A central goal of The Academy of Breastfeeding Medicine is the development of clinical protocols for managing common medical problems that may influence breastfeeding success. These protocols serve only as guidelines for the care of breastfeeding mothers and infants and do not delineate an exclusive course of treatment or serve as standards of medical care. Variations in treatment may be appropriate according to the needs of an individual patient.

### Clinical Protocol Number #13

**Contraception during Breastfeeding**

I. **Purpose:** The purpose of this protocol is to outline the contraceptive methods available for use during breastfeeding, and to provide additional background on the Lactational Amenorrhea Method (LAM) and its use.

II. **General Principles**

**Table 1 Principles for Consideration in Contraception During Lactation**

<table>
<thead>
<tr>
<th>When helping a breastfeeding mother choose a method of family planning, consider her:</th>
<th>In regards to:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. breastfeeding patterns, status and plans</td>
<td>issues concerning LAM and hormonal methods</td>
</tr>
<tr>
<td>2. child’s age</td>
<td>issues concerning LAM, hormonal methods, IUD insertion and barrier sizing</td>
</tr>
<tr>
<td>3. age</td>
<td>issues concerning hormonal methods</td>
</tr>
<tr>
<td>4. previous contraceptive experience</td>
<td>social and use issues, as well as sensitivities</td>
</tr>
<tr>
<td>5. husband’s (partner’s) opinions on various methods</td>
<td>social and use issues</td>
</tr>
<tr>
<td>6. childbearing plans</td>
<td>spacing versus limiting methods</td>
</tr>
<tr>
<td>7. health status</td>
<td>spacing versus limiting methods and hormonal methods</td>
</tr>
<tr>
<td>8. accessibility of family planning methods, health care personnel, and socio-economic status</td>
<td>local access, availability issues and affordability issues</td>
</tr>
</tbody>
</table>
Table 2 Effectiveness of Contraceptive Methods during Breastfeeding

<table>
<thead>
<tr>
<th>TYPE</th>
<th>PROPORTION PREGNANT BY LIFE TABLE</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Typical Use</td>
</tr>
<tr>
<td>Pill - Progestin only</td>
<td>5</td>
</tr>
<tr>
<td>Pill - Combination</td>
<td>5</td>
</tr>
<tr>
<td>IUD - Copper</td>
<td>0.8</td>
</tr>
<tr>
<td>IUD - Levonorgestrel</td>
<td>0.1</td>
</tr>
<tr>
<td>Injectable – Progestin only</td>
<td>0.3</td>
</tr>
<tr>
<td>Barrier Methods</td>
<td></td>
</tr>
<tr>
<td>Diaphragm</td>
<td>20</td>
</tr>
<tr>
<td>Cap</td>
<td>40</td>
</tr>
<tr>
<td>Male Condom</td>
<td>14</td>
</tr>
<tr>
<td>Sterilization</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>0.5</td>
</tr>
<tr>
<td>Male</td>
<td>0.15</td>
</tr>
<tr>
<td>Periodic abstinence methods</td>
<td>25</td>
</tr>
<tr>
<td>Calendar</td>
<td></td>
</tr>
<tr>
<td>Ovulation Method</td>
<td>9</td>
</tr>
<tr>
<td>Sympto-Thermal</td>
<td>3</td>
</tr>
<tr>
<td>Post-Ovulation</td>
<td>2</td>
</tr>
<tr>
<td>Lactational Amenorrhea Method</td>
<td>2 (6 months)</td>
</tr>
</tbody>
</table>

*Statistics represent general population, and are not available for breastfeeding women specifically. These methods may be more difficult to use during fertility return. Table adapted with permission from Hatcher, RA et al. Contraceptive Technology, 17th ed. 1998, Contraceptive Technology Communications, Inc., Ardent Media, Inc., New York.

IV. Lactational Amenorrhea Method (LAM) of postpartum contraception

A. Background and Biological Basis

Data published in the early 1970s showed that women who breastfed were less likely to ovulate early postpartum, and that if breastfeeding were more intensive, they were less likely than partial or non-breastfeeders to experience a normal ovulation prior to the first menstrual-like bleed. In 1988, researchers from several centers around the world met to share their findings at the Rockefeller Bellagio Conference Center, and agreed that three criteria could be sufficient to predict fertility return. These findings were then presented to a group of family planning service providers at Georgetown University, resulting in the codification of LAM as a family planning method (Figure 1). Participants in a second Bellagio meeting held in 1995 brought additional studies that reflected improved knowledge of breastfeeding and fertility, and included studies of Lactational Amenorrhea Method (LAM) in use. All studies presented confirmed the original findings and demonstrated the potential, efficacy, and usefulness of the LAM. Subsequently, studies
continue to support these initial findings.

