

## Faculty of Family Planning and Reproductive Health Care Clinical Effectiveness Unit

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### FFPRHC Guidance (July 2004)

## Contraceptive choices for breastfeeding women

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This Guidance provides information for clinicians and women considering the use of contraception whilst breastfeeding. A key to the grades of recommendations, based on levels of evidence, is given at the end of this document. Details of the methods used by the Clinical Effectiveness Unit (CEU) in developing this Guidance and evidence tables summarising the research basis of the recommendations are available on the Faculty website ([www.ffprhc.org.uk](http://www.ffprhc.org.uk)). Abbreviations (in alphabetical order) used include: CEU, Clinical Effectiveness Unit; CI, confidence interval; COC, combined oral contraception; IUD, copper-bearing intrauterine contraceptive device; DMPA, depot medroxyprogesterone acetate; EC, emergency contraception; GnRH, gonadotrophin-releasing hormone; hCG, human chorionic gonadotrophin; LAM, lactational amenorrhoea method; LNG-IUS, levonorgestrel-releasing intrauterine system; N-9, nonoxynol-9; POP, progestogen-only pill; RCT, randomised controlled trial; SPC, Summary of Product Characteristics; WHO, World Health Organization; WHOMEC, WHO *Medical Eligibility Criteria*; WHOSPR, WHO *Selected Practice Recommendations for Contraceptive Use*.

### Background

It is estimated that 69% of women initiate breastfeeding in the UK.<sup>1</sup> The number breastfeeding then falls and by 6 months postpartum only 21% of women continue.<sup>1</sup> Exclusive breastfeeding for 6 months or more is promoted worldwide to achieve optimal infant and maternal health.<sup>2</sup> In the UK it is difficult to ascertain the number of women who are exclusively breastfeeding and only around 1 in 10 women breastfeeding at 6 months are providing breast milk only. Clinicians and women may have concerns about the effects of hormonal contraception on breastfeeding, breast milk, infant growth and development, and maternal health.

The World Health Organization (WHO) provides recommendations on contraception for women who are breastfeeding.<sup>3,4</sup> These WHO documents were developed to facilitate safe and effective contraceptive use in developing countries, where access to alternative sources of infant feeding is limited and anything which may inhibit or reduce the success of breastfeeding may have serious consequences for infant survival. The WHO *Selected Practice Recommendations for Contraceptive Use* (WHOSPR)<sup>4</sup> has been adapted for use in the UK.<sup>5,6</sup> However, the adapted recommendations provide incomplete advice regarding breastfeeding women and some are at odds with accepted UK practice.

This evidence-based guidance summarises contraceptive options and effects of hormonal contraception on breast milk and infant growth (*what women need to know*). The Clinical Effectiveness Unit (CEU) provides recommendations and good practice points on which contraceptive methods can be used by breastfeeding women and when to start these methods (*when to start methods*).

### What should a clinician assess when considering contraception for a breastfeeding woman?

- ✓ A clinician should assess a woman's postpartum contraceptive needs by taking account of her personal choice, sexual activity, breastfeeding pattern, menstruation, medical and social factors.

- ✓ Breastfeeding women should be given information about all hormonal and non-hormonal contraceptive methods.

- ✓ Breastfeeding women should be offered information and support to use their chosen method of contraception effectively.

A clinician should assess:

- A woman's own beliefs, attitudes, and personal preferences.
- Contraceptive needs – has sexual activity resumed, any sexual problems, what degree of efficacy is required?
- Resumption of ovulation – often identified in retrospect by the occurrence of menstruation.
- Pattern of infant feeding – exclusively breastfeeding, supplementary feeds or now bottle-feeding?
- Pattern of breastfeeding – frequency, duration of suckling episodes, feeding on demand day and night?
- Social factors (e.g. return to full time employment).
- Medical problems (e.g. hypertension, venous thromboembolism, or previous trophoblastic disease).

With this information, the clinician may provide each woman with information on her contraceptive options. The WHO *Medical Eligibility Criteria for Contraceptive Use* (WHOMEC) provides recommendations to ensure women choose the most appropriate method of contraception. Eligibility criteria rather than ineligibility criteria (contraindications) are described.<sup>3</sup> The CEU supports WHOMEC recommendations unless otherwise stated.

### What are the effects of breastfeeding on ovulation and fertility?

- 1 Women should be advised that breastfeeding delays the return of ovulation (Grade B).

- 2 Women should be advised that because breastfeeding delays the return of ovulation, all contraceptive methods have low failure rates when used consistently and correctly (Grade C).

**3 Women should be informed that awaiting the onset of menstruation before starting contraception is not advised, as it might put them at risk of unintended pregnancy (Grade B).**

The concentration of prolactin is increased 20-fold during pregnancy and high levels are maintained during lactation.<sup>7-10</sup> During pregnancy, high levels of sex steroid hormones suppress gonadotrophins. Within 30 days of delivery, placental sex steroid levels decrease and gonadotrophins increase.<sup>8</sup> This change occurs in women who are breastfeeding or bottle-feeding. Suckling disrupts the frequency and amplitude of gonadotrophin pulses but despite ovarian follicular activity, ovulation does not occur.<sup>7,11</sup> Fertility is thus reduced while breastfeeding and therefore any contraceptive method will be more effective when used by a breastfeeding woman.

