a theoretical risk from fetal exposure to contraceptive hormones but most evidence indicates no harm
- Aware that pregnancy cannot be excluded until she has had a pregnancy test no sooner than 3 weeks after the last episode of unprotected sexual intercourse
- Provided with a pregnancy testing kit or informed of alternative options for pregnancy testing, including local providers of free testing
- Given advice on additional contraceptive precautions (Table 1)
- Offered a supply of condoms or informed of local providers of condoms
- Advised to return if there are any concerns or problems with her contraception

✓ Women requesting the progestogen-only injectable should ideally be offered a bridging method if pregnancy cannot be excluded, but immediate start is acceptable if other methods are not appropriate or acceptable.

✓ If contraception is quick started in a woman for whom pregnancy cannot be excluded, a pregnancy test should be advised no sooner than 3 weeks after the last episode of UPSI.

✓ If pregnancy cannot be excluded and the woman's preferred method is not available or appropriate, CHC or POP may be used as bridging methods; the progestogen-only injectable should only be considered as a bridging method if other methods are not appropriate or acceptable.

C If starting hormonal contraception immediately after POEC, condoms or avoidance of sex should be advised for 7 days (2 days for POP, 9 days for Qlaira).

✓ If starting hormonal contraception immediately after UPA EC, the CEU recommends condoms or avoidance of sex for 14 days (9 days if starting POP, 16 days for Qlaira) (outside product licence).

8 What Should be Done if Pregnancy is Diagnosed After Starting Contraception?

If pregnancy is diagnosed after starting contraception, and the woman wishes to continue the pregnancy, the method should usually be stopped or removed. Women should be informed that contraceptive hormones are not thought to cause harm to the fetus and they should not be advised to terminate the pregnancy for this reason.

If a woman is using the progestogen-only implant and she opts to abort the pregnancy, the implant can be left *in situ* for ongoing contraception. There is a theoretical risk that progestogen from the implant may interact with the progesterone receptor antagonist, mifepristone, used in medical termination. However, there is no evidence that any interaction is clinically significant.

Women who become pregnant with an intrauterine method *in situ* should be informed of the increased risks of second-trimester miscarriage, preterm delivery and infection if the intrauterine method 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. If the threads are visible, or can easily be retrieved from the endocervical canal, the intrauterine contraceptive should be removed up to 12 weeks' gestation.[5]

✓ If pregnancy is diagnosed after starting contraception and the woman wishes to continue with the pregnancy, the method should usually be stopped or removed. Intrauterine contraceptives should not be removed if pregnancy is diagnosed after 12 weeks' gestation.

References

1 Faculty of Family Planning and Reproductive Health Care Clinical Effectiveness Unit. *First Prescription of Combined Oral Contraception*. 2007. http://www.fsrh.org/admin/uploads/FirstPrescCombOralContJan06.pdf [Accessed 26 August 2010].

2 Faculty of Sexual and Reproductive Health Care Clinical Effectiveness Unit. *Progestogen-only Implants*. 2008. http://www.fsrh.org/admin/uploads/CEUGuidanceProgestogenOnlyImplantsApril08.pdf [Accessed 26 August 2010].

3 Faculty of Sexual and Reproductive Health Care Clinical Effectiveness Unit. *Progestogen-only Injectable Contraception*. 2009. http://www.fsrh.org/admin/uploads/CEUGuidanceProgestogenOnlyInjectables09.pdf [Accessed 26 August 2010].

4 Faculty of Sexual and Reproductive Health Care Clinical Effectiveness Unit. *Progestogen-only Pills*. 2009. http://www.fsrh.org/admin/uploads/CEUGuidanceProgestogenOnlyPill09.pdf [Accessed 26 August 2010].

5 . Faculty of Sexual and Reproductive Health Care Clinical Effectiveness Unit. *Intrauterine Contraception*. 2007. http://www.fsrh.org/admin/uploads/CEUGuidanceIntrauterineContraceptionNov07.pdf [Accessed 26 August 2010].

6 Bayer plc. Mirena: Summary of Product Characteristics (SPC). 2009. http://www.emc.medicines.org.uk [Accessed 26 August 2010].

7 Faculty of Sexual and Reproductive Healthcare Clinical Effectiveness Unit. *Postnatal Sexual and Reproductive Health*. 2009. http://www.fsrh.org/admin/uploads/CEUGuidancePostnatal09.pdf [Accessed 26 August 2010].