**B. Method: What is LAM?**

The Lactational Amenorrhea Method (LAM) is presented as an algorithm (Fig. 1) and includes three criteria for defining the period of lowest pregnancy risk. Furthermore, it advises the immediate commencement of other methods if any one of the three criteria is not met. Clinically, the mother is asked:

- Have you had a menstrual bleed?
- Are you giving any supplementary foods or fluids in addition to breastfeeding?
- Is your infant older than six months of age?

If she answers negatively to all three criteria, she meets the requirements for LAM efficacy. She should be advised to initiate another form of contraception if any of the above three criteria are answered affirmatively to achieve adequate efficacy for birth spacing or fertility limitation. If the mother is interested in, and qualifies for LAM, she is advised to ask herself the same three questions in an ongoing manner. It is advisable to ensure that she has her next method on hand, and initiates its use whenever her answer to any of the three questions changes. She should be advised to contact her health care professional immediately if she has any questions as to whether or not the method still applies.

**C. Definitions for LAM Use:**

To use LAM correctly, it is important that the patient understand each of the three criteria. Menses return, for the purposes of LAM use, is defined as any bleeding that occurs after 56 days postpartum that is perceived by the patient as a menses, or any two consecutive days of bleeding. Full or nearly full breastfeeding is shown in Figure 2, and includes exclusive, nearly exclusive and some irregularly provided supplements, as long as they do not disrupt the frequency of feeds. This method of family planning is now used in more than 30 countries and has been included in the family planning and Maternal and Child Health policy in several countries. It has been widely accepted as a natural family planning method that demands no abstinence. It is used as an introductory method for the postpartum period, or for the woman who hesitates to use a commodity-based method.
has the added benefit of encouraging optimal breastfeeding behavior, providing synergistic support for primary health of the mother and the child.

D. Efficacy:
LAM has been found to be 98% effective (Figure 3) and it has been used in a wide variety of settings, including different cultures, socio-economic groups, and health care venues. Figure 3 illustrates the LAM efficacy in a variety of studies.

The three questions used in ascertaining whether the method is in place are in descending order of importance. Amenorrhea is the most important of the three questions, as it alone is associated with a significant reduction in fertility. The intensity of the breastfeeding is also very important since it contributes both to the duration of amenorrhea and to the suppression of normal ovulation in the first postpartum cycle, creating the physiological conditions to ensure that the first bleed will tend to precede the first adequate ovulatory development.

The “six months” criterion is added primarily because this is the time that complementary feeding should begin. However, if breastfeeding continues at a high level even after complementary feeding is started, efficacy apparently remains high. In Rwanda, the method was used up to 9 months, maintaining breastfeeding frequency by feeding before each complementary feeding. In a study involving working women, expressing milk after separation at least as often as breastfeeding would occur when together, LAM was found to be 96.5% effective. Although, this finding is not statistically different from the results of other studies, it suggests a small increased risk of conception in women separated from their infants. This information should be given to the affected women so that they may make informed decisions.

The World Health Organization (WHO) carried out a prospective trial on lactational amenorrhea and fertility return. Although this was not a study of women selecting and using LAM, the findings confirmed the high efficacy of these LAM trials.

A Cochrane literature review on efficacy in 2003 was carried out using MEDLINE and EMBASE search from 1966-2002, as well as other publications and data sources on lactational amenorrhea. [NB: LAM was not developed and tested as a method until 1990]. Thirteen publications, reporting on nine intervention and two control groups, met the inclusion criteria. The reviewers concluded that LAM is a viable contraceptive method, available and accessible to many women. Life table pregnancy rates at 6 months
among LAM users ranged from 0.45 to 2.45 percent. Life table pregnancy rates of women fully breastfeeding and amenorrheic but not actively using LAM or other contraceptive methods were 0.88 in one study and 0.9-1.2 percent (95% CI 0.0-2.4) in a second study, depending on the definition of menstruation used. The life table menstruation rate at 6 months ranged from 11.1 to 39.4 percent in these studies and included women who exclusively breastfed for various lengths of time.

E. Considerations for Physician Counseling and Method Use:
Postpartum contraception, like breastfeeding, should be discussed with patients during prenatal visits. The contraceptive choice a woman makes, with or without her partner’s input, depends on factors such as previous experience with contraceptives, future childbearing plans, husband or partner’s attitude, and her lactation status. If a patient is not comfortable with a method, she may use it ineffectively or not at all, even if she does not wish to become pregnant.