Prospective studies have shown that ovarian follicular activity returns when the frequency and duration of suckling episodes decrease.<sup>12-14</sup> Such changes in the pattern of breastfeeding will reduce the efficacy of the lactational amenorrhoea method (LAM) and other contraceptive methods.

Prospective studies have shown that menstruation occurs on average 28.4 (range, 15-48) weeks after delivery for women who are breastfeeding.<sup>15</sup> Initial cycles are often associated with an inadequate luteal phase and relative infertility and the mean time to initiation of ovulation is 33.6 (range, 14-51) weeks.<sup>15</sup> In clinical practice, however, the return of menstruation is often the first sign of returning fertility. Awaiting the first menstrual period to start contraception may put some women at risk of pregnancy.

**What do women need to know about their contraceptive choices: efficacy, effect on breast milk or infant growth?**

*Lactational amenorrhoea method*

**4 Women may be advised that if they are <6 months postpartum, amenorrhoeic, and fully breastfeeding, the LAM is over 98% effective in preventing pregnancy (Grade B).**

**5 Women using the LAM should be advised that the risk of pregnancy is increased if breastfeeding decreases (particularly stopping night feeds), when menstruation recurs, or when >6 months postpartum (Grade C).**

WHOMECC recommends that there are no medical conditions where use of the LAM is restricted and there is no evidence of any negative effect on maternal health.<sup>3</sup> Women who are <6 months postpartum, amenorrhoeic (i.e. no vaginal bleeding after the first 56 days postpartum) and fully breastfeeding day and night may use the LAM.<sup>16,17</sup> An infant is considered fully breastfed when breast milk is the only source of nutrition (Table

**Table 1** Definition of breastfeeding (adapted from Knight and Pyper<sup>17</sup>)

Definition of breastfeeding	Contraceptive efficacy
Full breastfeeding Exclusive: no other liquids or solids given Almost exclusive: vitamins, water or juice given infrequently in addition to breastfeeds	Over 98% effective if also: Amenorrhoeic (no vaginal bleeding after the first 56 days postpartum) <6 months postpartum No long intervals between feeds day or night
Partial or token breastfeeding High: vast majority of feeds are breastfeeds Medium: about half of feeds are breastfeeds Low: vast majority of feeds are not breastfeeds Minimal: occasional irregular breastfeeds	Less impact reducing to little impact on fertility

1).<sup>2,17</sup> A Cochrane Review established that the LAM is over 98% effective for women who fulfil these criteria.<sup>18,19</sup> A large, prospective, observational study found cumulative pregnancy rates of 0.9% (95% CI 0%-2%) to 1.2% (95% CI 0%-2.4%) in the first 6 months postpartum if women were fully breastfeeding and amenorrhoeic.<sup>20</sup> The Cochrane Review did not identify any significant difference in the life-table pregnancy rates between women using LAM and similar women not using the formal LAM.

Few women in the UK can maintain full breastfeeding up to 6 months postpartum<sup>1</sup> but women may use the LAM effectively for even a few months. Factors which may precipitate the return to fertility include:

- Reducing the frequency of breastfeeding.
- Stopping the night feed or when the baby sleeps through the night.
- Separation from the baby (e.g. returning to work).
- Introducing supplements – this includes extra drinks of fruit juice or even small amounts of solids.
- Anxiety, stress or illness in either the mother or infant.

A woman may be using only breast milk to feed her baby, but if she has returned to work and is relying on expressed milk for daytime feeds this may result in a return of fertility. Women who choose to use the LAM should be told that contraceptive efficacy will be reduced when breastfeeding decreases, when menstruation returns or when the woman is >6 months postpartum.<sup>14,17</sup> The first 'true period' is any bleeding lasting at least 2 days, requiring the use of sanitary protection for at least 1 day, followed by a second bleeding episode within the next 21-70 days.<sup>20</sup>

*Hormonal contraception*

**6 Women should be informed that the level of hormone in breast milk when using a hormonal method of contraception is comparable to levels observed when they have an ovulatory cycle (Grade C).**

**7 Women should be advised that the available evidence is unable to prove if hormonal contraception has any effect on breast milk volume (Grade C).**

**8 Women should be advised that the available evidence indicates that hormonal contraception has no adverse effect on infant growth (Grade A).**

Contraceptive hormones will be excreted in very small amounts (<1% of the maternal dose) into breast milk. With combined oral contraception (COC) these levels may be similar to levels of oestradiol and progesterone in breast milk of women with ovulatory cycles.<sup>21</sup> A non-systematic review on progestogen-only implants and lactation summarised the very low daily intake of

hormones by infants whose mothers were using progestogen-only methods of contraception.<sup>22</sup> Calculations were based on an estimated 600–800 ml daily intake of breast milk. Only 0.2% of the maternal daily dose of etonorgestrel is excreted into breast milk with the implant.<sup>23</sup> Similar low levels of hormones are identified in breast milk with progestogen-only pills (POPs), injectables<sup>22</sup> and the levonorgestrel-releasing intrauterine system (LNG-IUS).<sup>24</sup> There is little evidence published on how infants metabolise exogenous sex steroids but 8-year follow-up studies of infants whose mothers were using COC<sup>25</sup> or depot medroxyprogesterone acetate (DMPA)<sup>26,27</sup> while breastfeeding have not shown any detrimental effect on growth or development.

