# ABM Clinical Protocol #13: Contraception During Breastfeeding, Revised 2015

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A central goal of The Academy of Breastfeeding Medicine is the development of clinical protocols for managing common medical problems that may impact 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.

#### Purpose

THE PURPOSE OF THIS PROTOCOL is to outline considerations in assisting breastfeeding families to achieve optimal birth spacing by selecting a contraceptive method that is effective, unlikely to disrupt lactation, and satisfactory for the mother and her partner. The protocol covers the use of contraceptive methods during breastfeeding and provides guidance on the lactational amenorrhea method (LAM).

This protocol assumes that the practitioner is well versed in the risks and benefits of different types of contraception, including all pharmaceutical, permanent, and periodic abstinence/natural family planning methods.

## Issues in Counseling and Selection of Contraceptives During Breastfeeding

# 1. Considerations for clinician counseling and method use

Postpartum contraception, like breastfeeding, should be discussed with women during their own obstetric prenatal and postpartum visits and the infant's pediatric well baby visits. A woman's contraceptive choice depends on many factors such as previous experience with contraceptives, future childbearing plans, husband or partner's attitude, level of user attention required for use, medical considerations, return of menses, *and* the woman's lactation status. If a woman is not comfortable with a method, she may not use it effectively.

#### 2. Advantages and disadvantages of available options

Contraceptive counseling during breastfeeding extends beyond issues of efficacy, because the selected method must be appropriate for a woman's breastfeeding expectations. Table 1 provides useful information for counseling the breastfeeding mother Considerations include the potential for hormonal methods to either disrupt milk synthesis or expose the infant to synthetic hormones. Because a falling progesterone level after birth is necessary for onset of milk production, initiation of hormonal contraception before lactation is established is of particular concern. Published evidence is insufficient to exclude these risks. At the same time, longacting reversible hormonal methods have high contraceptive efficacy. Healthcare providers should discuss the limitations of the available data within the context of a mother's desire to breastfeed, her risk of low milk production, and her risk of unplanned pregnancy, so that she can make an autonomous and informed decision.

# LAM for Contraception in the Early Postpartum Period and for Introduction of Other Methods

### A. Background

Data published in the 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 nonbreastfeeders to experience a normal ovulation prior to the first menstrual-like bleed.<sup>1</sup> In 1988, at a Bellagio Conference, a group of expert scientists proposed three criteria as sufficient to predict fertility return. This three-criteria approach described in further detail below as the "Lactational Amenorrhea Method" was subsequently tested.<sup>2,3</sup> Studies of the acceptability and contraceptive efficacy of active LAM use continue to confirm the original findings, demonstrating that LAM is acceptable, learn-able, user-friendly, and as effective as many other alternatives.<sup>4–9</sup> (II-2) (Quality of evidence [levels of evidence I, II-1, II-2, II-3, and III] is based on the U.S. Preventive Services Task Force

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TABLE 1.	General	PRINCIPLES FOR	COUNSELING ]	BREASTFEEDING	WOMEN (	Concerning (	CONTRACEPTIVE
Selection and Birth Spacing							