There are several common reasons why a woman may choose LAM: she may prefer a period of time without taking medicine or using any devices, she may prefer more time for selection of a long-term or permanent method, or she may wish to try something based on her natural physiology.

Frequent nursing and milk expression alters the hypothalamic pulsatility of gonadotropin releasing hormone (GnRH) production, which in turn mediates follicle stimulating and luteinizing hormones, so that effective ovulation is less likely to occur. Several milk expression studies confirmed that the hormonal response is not identical to breastfeeding, so if the milk expression is a regular occurrence, some of the physiological responses may be modified. This is not directly mediated by prolactin. A patient, who has had a spontaneous or induced abortion prior to 20 weeks, usually will have spontaneous ovulation that results in the secretory portion of the menstrual cycle leading to menses. The patient will usually ovulate before any vaginal bleeding. If she delivers at term and is fully breastfeeding, however, vaginal bleeding (once the 6 weeks of lochia has stopped) nearly always occurs prior to first adequate ovulation during the first 6 months. Once regular feeding begins, there is an increase in fertile first cycles. Ovulation in the non-lactating woman may occur as early as 3 weeks postpartum.

F. LAM Management Issues:
There are several suggested behaviors that would contribute to method success and duration.

- LAM is not meant for patients who are giving regular supplemental feedings.

- Women can use LAM while working if they pump their breasts and provide milk to the baby’s caregiver during their absence. However, in one study using this approach, the efficacy was about 95%, slightly lower, but not significantly different than efficacy in women not separated from their infants. Further research is needed on this issue; however, if this is the only method a woman is willing to accept and is well informed of the possibility of decreased efficacy, LAM should remain an option.
for women who are regularly separated from their infants.

- One set of studies found that exclusively breastfeeding women using LAM are more likely to be amenorrheic at 6 months than exclusively breastfeeding controls (84% vs. 69.7%, respectively). Women who use LAM actively, have a higher feeding frequency, and, hence, shorter inter-feeding intervals, than other exclusive breastfeeding (Fig. 4). However, even with short inter-feeding intervals, some women experience earlier menses return. While we do not know whether these cycles are adequate for conception, no other sign of imminent fertility return are evident. Therefore, whether or not breastfeeding continues to be frequent, another method must be used for birth spacing when menses return.

- Three studies have indicated that the efficacy of LAM can be maintained during the 6 to 12 month period, provided the mother who originally followed this method, continues to breastfeed before giving complementary foods at less than 4 hours intervals during the day and 6 hours intervals at night while remaining amenorrheic.²

G. Transition to Other Methods:

When LAM no longer applies, or whenever a breastfeeding woman wishes to use an alternate family planning method, not all other methods have equal consequences for breastfeeding success. Therefore, alternative methods are presented ranked by increasing potential impact on breastfeeding success (Fig. 5). While not equally efficacious, the first choice methods are those that do not interfere with lactation. While studies show no major problems when progestin-only methods are introduced, the weight of anecdotal evidence, as well as the possible postpartum impact of progestins on prolactin, merits the second choice rating. Estrogen containing pills are known to reduce milk quantity. Optimal child spacing for maternal recovery, the support of lactation duration, and for child growth, development and survival may be influenced by particular demographics. A minimum of 18 months between births is recommended under all circumstances and at least three years or longer is recommended in developing countries.
V. Issues in counseling selection of contraceptives during breastfeeding.

A. Advantages and Disadvantages of Available Options.

The issues to be considered in counseling a pregnant or postpartum woman concerning contraceptive choice for use during breastfeeding extend beyond issues of efficacy. She will also wish to ensure that the selected method is appropriate for breastfeeding expectations (as listed in II. General Principles, above) in addition to the considerations for the non-lactating woman. Table 3 provides useful information for counseling the lactating mother and is not generally considered in contraception handbooks.