Many different outcomes have been used to determine the effect of hormonal contraception on breastfeeding. No single outcome can accurately reflect natural lactation, but the volume of breast milk expressed using a breast pump has been advocated as the most accurate.<sup>28</sup> Other outcomes used to assess the effect of contraceptive hormones on breast milk volume include: a mother's subjective impression of milk volume, the duration of breastfeeding, the proportion of women still breastfeeding at defined times postpartum, infant test weights before and after a breastfeed, longitudinal infant growth measurements and the initiation of supplement feeds. Milk composition may vary with time, suckling frequency or maternal health and nutrition and it can be difficult to interpret laboratory findings related to the nutritional and caloric value of milk.<sup>29</sup>

A recent systematic review of randomised controlled trials (RCTs) investigated the effects of hormonal contraception (COC, POPs and injectables) on breast milk volume, the initiation, maintenance and duration of breastfeeding, and infant growth.<sup>30,31</sup> The review concluded that there is insufficient evidence to establish if hormonal contraception has any effect on breast milk quantity or quality but provided reassurance that hormonal contraception does not have an adverse effect on infant growth or development.<sup>30</sup>

#### Combined hormonal contraception

**9 Women should be advised that use of COC in the first 6 weeks postpartum may have an adverse effect on breast milk volume (Grade B).**

**10 Breastfeeding women should be advised to avoid COC in the first 6 weeks postpartum (Grade B).**

**11 Breastfeeding women should be advised that COC can be used without restriction from 6 months postpartum (Grade C).**

**✓ Breastfeeding women should be advised that COC is not recommended between 6 weeks and 6 months postpartum. However, if breastfeeding is established, COC may be considered if other contraceptive methods are unacceptable.**

*In the first 6 weeks postpartum*, WHOMEC recommends that breastfeeding women should not use COC (WHO Category 4, unacceptable health risk).<sup>3</sup> An RCT suggested a reduction in milk volume (assessed by weight gain following morning feeds, weekly infant weight and supplements) associated with COC use from Day 14 postpartum.<sup>32</sup> Another RCT<sup>33</sup> showed that COC use reduces breastfeeding (measured by pre- and post-feed weights) when started before Day 10 postpartum. Case-control studies have shown a similar effect when

COC is started before 6 weeks postpartum.<sup>34,35</sup> These detrimental effects are more apparent with high doses of ethinylestradiol (50 µg) or with mestranol<sup>32,33</sup> and the sooner postpartum COC is initiated.<sup>35</sup> The CEU does not recommend the use of COC before 6 weeks postpartum by breastfeeding women.

*Between 6 weeks and 6 months postpartum*, WHOMEC recommends that the risks of COC use for breastfeeding women outweigh the benefits (WHO Category 3).<sup>3</sup> Similarly, the WHOSPR does not recommend COC use before 6 months postpartum unless other more appropriate methods are unacceptable.<sup>4</sup>

A recent systematic review of RCTs concluded that there is insufficient evidence to establish if hormonal contraception has any effect on breast milk quantity or quality and challenged the 'Category 3' given by WHO.<sup>30,31</sup> The review included a RCT<sup>36</sup> that found no adverse effects on breast milk volume (by pump expression) or rate of infant growth with a 30 µg COC started at 6 weeks postpartum. Previous case-control, cohort and observational studies showed an adverse effect on breast milk volume with COCs containing mestranol,<sup>37–45</sup> 50 µg ethinylestradiol<sup>29,39,46</sup> or 30 µg ethinyl oestradiol.<sup>29</sup> However, other studies did not show an adverse effect on breast milk volume with 30 µg COCs.<sup>36,47,48</sup> The systematic review was able to provide reassurance that hormonal contraception does not have an adverse effect on infant growth or development.<sup>30</sup>

If breastfeeding is established, the CEU suggests that the use of COC may be considered from 6 weeks postpartum if alternative methods of contraception are unacceptable (Table 2).

*After 6 months postpartum*, WHOMEC recommends that the benefits of COC use generally outweigh the risks (WHO Category 2).<sup>3</sup>

#### Progestogen-only contraception

**12 Women should be advised that the use of progestogen-only methods in the first 6 weeks postpartum does not appear to have an adverse effect on breast milk volume (Grade B).**

**13 Women should be advised that the use of progestogen-only methods when breastfeeding provides over 99% efficacy (Grade B).**

**14 Women should be advised that the problematic bleeding associated with progestogen-only methods appears to be more acceptable than that experienced by women who are not breastfeeding (Grade B).**

**✓ After counselling, breastfeeding women may choose to use a progestogen-only method of contraception before 6 weeks postpartum if other contraceptive methods are unacceptable.**

The majority of studies show no adverse effects of POPs<sup>30,31,36,45,46</sup> or DMPA<sup>30,31,36,39–42,49</sup> on breastfeeding, milk volume, infant growth or development.