Issues	Considerations
1. Breastfeeding pattern status, and plans	<ul> <li>Consider both short- and long-term breastfeeding intent as well as well birth spacing plans. There is the potential for hormonal methods to have an impact depending on when they are started.</li> <li>Mothers may plan to exclusively breastfeed; some may do so to use LAM, others may use LAM because they are already fully breastfeeding. LAM users should be counseled to have another method in hand for when menses return or breastfeeding patterns change. Effectiveness of LAM in exclusively breastmilk pumping mothers may not be equivalent to direct breastfeeding.</li> <li>Many women who intend to breastfeed exclusively are not able to achieve their goals.</li> </ul>
2. Child's age/time postpartum	• Many methods should not be introduced until breastfeeding is well established (i.e., at 4–6 weeks), as there may be potential for hormonal methods to directly impact lactogenesis and/or to impact the infant.
3. Maternal age and fu childbearing plans	• Choices depend on desire to space births or desire to limit family size. Globally recommended interpregnancy intervals are at least 18 months to 2+ years for maternal health, depending on the setting, and about 3–5 years for child health outcomes.
4. Previous contracepti experience	• Discussion of previous contraceptive experience, including compliance, satisfaction, side effects, and social issues, is essential. These issues can influence compliance and satisfaction, particularly as they pertain to prior lactation experiences.
5. Partners/interactions	<ul> <li>Partner's experiences and opinions may impact compliance, particularly for barrier methods, LAM, and natural family planning.</li> <li>The woman's social and behavioral considerations, such as number of partners and sexual activity, should be explored. A woman's history of unplanned pregnancy and short interpregnancy interval should be reviewed and discussed.</li> </ul>
6. Previous lactation experience/medical conditions	<ul> <li>Prior insufficient milk supply or inadequate infant growth</li> <li>Prior breastfeeding experience did NOT meet goals (either exclusivity or duration), AND supply was a potential reason.</li> <li>Physical examination suggestive of insufficient glandular tissue</li> <li>Prior breast surgery</li> <li>Medical conditions potentially adversely affecting supply (polycystic ovary syndrome, infertility, obesity)</li> <li>Multiple gestation</li> <li>Preterm infant(s)</li> </ul>

LAM, lactational amenorrhea method.

Appendix A Task Force Ratings<sup>10</sup> and is noted throughout this protocol in parentheses.)

#### B. Method: what is LAM?

LAM is presented as an algorithm (Fig. 1) and includes three criteria for defining the period of lowest pregnancy risk. If one of these criteria is not met, women should immediately initiate another method. Clinically, the mother is asked these three questions:

- "Are you amenorrheic?" meaning that you have you not had a menstrual bleed, or any bleed of >2 days in duration (discounting any bleed in the first 2 months).
- "Are you fully or nearly fully breastfeeding?" This includes not giving your baby any supplementary foods or fluids in addition to breastfeeding (greater than once or twice a week)?
- "Is your infant less than 6 months of age?"

If she answers "yes" to all three questions, she meets the requirements for LAM. If *any* of the above three questions is answered "no," then her chance of pregnancy is increased, and she should be advised to initiate another form of contraception to prevent pregnancy. If the mother is interested in and qualifies for LAM, she should review these three questions regularly. Clinicians should ensure that she has chosen her next method of contraception and either has it on hand or knows how to obtain it if it is an implant or intrauterine device (IUD).

#### C. Definitions for LAM use

To use LAM correctly, it is important that the patient understand each of the three criteria, which can be remembered using the letters "LAM" to indicate Lactation, Amenorrhea, and the number of Months:

- 1. *Lactation.* Full or nearly full breastfeeding includes exclusive, nearly exclusive, and some irregularly provided supplements, as long as they do not disrupt the frequency of feeds.<sup>11</sup>
- 2. *Amenorrhea.* For the purposes of LAM use, menses return 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.
- 3. *Months.* The "6 months" criterion is added primarily because this is the time that complementary feeding



The Lactational Amenorrhea Method -- LAM Ask the mother, or advise her to ask herself, these three questions:

FIG. 1. The lactational amenorrhea method.

should begin. If breastfeeding continues at the same frequency and complementary foods are offered after the breastfeed, efficacy apparently remains high as long as amenorrhea continues. In Rwanda, the method was used up to 9 months, by maintaining the breastfeeding frequency experienced during month  $6.^{12}$  This was achieved by feeding before each complementary feeding. Another study in Pakistan found a continued high efficacy under these conditions for up to 12 months.<sup>13</sup> (II-2)

#### D. Efficacy

A Cochrane literature review<sup>14</sup> (and assessed as up to date in 2008) concluded that fertility rates are low among fully breastfeeding, amenorrheic women. In controlled studies of LAM, pregnancy rates for 6 months ranged from 0.45% to 2.45%. In six uncontrolled studies of LAM users, pregnancy ranged from 0% to 7.5%. 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 physiological potential for high efficacy as seen in the LAM trials.<sup>4,5</sup> Subsequently, studies of method use have consistently found a 6-month pregnancy rate averaging 2%.<sup>15</sup> (I, II-2)

## E. LAM management issues

Suggested behaviors contributing to method success and duration include:

- Number of feedings. One controlled study found exclusively breastfeeding women using LAM are more likely to be amenorrheic at 6 months than exclusively breastfeeding controls (84% vs. 69.7%, respectively).<sup>16</sup> Women using LAM had a higher feeding frequency and a shorter interfeeding interval than other exclusive breastfeeding women.
- LAM can be used beyond the sixth month. The two studies mentioned above in Rwanda<sup>12</sup> and Pakistan<sup>13</sup> have indicated that the efficacy of LAM can be maintained during

the 6–12-month period, provided the mother continues to breastfeed before giving complementary foods at less than 4-hour intervals during the day and 6-hour intervals at night while remaining amenorrheic. (II-2)

3. LAM effectiveness has not as yet been adequately tested to offer the method with confidence to women who are giving supplemental feedings daily or expressing milk by hand or pump instead of breast-feeding.<sup>17</sup> (II-2) Women who are expressing milk more than a few times per week should be counseled to initiate an additional contraceptive method. (III)

# F. Transition to other methods

LAM may also be used as an introductory method to inform the user when it is time to initiate use of another method. Of note is that fully breastfeeding women are very unlikely to conceive in the first 56 days postpartum so secondary methods can be delayed until at least 8 weeks postpartum. When LAM criteria no longer apply or whenever a breastfeeding woman wishes to use an alternate family planning method, she should have an alternative method readily available. Alternative methods are discussed in terms of advantages and disadvantages and special issues related to breastfeeding.

#### Additional Comments on Individual Methods

Table 2 provides additional specific information for many individual methods, including advantages, disadvantages, and potential issues related to breastfeeding for each.

#### Natural family planning

Four methods of "fertility awareness" natural family planning include the Billings ovulation method (OM), the Creighton model system, the symptothermal method, and the Marquette method. Each of these methods can be used even when a woman's menses has not yet returned because of breastfeeding. These methods rely on observation of various combinations of cervical mucus, temperature, and/or

	TABLE 2. USE OF CON	RACEPTIVE METHODS DURING LACTATION: A	Advantages, Disadvantages, and Impac	t on Lactation
	Method	Advantages	Disadvantages	Effects related to breastfeeding
	Lactational amenorrheic method Natural family planning • Billings ovulation • Creighton model • Marquette • Symptothermal	<ul> <li>No side effects</li> <li>Effectiveness rates comparable with other user-directed methods of birth control (i.e., pills or barriers)</li> <li>Low cost for most methods</li> </ul>	<ul> <li>Requires special instruction for use during breastfeeding</li> <li>ClearBlue fertility monitor expense with Marquette</li> <li>May require long periods of abstinence</li> </ul>	• None
	<ul><li>Barrier methods</li><li>Diaphragm/cap</li><li>Spermicide</li><li>Condoms</li></ul>	<ul> <li>Few side effects</li> <li>Effective with diligent and appropriate use</li> <li>Easily accessible as "back up"</li> <li>Low cost</li> <li>Also provide protection from sexually transmitted infection</li> </ul>	<ul> <li>Potential for user error</li> <li>Allergy possible</li> <li>May be inconvenient and limit spontaneity</li> <li>Cervical cap and diaphragm require fitting.</li> </ul>	<ul> <li>None</li> <li>Use of lubricant may be beneficial with condoms in setting of vaginal atrophy.</li> </ul>
4	Other contraceptive options IUDs • Copper IUD (ParaGard T380A), 10 years • Levonorgestrel IUD (Mirena), 5 years • Levonorgestrel IUD (Skyla), 3 years	<ul> <li>Highly effective</li> <li>Reversible</li> <li>Long-term contraceptives</li> <li>Little user attention required (typical use and perfect use are similar)</li> </ul>	<ul> <li>Small risk of infection, perforation, expulsion</li> <li>Requires provider insertion and removal</li> <li>Copper contraindicated with Wilson's disease and copper allergy</li> <li>Short-term use costly; long-term use cost-effective</li> </ul>	<ul> <li>Copper IUD: no known impact on lactation</li> <li>Possible risk of perforation at insertion requiring surgical removal, which may necessitate short interruption in breastfeeding</li> <li>Levonorgestrel IUD (Mirena) placed immediately</li> </ul>
	Sterilization • Male (vasectomy) • Female: postpartum; laparoscopic; hysteroscopic	<ul> <li>Highly effective</li> <li>Male vasectomy and female hysteroscopic occlusion may be performed on an outpatient basis.</li> </ul>	<ul> <li>Permanent: risk of regret</li> <li>Surgical procedural risks</li> <li>Cost related to surgery</li> <li>Requires surgeon</li> <li>Risk of ectopic pregnancy with female procedures</li> </ul>	<ul> <li>postpartum may be associated with shorter duration of breastfeeding. No adverse effect on breastfeeding reported when placed 6 weeks postpartum or later.</li> <li>Male sterilization: none</li> <li>Female sterilization: none</li> <li>Female sterilization: none</li> <li>repostpartum procedure</li> <li>separates mother and infant and may require use of maternal narcotics (ideally avoid procedures in first 1–2 hours to allow skin to skin, initial breastfeeding, etc.).</li> </ul>
				(mmmmn)