Figure 5. Family Planning during Lactation: Minimizing physiologic impact on breastfeeding

- First Choice Methods
  - LAM
  - Natural Family Planning
  - Barriers
  - IUDs
- Second Choice Methods
  - Progestin-only methods
- Third Choice Methods
  - Estrogen containing contraceptives
Table 3
Use of Contraceptive Methods during Lactation: Advantages, Disadvantages and Impact on Lactation

<table>
<thead>
<tr>
<th>Method</th>
<th>Advantages</th>
<th>Disadvantages</th>
<th>Effect on Breastfeeding</th>
</tr>
</thead>
<tbody>
<tr>
<td>No known impact on lactation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LAM</td>
<td></td>
<td></td>
<td>None</td>
</tr>
<tr>
<td>Barrier Methods</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Diaphragm/cap</td>
<td>Few side effects; Highly effective if used consistently and correctly. Good</td>
<td>Subject to user error; Some individuals have allergies to ingredients. Some couples may find methods inconvenient.</td>
<td></td>
</tr>
<tr>
<td>• Spermicides</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Condoms</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Little to no known impact on lactation</td>
<td>Highly reliable; Once inserted requires no action by user. Can be inserted 4 - 6 weeks postpartum. Good for long-term contraception.</td>
<td>Not suitable for non-monogamous women or those with history of ectopic pregnancy or pelvic inflammatory disease. Copper contraindicated with Wilson’s disease or copper allergy.</td>
<td>None with copper; Progestin IUD typically minimal impact but has potential as with other progestin only methods.</td>
</tr>
<tr>
<td>Intrauterine devices</td>
<td>Highly effective; Both may be outpatient procedures. Male sterilization is easier and safer and may be performed in an office setting.</td>
<td>Permanent decision; Reversal is expensive, requires surgical expertise, and may not be successful.</td>
<td>None Tubal ligation - temporary interruption in breastfeeding while surgery takes place.</td>
</tr>
<tr>
<td>• Copper bearing [e.g. Copper T380A 10 yrs]</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Progestin IUD [e.g. Mirena, levonorgestrel 5 yrs]</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surgical Sterilization</td>
<td>Highly effective; Both may be outpatient procedures. Male sterilization is easier and safer and may be performed in an office setting.</td>
<td>Permanent decision; Reversal is expensive, requires surgical expertise, and may not be successful.</td>
<td>None Tubal ligation - temporary interruption in breastfeeding while surgery takes place.</td>
</tr>
<tr>
<td>• Male-vasectomy</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Female-tubal ligation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Some reports of negative impact on lactation</td>
<td>Highly reliable; Easy methods to use after baby is 6 weeks old.</td>
<td>Common side effects of irregular bleeding (less common in predominantly breastfeeding women), weight gain, and headaches may discourage use. Potential decrease in milk production; Return to fertility with injections may be much longer than duration of highly reliable contraception – of potential concern for some women. Must develop routine for taking daily pills; Ring and implants not yet available in US; Implants require procedure for placement and removal.</td>
<td>May decrease milk supply if started before milk supply well established.</td>
</tr>
<tr>
<td>Hormonal – Progestin only</td>
<td>Highly reliable; Easy methods to use after baby is 6 weeks old.</td>
<td>Common side effects of irregular bleeding (less common in predominantly breastfeeding women), weight gain, and headaches may discourage use. Potential decrease in milk production; Return to fertility with injections may be much longer than duration of highly reliable contraception – of potential concern for some women. Must develop routine for taking daily pills; Ring and implants not yet available in US; Implants require procedure for placement and removal.</td>
<td>May decrease milk supply if started before milk supply well established.</td>
</tr>
<tr>
<td>• Injectables [e.g. Depoprovera (DMPA) 3 mos; NET-EN (norethisterone) 2 mos]</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Oral pills [e.g. Micronor, Nor QD (norethindrone)]</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Progestin IUD (see below)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Vaginal ring</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Implants [e.g. Implanon (etonogestrel) 3 yrs; Norplant, Jadelle (levonorgestrel) 5 yrs]</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Expected to have negative impact on lactation
### Hormonal – Combination

- **Oral (The Pill)**
  - Contraceptive patch [e.g. Ortho Evra (ethinyl estradiol/norelgestromin)]
  - Vaginal ring [e.g. Nuva-ring (ethinyl estradiol/etonogestrel)]
  - Injectables [estradiol/medroxyprogesterone 1 mo]

Highly reliable; Several good noncontraceptive effects, e.g., reduced risk of ovarian and endometrial cancers, decreased anemia, and regular menses.

Significant risk of reducing milk supply if started before baby is 6 months old – reduced supply appears dose dependent – use lowest possible estrogen dose, e.g. 20-microgram pill or vaginal ring. Oral pills may be forgotten; side effects of weight gain, headache, etc. may discourage use. Not suitable for women with history of clotting problems, estrogen-dependent cancers, severe migraines or women over 35 yo who smoke. Patch has decreased efficacy if weight >196 lbs.

Best to avoid use until after baby weaned; Unlike oral or implant methods, the injection cannot be stopped or removed - the woman must wait for the effect to wear off.