*In the first 6 weeks postpartum*, WHOMEC recommends that the risks for breastfeeding women of using progestogen-only contraception (pills, injectables, implants or the LNG-IUS) outweigh any benefits (WHO 3).<sup>3</sup> Similar advice was provided in the WHOSPR. Using formal consensus methods, the Faculty of Family Planning and

**Table 2** Contraceptive starting regimens for breastfeeding women

Time postpartum	Contraceptive method	Advice for breastfeeding women on when to start contraceptive method
Immediately	Lactational amenorrhoea method (LAM)	Start immediately postpartum to provide effective contraception. Remind women that the LAM is an interim method effective for the first 6 months postpartum only.
	Intrauterine device (IUD)	Insert within the first 48 hours postpartum to provide immediate protection.
	Condoms and spermicides	Can be used immediately.
	Female sterilisation	Can be performed at the time of Caesarean section if there has been appropriate counselling and consent antenatally.
Under 4 weeks	Progestogen-only pill (POP)	May start any time postpartum. If started up to Day 21 postpartum no additional contraceptive protection required. If started after Day 21 additional contraceptive protection is required for 2 days.
	Progestogen-only implant	Insert up to Day 28 postpartum without the need for additional contraceptive protection. If inserted after Day 28 additional contraceptive protection is required for 7 days. May be considered before Day 21 if a woman is unlikely to return for insertion, if the risk of pregnancy is high and if other methods are unacceptable. Counsel regarding bleeding.
	Emergency contraception (EC)	Indicated if there has been unprotected intercourse or potential contraceptive failure after Day 21. Progestogen-only EC can be used without restriction in breastfeeding women.
From 4 weeks	Intrauterine device (IUD)	Insert from 4 weeks postpartum.
	Levonorgestrel-releasing intrauterine system (LNG-IUS)	Insert from 4 weeks postpartum with additional contraception for 7 days.
From 6 weeks	Progestogen-only injectable	Give from 6 weeks postpartum if reasonably certain woman is not pregnant with additional contraceptive protection for 7 days. May be considered at less than 6 weeks if the risk of subsequent pregnancy is high and other contraceptive methods are unacceptable.
	Combined oral contraception (COC)	May be started from 6 weeks if breastfeeding is established and other contraceptive methods are unacceptable. Additional contraceptive protection is required for 7 days
	Diaphragms and cervical caps	Fit for a new diaphragm or cap from 6 weeks when uterine involution is complete.
	Sterilisation	Male and female sterilisation can be considered after an appropriate interval following pregnancy.

Reproductive Health Care (FFPRHC) adapted the WHOSPR for use in the UK but controversy remains.<sup>5,6</sup>

**Progestogen-only injectables:** The FFPRHC consensus group agreed with the WHOSPR recommendation to avoid using progestogen-only injectable contraception in the first 6 weeks postpartum.<sup>5</sup> Most of the concerns about the use of DMPA relate to theoretical risks of sex steroids to an infant with an immature central nervous system, liver and other organs. Small follow-up studies of infants whose mothers were using DMPA while breastfeeding are reassuring.<sup>26</sup> The CEU supports the FFPRHC UK recommendations that DMPA use for breastfeeding women before 6 weeks postpartum is not advised.<sup>5</sup> No evidence regarding the use of norethisterone enantate by breastfeeding women was identified.

**Progestogen-only pills and implants:** The FFPRHC consensus group disagreed with the WHOSPR recommendations that POPs and implants should not be used before 6 weeks postpartum for breastfeeding women.

Case-control and observational studies, randomised trials and a systematic review do not find that POP use has a detrimental effect on breast milk volume.<sup>29,30,31,46,50,51</sup> No significant differences were identified in milk volume and composition when comparing a POP (containing norethindrone) used in the first 14 days postpartum with a placebo.<sup>50</sup>

A prospective, group, comparative trial found that insertion of the etonorgestrel-only implant between Days 28 and 56 postpartum did not affect the volume of breast milk (test weight and number of supplementary feeds), breast milk composition or infant growth compared to copper-bearing intrauterine contraceptive device (IUD) use.<sup>52</sup> Other progestogen-only implants release progestogens which are orally active (levonorgestrel) or orally inactive

for the infant (nestorone) and have also been shown to have little effect on breastfeeding.<sup>22</sup> Evidence to support a restrictive use of these progestogen-only methods in the first 6 weeks of breastfeeding is lacking.<sup>30,31</sup>

In developing the UK version of the WHOSPR no consensus was achieved on an alternative recommendation for use of POPs and progestogen-only implants by breastfeeding women and no UK recommendation was made. Clinicians were advised to agree policies locally regarding the use of these methods by breastfeeding women.<sup>5</sup> In this Guidance, however, the CEU provides recommendations and good practice points on when to start hormonal methods (Recommendations 17–21), which will aid clinicians and women in their decision-making.