8 Faculty of Family Planning and Reproductive Health Care Clinical Effectiveness Unit. *UK Selected Practice Recommendations for Contraceptive Use*. 2002. http://www.fsrh.org/admin/uploads/SelectedPractice Recommendations2002.pdf [Accessed 26 August 2010].

9 Wilcox AJ, Dunson D, Baird DD. The timing of the "fertile window" in the menstrual cycle: day specific estimates from a prospective study. *BMJ* 2000; **321**: 1259–1262.

10 Wilcox AJ, Dunson DB, Weinberg CR, Trussell J, Baird DD. Likelihood of conception with a single act of intercourse: providing benchmark rates for assessment of post-coital contraceptives. *Contraception* 2001; **63**: 211–215.

11 Faculty of Family Planning and Reproductive Health Care Clinical Effectiveness Unit. *Emergency Contraception*. 2006. http://www.fsrh.org/admin/uploads/449_EmergencyContraceptionCEUguidance.pdf [Accessed 26 August 2010].

12 Cheng L, Gulmezoglu AM, Van Look PFA. Interventions for emergency contraception. *Cochrane Database Syst Rev* 2008; **2**: CD001324.

13 Westhoff C, Kerns J, Morroni C, Cushman L, Tiezzi L, Murphy P. Quick start: a novel oral contraceptive initiation method. *Contraception* 2002; **66**: 141–145.

14 Lara-Torre E, Schroeder B. Adolescent compliance and side effects with Quick start initiation of oral contraceptive pills. *Contraception* 2002; **66**: 81–85.

15 Lopez LM, Newmann SJ, Grimes DA, Nanda K, Schulz KF. Immediate start of hormonal contraceptives for contraception. *Cochrane Database Syst Rev* 2008; **2**: CD006260.

16 Westhoff C, Heartwell S, Edwards S, Zieman M, Cushman L, Robilotto C, *et al*. Initiation of oral contraceptives using a quick start compared with a conventional start: a randomized controlled trial. *Obstet Gynecol* 2007; **109**: 1270–1276.

17 Westhoff C, Morroni C, Kerns J, Murphy PA. Bleeding patterns after immediate vs conventional oral contraceptive initation: a randomized controlled trial. *Fertil Steril* 2003; **79**: 322–329.

18 Westhoff C, Osborne LM, Schafer JE, Morroni C. Bleeding patterns after immediate initiation of an oral compared with a vaginal hormonal contraceptive. *Obstet Gynecol* 2005; **106**: 89–96.

19 Rickert VI, Tiezzi L, Lipshutz J, Leon J, Vaughan RD, Westhoff C. Depo now: preventing unintended pregnancies among adolescents and young adults. *J Adolesc Health* 2007; **40**: 22–28.

20 Sneed R, Westhoff C, Morroni C, Tiezzi L. A prospective study of immediate initiation of depo medroxyprogesterone acetate contraceptive injection. *Contraception* 2005; **71**: 99–103.

21 Murthy AS, Creinin MD, Harwood B, Schreiber CA. Same-day initation of the transdermal hormone delivery system (contraceptive patch) versus traditional initiation methods. *Contraception* 2005; **72**: 333–336.

22 Nelson AL, Katz T. Initiation and continuation rates seen in 2-year experience with same day injections of DMPA. *Contraception* 2007; **75**: 84–87.

23 Shino PH, Harlap S, Ramcharan S, Berendes H, Gupta S, Pellegrin F. Use of contraceptives prior to and after conception and exposure to other fetal hazards. *Contraception* 1979; **20**: 105–120.

24 Burstein R, Wasserman HC. The effect of Provera on the fetus. *Obstet Gynecol* 1964; **23**: 931–934.

25 Pharmacia Limited. Depo-Provera 150mg/ml Injection: Summary of Product Characteristics (SPC). http://www.emc.medicines.org.uk. 2007 [Accessed 26 August 2010].

26 Pardthaisong T, Yenchit C, Gray R. The long-term growth and development of children exposed to Depo-Provera during pregnancy or lactation. *Contraception* 1992; **45**: 313–324.

27 Gray RH, Pardthaisong T. *In utero* exposure to steroid contraceptives and survival during infancy. *Am J Epidemiol* 1991; **134**: 804–811.