Method	Advantages	Disadvantages	Effects related to breastfeeding
<ul> <li>Progestin-only hormonal options<sup>a</sup></li> <li>Injectible (DMPA) every 3 months</li> <li>Oral daily pills (norethindrone)</li> <li>Progestin-releasing IUD (see above): LNG IUD (Mirena), 5 years; LNG IUD (Skyla), 3 years</li> <li>Progestin vaginal rings</li> <li>Implants: etonogestrel (Implanon/ Nexplanon), 3 years (Jadelle), 5 years</li> </ul>	• Long-term options highly reliable	<ul> <li>Common side effect of irregular bleeding may be less problematic in breastfeeding mothers.</li> <li>Potential for user failure with daily pills</li> <li>Other progestin side effects: headache, acne, weight gain, bloating, depressed mood</li> <li>DMPA may have delayed return to fertility</li> <li>Implant and IUDs require provider insertion and removal.</li> </ul>	<ul> <li>Theoretical potential to adversely impact milk supply when started in the early postpartum period prior to establishing a milk supply. Insufficient data to determine risk at this time.</li> <li>If milk supply decreases with DMPA, cannot be discontinued or removed</li> <li>LNG IUD (Mirena) placed immediately postpartum may be associated with shorter duration of breastfeeding (single study). No adverse effect on breastfeeding reported when placed 6 weeks postpartum or later</li> </ul>
<ul> <li>Estrogen-containing combined hormonal of</li> <li>COC pills, daily</li> <li>Estrogen-containing vaginal ring (NuvaRing), monthly</li> <li>Estrogen-containing transdermal patch (Ortho-Evra), weekly</li> </ul>	<ul> <li>otions</li> <li>Options can be self-administered.</li> <li>Regular menstrual cycles (extended cycle options have more breakthrough bleeding)</li> <li>Non-contraceptive benefits: decreased bleeding, less anemia, improved acne, improved dysmenorrhea</li> </ul>	<ul> <li>Potential for user failure</li> <li>(especially with COCs)</li> <li>Increased risk of blood clots</li> <li>Potential for drug interactions</li> <li>Multiple medical contraindications</li> </ul>	<ul> <li>Ideally avoid until lactation/milk supply well established</li> <li>Potential for adverse effect on milk supply. Risk appears more pronounced with higher estrogen levels than used in contemporary products.</li> <li>If used by a breastfeeding mother, begin lowest possible into well-established</li> </ul>
<ul> <li>Emergency contraceptives</li> <li>Combined estrogen/progestin pills (Preven, Yuzpe method)</li> <li>Progestin-only pills—LNG (Plan B)</li> <li>Mifepristone</li> <li>Ulipristal</li> <li>Copper IUD</li> </ul>	<ul> <li>Most effective within 72 hours of exposure</li> <li>LNG options appear to have superior efficacy to COC with fewer side effects.</li> <li>Copper IUD most effective and provides continued contraception</li> <li>Mifepristone similar or superior to LNG in efficacy</li> </ul>	<ul> <li>Estrogen-containing options cause nausea/vomiting and often require use of antiemetics.</li> <li>No data for ulipristal in lactation currently available</li> <li>Limited data on mifepristone in lactation</li> </ul>	<ul> <li>LNG preferred over estrogen- containing options in breastfeeding mothers owing to previously described concerns related to estrogen and milk supply</li> </ul>