**Levonorgestrel-releasing intrauterine system:** The WHOMEK recommends that the risks of LNG-IUS use outweigh the benefits (WHO 3) for breastfeeding women before 6 weeks postpartum.<sup>3</sup> No adverse effects on breast milk volume or infant growth were identified.<sup>24</sup> Serum levels of levonorgestrel associated with LNG-IUS are less than with oral progestogen-only methods. We would anticipate, therefore, that in common with POPs, it would have little or no effect on breastfeeding. In line with previous CEU Guidance,<sup>53</sup> the LNG-IUS can be inserted from 4 weeks postpartum, regardless of the method of infant feeding.

**After 6 weeks postpartum,** WHOMEK recommends that progestogen-only methods may be used without restriction for breastfeeding women (WHO Category 1).<sup>3</sup>

**Efficacy of progestogen-only methods.** A non-randomised study compared progestogen-only vaginal rings, pills and implants with a copper IUD or the LAM.<sup>54</sup> Low pregnancy rates (<1%) were reported for all methods.

*Bleeding associated with progestogen-only methods.* Studies have shown that bleeding patterns associated with progestogen-only contraception in breastfeeding women are more acceptable than those experienced by women who are not breastfeeding.<sup>54</sup> A non-randomised study compared progestogen-only vaginal rings, pills or implants with IUD or the LAM from around 8 weeks postpartum.<sup>54</sup> Women using progestogen-only contraceptives had a longer period of lactational amenorrhoea (4–5 months) than IUD users or women using the LAM.<sup>54</sup> Frequent or prolonged bleeding was uncommon with all methods. The proportion of women with bleeding lasting more than 10 days was least in the POP group (none) and was up to 7% in implant users.

#### *Non-hormonal methods*

##### *Intrauterine device*

**15 Unless an IUD can be inserted within the first 48 hours postpartum, insertion should be delayed until 4 weeks postpartum (Grade C).**

WHOMECEC recommends that unless an IUD can be inserted within the first 48 hours postpartum, insertion should be delayed until 4 weeks postpartum, when its use is unrestricted (WHO 1).<sup>3</sup> Previous CEU Guidance supports this recommendation.<sup>55</sup> The IUD has no effect on breast milk.<sup>54,56</sup>

Women should be informed that failure rates with IUD use are consistently low and that the most likely cause of IUD failure is expulsion. The risk of IUD expulsion is around 1 in 20.<sup>55</sup> Trials evaluating IUD insertion immediately postpartum have suggested that expulsion rates are lower for women who are breastfeeding compared to women who are bottle-feeding, but no differences in pregnancy rates were shown.<sup>57</sup> Low rates of discontinuation of IUD occur when inserted between 4 and 9 weeks postpartum.<sup>58</sup>

##### *Barrier methods, spermicides and fertility awareness*

**16 Women can be advised that the use of diaphragms and cervical caps should be delayed until uterine involution is complete (from 6 weeks postpartum) (Grade C).**

WHOMECEC recommends that condoms and spermicides can be used by breastfeeding women without restriction (WHO 1) before and after 6 weeks postpartum.<sup>3</sup> Recent WHO recommendations suggest that only women at low risk of sexually transmitted infections use spermicides containing nonoxynol-9 (N-9) and that condoms without N-9 are as effective as those with N-9.<sup>59</sup> WHOMECEC recommends that the use of diaphragms and caps should be postponed until involution of the uterus is complete (from 6 weeks postpartum). WHOMECEC recommends caution with fertility-awareness methods whilst breastfeeding, even when menstruation recurs.<sup>3</sup> Women who choose to move from the LAM to fertility awareness methods will require the support of an experienced practitioner.<sup>60</sup>

##### *Sterilisation*

Recent Guidance from the Royal College of Obstetricians and Gynaecologists on 'Male and Female Sterilisation' suggests that tubal occlusion should be performed after an appropriate interval following pregnancy whenever possible.<sup>61</sup> Women requesting tubal occlusion immediately postpartum should be made aware of the increased regret rate and possible increased failure rate. Male sterilisation is an effective method of contraception that some couples may wish to consider.

#### **When can breastfeeding women be advised to start contraception?**

Advice from the CEU on starting contraception postpartum is given in Table 2. This has been adapted from WHOSPR<sup>4</sup> and the UK version of this document.<sup>5</sup>

WHOSPR suggests that clinicians can be 'reasonably certain' a woman is not pregnant if she has no signs and symptoms of pregnancy and is fully or nearly fully breastfeeding, amenorrhoeic and less than 6 months postpartum.<sup>4</sup> Clinicians may also be reasonably certain a woman is not pregnant if she is within 4 weeks postpartum and not breastfeeding; if she is within the first 7 days of the start of a normal period; and if she has not had intercourse since her last menstrual period.<sup>4</sup>

The timing of a pregnancy test following unprotected intercourse is important, particularly if a woman is amenorrhoeic or has an irregular cycle. The CEU advises that a standard urine pregnancy test for human chorionic gonadotrophin (hCG) can be expected to be reasonably reliable in detecting a pregnancy if performed more than 3 weeks after unprotected intercourse.<sup>62–64</sup> If there is an urgency in identifying pregnancy, however, serum hCG levels can be quantified but this will not be positive until after implantation and for some women serial hCG testing (urine or serum) may be required.