### Emergency Contraception

- **Combined estrogen/progestin** [e.g. Preven (levonorgestrel and ethinyl estradiol)]
- **Progestin only** [e.g. Plan B (levonorgestrel)]

Combined: wide range available, years of experience. Progestin only: less frequent and severe side effects than combined; Either can be used up to 72 hours post-coital, sooner is better.

Combined: hormonal side effects – nausea, vomiting, breast tenderness, moodiness, change in next menses; GI side effects minimized with antiemetic pretreatment.

As above for combination vs. progestin only OCP – progestin only preferred.

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**B. Additional Comments on Individual Methods**

**Hormonal Contraceptive Methods**

Although Koetsawang\(^{15,16}\) reported an increase, Tankeyoon\(^{16}\) noted a 12% decline in milk supply with progestin-only contraception compared to placebo. A recent Cochrane review indicated that evidence from randomized controlled trials on the effect of hormonal contraceptives during lactation is limited and of poor quality: “Evidence is inadequate to make recommendations regarding hormonal contraceptive use for lactating women.”\(^{17}\) It would be prudent to consider all hormonal contraceptive methods having some risk of decreasing mother’s milk supply. These methods, especially their early use should be discouraged in several circumstances:

1. existing low milk supply or history of lactation failure
2. history of breast surgery
3. multiple birth (twins, triplets)
4. preterm birth
5. compromised health of mother and/or baby

If progestin only methods are utilized, the breastfeeding mother may experience dyspareunia secondary to vaginal atrophy that may be alleviated by vaginal lubricants.

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Adapted with permission from Chapter 62, Gynecology and Obstetrics, ed. Sciarra J\(^{15}\)
**Barrier Methods**
The male condom can provide some protection against sexually transmitted diseases. If a patient has previously used a diaphragm or cervical cap, it should be refitted at the six-week postpartum visit. As noted above, vaginal lubricants may be helpful for breastfeeding patients as vaginal atrophy during lactation may cause dyspareunia.

**Intrauterine Devices (IUD)**
The IUD is one of the most frequently used contraceptives in the world. Various types of IUD’s are available (see Appendix A). IUD use in the United States had trouble regaining popularity due to the widely publicized litigation resulting from the side-effects of previous IUD’s.

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IUDs Available in the U.S.

**TCu-380A (380 mm² copper)**
- **Areas of major use:**
  - Worldwide
  - TCu-380A: Canada, Western Europe and Hong Kong
- **Approved length of use:**
  - TCu-380A: U.S.: 10 years, Commonwealth of Independent States (formerly the USSR): 8 years
  - TCu-380A: Canada: 5 years

**Progestrone T IUD (releases 63 mcg/day progesterone)**
- **Areas of major use:**
  - United States, France
- **Approved length of use:**
  - U.S.: 1 year
  - France: 18 months

IUDs Available Outside the U.S.

**NovaT and CuNovaT**
- **(200 mm² copper)**
- **(180 mm² copper)**
- **Areas of major use:**
  - Europe, Canada, Asia, and Pacific
- **Approved length of use:**
  - European countries: 3 years

**Multiload-250 and Multiload-375**
- **(250 mm² copper)**
- **(375 mm² copper)**
- **Each comes in 2 sizes:**
  - Standard and Short
- **Areas of major use:**
  - Europe (including Russia and other member states of the Commonwealth of Independent States), Australia, India, Vietnam and other Southeast Asian countries, New Zealand, Latin America
- **Approved length of use:**
  - ML-250: 3 years
  - ML-375: 5 years

**TCu-200 and TCu-200B**
- **(200 mm² copper)**
- **(200 mm² copper with ball at end)**
- **Areas of major use:**
  - Bangladesh, India
- **Approved length of use:**
  - European countries: 3 years
  - Canada: 5 years

**Lippes Loop**
- **(Non-medicated plastic)**
- **Comes in 4 sizes**
- **Area of major use:**
  - Indonesia
- **Approved length of use:**
  - No limit

**TCu-220C (220 mm² copper on 7 sleeves)**
- **Areas of major use:**
  - Mexico, China
- **Approved length of use:**
  - Mexico: 3 years

**Levonorgestrel 20 mcg**
- **Areas of major use:**
  - Denmark, Finland, Norway, Sweden. Available in the United Kingdom (U.K.) and Singapore since 1995.
- **Approved for use in:**
  - Belgium, France, Iceland, and Switzerland
- **Approved length of use:**
  - 5 years

Source: Adapted from Trimaco R, et al. 1995 (see reference 19)

REFERENCE LIST


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