28 Jaffe B, Shye D, Harlap S, Baras M, Belmaker E, Gordon L, *et al*. Health, growth and sexual development of teenagers exposed *in utero* to medroxyprogesterone acetate. *Paediatr Perinat Epidemiol* 1990; **4**: 184–195.

29 Bayer plc. Dianette: Summary of Product Characteristics (SPC). http://www.emc.medicines.org.uk. 2010 [Accessed 26 August 2010].

30 American College of Obstetrics and Gynecology (ACOG) Committee Opinion: Committee on Gynecologic Practice. Contraceptives and congenital anomalies. *Int J Gynaecol Obstet* 1993; **42**: 316–317.

31 General Medical Council. *Good Practice in Prescribing Medicines.* 2008. http://www.gmcuk.org/guidance/current/library/prescriptions_faqs.asp#p19 [Accessed 26 August 2010].

32 Faculty of Sexual and Reproductive Health Care. Statement from the FSRH Clinical Standards Committee, the Clinical Effectiveness Committee and the Associate Members' Working Group on the Prescription, Administration or Supply of Contraceptive Medicines for Use Outside the Terms of Their Licences. http://www.fsrh.org/admin/uploads/JointStatementOffLabelPrescribing.pdf. 2010 [Accessed 26 August 2010].

33 Nursing and Midwifery Council. *Standards of Proficiency for Nurse and Midwife Prescribers.* Practice Standard 18; page 38. 2006. http://www.nmc-uk.org/aDisplayDocument.aspx?documentID=6942 [Accessed 26 August 2010].

34 Nursing and Midwifery Council. *Standards for Medicines Management.* Practice Standard 22; page 45. 2008. http://www.nmc-uk.org/aDisplayDocument.aspx?DocumentID=6978 [Accessed 26 August 2010].

35 HRA Pharma UK Ltd. ellaOne: Summary of Product Characteristics (SPC). 2009. http://www.emc.medicines.org.uk [Accessed 26 August 2010].

36 Faculty of Sexual and Reproductive Health Care Clinical Effectiveness Unit. *New Product Review: Ulipristal Acetate (ellaOne®).* 2009. http://www.fsrh.org/admin/uploads/ellaOneNewProductReview1009.pdf [Accessed 26 August 2010].

APPENDIX 1: DEVELOPMENT OF CEU GUIDANCE

GUIDELINE DEVELOPMENT GROUP

Dr Louise Melvin – Director, Clinical Effectiveness Unit
Ms Julie Craik – Researcher, Clinical Effectiveness Unit
Dr Soe Nyunt Aung – FSRH Clinical Standards Committee representative, Subspecialty Trainee in Sexual & Reproductive Health, Hull
Dr Elizabeth Azzopardi – FSRH Education Committee representative; Associate Specialist in Sexual & Reproductive Health, Garden Clinic, Upton Hospital, Slough
Ms Jane Bass – Senior Pharmacist, Women's Services, Guy's & St Thomas' NHS Trust, London
Dr Anne Bennett – Associate Specialist in Sexual and Reproductive Health, Chapeltown Health Centre, NHS Leeds Community Healthcare
Dr Eileen Blackwood – General Practitioner, Kersland House Surgery, Milngavie
Dr Susan Brechin – Consultant in Sexual and Reproductive Health, Square 13 Clinic, Aberdeen
Dr Sharon Cameron – Consultant Gynaecologist, Family Planning & Well Woman Clinic, Dean Terrace, Edinburgh
Dr Kathy French – Nurse Member of the Independent Advisory Group Sexual Health; Clinical Director, Brook National, London
Dr Tamsin Groom – Consultant in Sexual and Reproductive Health, Sandyford & Archway, NHS Greater Glasgow & Clyde, Glasgow
Dr Zara Haider – FSRH Education Committee representative; Subspecialty Trainee in Sexual & Reproductive Health, UCL Partners Darzi fellow, Margaret Pyke Centre, London
Mrs Lynn Hearton – FSRH Clinical Effectiveness Committee representative; Helpline & Information Services Manager, Family Planning Association, London
Dr Kulsum Jaffer – Consultant in Sexual and Reproductive Health, BRASH Contraceptive Service, Birmingham
Dr Meera Kishen – Consultant in Sexual and Reproductive Healthcare, Liverpool
Dr Louise Massey – FSRH Clinical Standards Committee member; Consultant in Public Health, Wolverhampton Primary Care Trust
Mrs Margaret McArthur – Lead Nurse/SHPDN, Sexual Health, Stirling Royal Infirmary
Dr Anne Webb – Consultant in Sexual and Reproductive Healthcare, Abacus Clinics, Liverpool

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

No conflicts of interest were declared by any members of the multidisciplinary group.