##### *Lactational amenorrhoea method*

✓ **Women should be advised to start the LAM immediately postpartum.**

The LAM relies on full breastfeeding, which should be initiated immediately postpartum.

##### *Combined hormonal contraception*

✓ **If breastfeeding is established, a woman who is more than 6 weeks postpartum may start COC at any time if it is reasonably certain she is not pregnant. Additional contraceptive protection is required for 7 days.**

✓ **Breastfeeding women who are more than 6 weeks postpartum and having regular menstrual cycles can start COC as for non-breastfeeding women.**

✓ **Women should be advised that the use of COC while breastfeeding is outside product licences.**

The CEU advises against the use of COC in the first 6 weeks postpartum while breastfeeding. If breastfeeding is established a woman may choose to use a COC after 6 weeks postpartum if other contraceptive methods are unacceptable. If a woman chooses COC, starting regimens are as for non-breastfeeding women with additional contraceptive protection for 7 days. Women should be informed that the Summaries of Product Characteristics (SPCs) for COC and the transdermal combined contraceptive system advise against use by breastfeeding women.<sup>65</sup>

##### *Progestogen-only pills*

✓ **A breastfeeding woman can start a POP up to Day 21 postpartum without the need for additional contraceptive protection.**

✓ **A breastfeeding woman can start POP after Day 21 postpartum if it is reasonably certain she is not pregnant. Additional contraceptive protection is required for 2 days.**

- ✓ **A breastfeeding woman who chooses to use a POP before 6 weeks postpartum should be informed that this is outside the product licence for some pills.**

For breastfeeding women, the POP does not need to be started until Day 21 postpartum but it can be started any time before this without the need for additional contraceptive protection. If commenced after Day 21, an additional contraceptive method (such as condoms) should be used for 2 days.<sup>5</sup> If a woman has regular menstrual cycles, POP can be started up to and including Day 5 of the menstrual cycle without the need for additional barrier methods.<sup>5</sup> The SPCs for POPs provide different recommendations regarding postpartum use and additional contraceptive requirements.<sup>66-68</sup> The SPCs for norethisterone POPs do not recommend use until the infant is weaned.<sup>68</sup> Other SPCs (for levonorgestrel,<sup>66</sup> etynodiol acetate<sup>67</sup> and desogestrel<sup>69</sup>) suggest these POPs may be used by breastfeeding women, with monitoring of infant growth and development.

#### *Progestogen-only injectable*

- 17 Breastfeeding women should be advised that DMPA use before 6 weeks postpartum is not usually recommended (Grade C).**

- 18 Women should be advised that troublesome bleeding can occur with DMPA use in the early postpartum period (Grade C).**

- ✓ **Breastfeeding women who choose DMPA will not require the injection until Day 21 postpartum, but if the risk of immediate subsequent pregnancy is high it may be given before this time.**

- ✓ **Breastfeeding women who choose to use DMPA before 6 weeks postpartum should be informed that such use is outside the product licence.**

The SPC for DMPA advises that for women who are breastfeeding, the first injection should be delayed until at least 6 weeks postpartum.<sup>70</sup> WHOMECEC recommends that the risks for breastfeeding women associated with DMPA use before 6 weeks postpartum outweigh any benefits (WHO 3).<sup>3</sup> This judgement is supported by the WHOSPR,<sup>4</sup> the UK version and the CEU.<sup>5</sup>

However, evidence suggests that DMPA has no detrimental effect on infant growth.<sup>30,71</sup> Nor is there evidence of a reduction in breast milk volume or duration of breastfeeding. Indeed, studies have suggested an increase in breast milk volume with DMPA use.<sup>49</sup> A prospective observational study found that women using DMPA appeared to breastfeed for significantly longer than controls (21 months for DMPA users compared to 13 months for controls).<sup>26</sup> Use of DMPA also appeared to significantly increase the duration of exclusive breastfeeding (7 months for DMPA users compared to 5 months for controls). A recent case-control study showed that serum prolactin levels were greater in DMPA users compared to IUD users, but this difference was only significant at 6 weeks postpartum.<sup>72</sup> Other factors, which may increase prolactin levels, were taken into account and this effect may be a mechanism by which DMPA may increase breast milk volume.

In situations where a breastfeeding woman is at risk of pregnancy and is unwilling to consider alternative contraceptive methods, DMPA may be considered before 6

weeks postpartum. The CEU advises that if DMPA is used then the first injection should be postponed until Day 21 postpartum. If DMPA is started on or before Day 21, no additional contraceptive protection is required. Starting after this time will require the use of additional contraceptive protection for 7 days. The use of DMPA before 6 weeks postpartum is outside the product licence and women should be informed of this fact. Women should be advised of bleeding which can be associated with DMPA use, particularly in the first 6 weeks postpartum.<sup>73</sup>

#### *Progestogen-only implants*

- ✓ **Breastfeeding women may choose to use a progestogen-only implant before Day 28 without the need for additional contraceptive protection.**

- ✓ **Breastfeeding women should be advised that the use of a progestogen-only implant before Day 21 postpartum is outside the product licence.**

The SPC for the etonorgestrel-only implant suggests it may be used when breastfeeding.<sup>23</sup> If an implant is inserted in a woman who is breastfeeding, the SPC advises that the growth and development of the infant be monitored.<sup>23</sup> The CEU advises that the progestogen-only implant can be inserted prior to 6 weeks postpartum but this should be postponed until Day 21 postpartum, in line with the product licence for non-breastfeeding women. However, if the woman is at risk of pregnancy and is unlikely to attend for further medical care a progestogen-only implant may be considered before Day 21. However, women should be counselled about bleeding that may occur with insertion before Day 21 and that its use in this situation is outside the product licence. If inserted after Day 28 additional contraceptive protection is required for 7 days.<sup>23</sup>

#### *Levonorgestrel-releasing intrauterine system*

- 19 Breastfeeding women may have a LNG-IUS inserted from 4 weeks postpartum (Grade C).**

The LNG-IUS may be inserted safely four or more weeks postpartum.<sup>53</sup>

#### *Intrauterine device*

- 20 Breastfeeding women may have an IUD inserted within the first 48 hours postpartum, otherwise insertion should be delayed until 4 weeks postpartum (Grade C).**

WHOMECEC recommends that the benefits of IUD use four or more weeks after delivery outweigh any risks (WHO 1). This recommendation was supported in previous CEU guidance.<sup>55</sup> This unrestricted use includes women who are breastfeeding. WHOMECEC suggests an increased risk of uterine perforation if an IUD is inserted between 48 hours and 4 weeks postpartum and therefore the risks of insertion during this time generally outweigh the benefits (WHO 3). A review of studies involving postpartum insertion provided 2-year follow-up data on 6816 woman-months of experience following insertion between 4 and 8 weeks postpartum and 19 733 women-months of experience following insertion more than 8 weeks postpartum.<sup>74</sup> No perforations were identified and discontinuation rates were similar in the two groups, suggesting an IUD can be inserted safely after 4 weeks postpartum.

*Diaphragms and cervical caps*

**21 Breastfeeding women who choose a diaphragm or cervical cap should be advised to wait until at least 6 weeks postpartum before attending for assessment of size required (Grade C).**

Women who wish to use a diaphragm or cervical cap should attend for fitting from 6 weeks postpartum.<sup>3</sup> A different size of diaphragm or cervical cap may be required for women who have used this method previously. Unless using the LAM, another method of contraception should be used from Day 21 until the woman is able to correctly insert and remove a correctly fitted diaphragm or cap.

**When do breastfeeding women require emergency contraception (EC)?**

✓ **Breastfeeding women can be advised that unprotected sexual intercourse or contraceptive failure before Day 21 postpartum is not an indication for EC.**

✓ **Breastfeeding women can be advised that once hormonal contraception has been initiated, potential contraceptive failures should be managed in the same way as for women not breastfeeding.**

✓ **Breastfeeding women may be offered an IUD as EC from 4 weeks postpartum.**

WHOMECS recommends that women who are breastfeeding can use progestogen-only EC without restriction (WHO 1). The SPC for progestogen-only EC suggests that following a single 1.5 mg dose of levonorgestrel there is only a very small amount of hormone in breast milk.<sup>75</sup> There is no evidence that this is harmful to the baby. The SPC recommends that progestogen-only EC should be taken after a breastfeed. However, there is no evidence regarding this and serum levels of levonorgestrel increase in the first 2 hours after ingestion and are maintained over 24 hours. If EC is indicated and the woman is over 4 weeks postpartum, an IUD may also be considered, particularly if she wishes to use this as an ongoing method of contraception.

Unprotected sexual intercourse or contraceptive failure before Day 21 postpartum is not an indication for EC (regardless of the method of feeding). The CEU considers that once hormonal contraception has been initiated, breastfeeding women who have potential contraceptive failures should be managed in the same way as women not breastfeeding.<sup>76,77</sup>

**What follow-up is required for breastfeeding women using contraceptive methods?**

**22 Breastfeeding women should be advised to return at any time to discuss side effects or other problems, or if they want to change their contraceptive method (Grade C).**

Women who are breastfeeding should be advised to return at anytime to discuss side effects or other problems, or if they want to change their contraceptive method. Women who are relying on the LAM should be advised to return for further contraceptive advice and counselling if they significantly reduce their frequency of breastfeeding, if menstruation recurs or at 6 months postpartum, whichever occurs earlier. Women using hormonal methods may also be advised to return at this time to discuss their ongoing contraceptive needs.