INDEPENDENT PEER REVIEWERS

Dr Diana Mansour – Clinical Director, Sexual Health Services, Newcastle and North Tyneside
Dr Jo Power – Consultant in Sexual and Reproductive Health, Margaret Pyke Centre, London

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

Evidence is identified using a systematic literature review and electronic searches are performed for: MEDLINE (CD Ovid version) (1996–2010); EMBASE (1996–2010); PubMed (1996–2010); The Cochrane Library (to 2010) and the US National Guideline Clearing House. The searches are performed using relevant medical subject headings (MeSH), terms and text words. The Cochrane Library is searched for relevant systematic reviews, meta-analyses and randomised controlled trials relevant to the topic under consideration. Previously existing guidelines from the FSRH (formerly the Faculty of Family Planning and Reproductive Health Care), the Royal College of Obstetricians and Gynaecologists (RCOG), the World Health Organization (WHO) and the British Association for Sexual Health and HIV (BASHH), and reference lists of identified publications, are also searched. Similar search strategies have been used in the development of other national guidelines. Selected key publications are appraised using standard methodological checklists similar to those used by the National Institute for Health and Clinical Excellence (NICE). All papers are graded according to the Grades of Recommendations Assessment, Development and Evaluation (GRADE) system. Recommendations are graded as in the table on the inside front cover of this document using a scheme similar to that adopted by the RCOG and other guideline development organisations. The clinical recommendations within this guidance are based on evidence whenever possible. Summary evidence tables are available on request from the CEU. An outline of the guideline development process is given in the table on the inside back cover of this guidance document.

STEPS INVOLVED IN THE DEVELOPMENT OF THIS GUIDANCE DOCUMENT

STEP	TIME TAKEN
Formulation of **key clinical questions** by the Clinical Effectiveness Unit (CEU). **Systematic literature review** involving searching electronic, bibliographic databases by CEU researcher. **Obtaining and reviewing** copies of the full papers of all relevant publications identified through the searches. **Formal, critical appraisal** of key papers and development of short evidence tables.	This process must be completed in a maximum of 8 weeks.
Draft one guidance document is written providing recommendations and good practice points based on the literature review.	The CEU has overall responsibility for writing the guidance document. The multidisciplinary group and other peer reviewers should highlight inconsistencies, errors, omissions or lack of clarity.
Peer review by multidisciplinary group comprising stakeholders, the FSRH Clinical Effectiveness Committee (CEC); representation from the FSRH Education Committee and Clinical Standards Committee; and where possible service user representation and representation from FSRH Council. Two independent peer reviewers also review the document.	
Preparation of draft two guidance document based on written comments of the multidisciplinary group.	
Peer review of draft two guidance document by the multidisciplinary group, the FSRH CEC and two independent peer reviewers.	
Preparation of draft three guidance document based on written comments from the peer reviewers.	
Draft document published on Faculty website for 1 month for public consultation.	
All **written feedback comments on draft three guidance document** reviewed by the CEU, multidisciplinary group, independent peer reviewers and FSRH CEC.	
CEU's response to consultation comments posted on FSRH website. Final draft prepared.	
The **final guidance document** is published by the FSRH.	Proofreading of the guidance document is then performed by three members of the CEU team independently and comments collated and sent back by the Unit Director. A pdf version of the guidance is available on the FSRH website.

COMMENTS AND FEEDBACK ON PUBLISHED GUIDANCE

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

You will receive an automated acknowledgment on receipt of your comments. If you do not receive this automated response please contact the CEU by telephone [+44 (0) 141 232 8459/8460] or e-mail (**ceu.members@ggc.scot.nhs.uk**).

The CEU is unable to respond individually to all feedback. However, the CEU will review all comments and collate an anonymised summary of comments and responses which are reviewed by the Clinical Effectiveness Committee and any necessary amendments made.