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This Guidance was developed by the Clinical Effectiveness Unit (CEU) of the Faculty of Family Planning and Reproductive Health Care (FFPRHC): Dr Gillian Penney (Director), Dr Susan Brechin (Unit Co-ordinator); Ms Alison de Souza and Ms Gillian Stephen (Research Assistants) in consultation with the Clinical Effectiveness Committee, which includes service user representation and an Expert Group of health care professionals involved in family planning and reproductive health care. The Expert Group comprised: Dr Caroline Boorer (SCMO, Family Planning, Mansfield District PCT), Dr Ruth Howlett-Shipley (SpR, Public Health, Dorset/Trainee Member of the CEU), Ms Jane Knight (Fertility Researcher, Department of Public Health, University of Oxford), Dr Ali Kubba (Consultant Community Gynaecologist and Senior Lecturer, Lambeth PCT and Guys and Kings School of Medicine, London), Ms Julie Lester (Registered General Nurse and Midwife, Aberdeen Maternity Hospital), Dr Fiona Mason (Consultant in Family Planning, Northampton), Ms Shelley Mehigan (Clinical Nurse Specialist, Berkshire) and Dr Mary Olliver (Associate Specialist in Sexual Health, Winchester/FFPRHC Education Committee and Council Representative). Written feedback was provided by: Ms Toni Belfield (Director of Information, fpa, London), Ms Cecilia Pyper (NHS Primary Care Career Scientist, Department of Public Health, University of Oxford), Dr Anne Szarewski (Editor, *Journal of Family Planning and Reproductive Health Care*) and Dr Alyson Elliman (Chairman, FFPRHC Education Committee).

This guidance is also available online at [www.ffprhc.uk](http://www.ffprhc.uk) Evidence tables are available on the FFPRHC website. These summarise relevant published evidence on contraception in breastfeeding women, which was identified and appraised in the development of this Guidance. The clinical recommendations within this Guidance (i.e. the text appearing within the red and blue boxes) are based on evidence whenever possible.

Grades of Recommendations	
<b>A</b>	Evidence based on randomised-controlled trials (RCTs)
<b>B</b>	Evidence based on other robust experimental or observational studies
<b>C</b>	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 Expert Group

Electronic searches were performed for: MEDLINE (CD Ovid version) (1960–2003); EMBASE (1960–2003); PubMed (1960–2003); the Cochrane Library (to February 2004) and the US National Guideline Clearing House. The searches were performed using relevant medical subject headings (MeSH), terms and text words. The Cochrane Library was searched for systematic reviews, meta-analyses and controlled trials relevant to contraception for breastfeeding women. Previously existing guidelines from the Faculty of Family Planning and Reproductive Health Care (FFPRHC), the Royal College of Obstetricians and Gynaecologists (RCOG), the World Health Organization (WHO) and reference lists of identified publications were also searched. Similar search strategies have been used in the development of other national guidelines. Selected key publications were appraised according to standard methodological checklists before conclusions were considered as evidence. Evidence was graded as above, using a scheme similar to that adopted by the RCOG and other guideline development organisations.

## Discussion Points for the Contraceptive Choices for Breastfeeding Women

The following discussion points have been developed by the FFPRHC Education Committee.

### Discussion Points

- 1 List the criteria for the lactational amenorrhoea method (LAM) of contraception and discuss the potential benefits and difficulties with this method.
- 2 Discuss the possible contraceptive options and starting regimes for a vulnerably housed, teenage mother who is seen 2 days postpartum.
- 3 Discuss the differences in contraceptive options and concerns between a breastfeeding and non-breastfeeding woman.

## Questions for the Contraceptive Choices for Breastfeeding Women

The following questions and answers have been developed by the FFPRHC Education Committee.

Indicate your answer by ticking the appropriate box for each question

	True	False
1 The earliest predicted ovulation postpartum occurs on Day 28 so contraception does not need to be used before this time.	<input type="checkbox"/>	<input type="checkbox"/>
2 The onset of ovulation can be predicted from the onset of menstruation.	<input type="checkbox"/>	<input type="checkbox"/>
3 Used correctly, the lactational amenorrhoea method (LAM) has approximately the same contraceptive efficacy as hormonal methods.	<input type="checkbox"/>	<input type="checkbox"/>
4 The mean time to first ovulation in breastfeeding women is 8–9 weeks.	<input type="checkbox"/>	<input type="checkbox"/>
5 The levels of hormones in breast milk when using a hormonal method of contraception are comparable to those found during an ovulatory menstrual cycle.	<input type="checkbox"/>	<input type="checkbox"/>
6 There is evidence of an adverse effect on infant growth when hormonal contraception is used during breastfeeding.	<input type="checkbox"/>	<input type="checkbox"/>
7 The use of progestogen-only contraceptive implants is contraindicated during breastfeeding until 6 months postpartum.	<input type="checkbox"/>	<input type="checkbox"/>
8 The combined oral contraceptive (COC) pill must be avoided when breastfeeding.	<input type="checkbox"/>	<input type="checkbox"/>
9 An intrauterine device (IUD) can be fitted within 48 hours postpartum irrespective of breastfeeding.	<input type="checkbox"/>	<input type="checkbox"/>
10 Progestogen-only emergency contraception (EC) can only be used with caution in women who are breastfeeding.	<input type="checkbox"/>	<input type="checkbox"/>

Answers: 1 False, 2 False, 3 True, 4 False, 5 True, 6 False, 7 False, 8 False, 9 True, 10 False