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COC, combined oral contraceptive; DMPA, depo-medroxyprogesterone acetate; IUD, intrauterine device; LNG, levonorgestrel.

hormonal monitoring, and then couples abstain during fertile periods. All of these methods have specific protocols for women to use during the postpartum period so they may plan accordingly if they wish to delay another pregnancy. The Marquette model has a recent peer-reviewed study to show the efficacy of its postpartum protocol.<sup>18</sup>

These methods may require significant periods of abstinence. Research on the use of the Billings OM during the postpartum period found that those who were using OM and were breastfeeding had a lower pregnancy rate than those using OM but not breastfeeding. The rate of unplanned pregnancy was less than 1% during the first 6 months of lactational amenorrhea. However, OM-associated pregnancy rates were elevated among breastfeeders after menses returned (36% vs. 13% for nonlactating women) and when infant feeding supplementation was started. This increase in unplanned pregnancies was not directly attributable to OM nonadherence. Special emphasis on both the need for improved breastfeeding support to delay menses return and the increased potential for method failure among new users during this period of time should be incorporated into OM training and support programs.<sup>19</sup>

#### Hormonal contraceptive method: general comments

Controversy exists in the literature regarding hormonal contraceptive effects on milk supply. Although Koetsawang<sup>20</sup> reported an increase, Tankeyoon et al.<sup>21</sup> noted a 12% decline in milk supply with progestin-only contraception compared with placebo. Other studies have not found an effect. A recent study quantified the effect of hormonal contraception on infant's milk ingestion between Days 42 and 63 using deuterium as a marker.<sup>22</sup> Forty women who had previously breastfed began contraception at 42 days postpartum with an estrogencontaining pill (150  $\mu$ g of levonorgestrel [LNG] and 30  $\mu$ g of ethinyl-estradiol), the LNG-IUD (Mirena®; Bayer Pharmaceuticals, Leverkeusen, Germany), the etonorgestrel implant (Implanon<sup>®</sup>; Merck & Co., Whitehouse Station, NJ), or the copper-containing IUD (ParaGard®; Teva Women's Health, Inc., North Wales, PA). No difference in the infants' milk intake was noted among groups in this study. A Cochrane review indicated that evidence from randomized controlled trials on the effect of hormonal contraceptives during lactation is limited and of poor quality: "The evidence is inadequate to make evidence-based recommendations regarding hormonal contraceptive use for lactating women."<sup>23</sup> Until better evidence exists, it is prudent to advise women that hormonal contraceptive methods may decrease milk supply especially in the early postpartum period. Hormonal methods should be discouraged in some circumstances (III):

- 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

# Hormonal contraceptive method: progestin-only options

There is theoretical concern related to milk supply when progesterone options are initiated in the initial 48 hours after delivery<sup>24</sup> as a drop in progesterone levels after birth is

necessary for secretory differentiation/lactogenesis II to occur. Progestin-containing contraceptives include the progestogen-only pill ("minipill") as well as contraceptive implants such as Nexplanon<sup>®</sup> (Merck & Co.), Depo-Provera<sup>®</sup> (depot medroxyprogesterone acetate [DMPA]; Pfizer, New York, NY), and the Mirena intrauterine system. A 2010 systematic review of the effects of progestin-only contraceptive options when initiated *after* the initial postpartum period found five randomized controlled trials and 38 observational trials addressing the topic.<sup>25</sup> No adverse effects on breastfeeding through 12 months of age, infant immunoglobulins, or infant sex hormones were noted. Research regarding the clinical implications of progestin contraceptive administration in the early postpartum period is contradictory.

Particularly controversial in clinical practice is the effect of DMPA. Prior studies of DMPA did not account for infant weight, milk supply, and the amount of supplement used. A systematic review of prospective studies on the effects of early postpartum DMPA use in lactating mothers by Brownell et al.<sup>26</sup> found all studies to be of low quality with inadequate control of confounders. Another study of low-income new mothers found that of the 31.3% who received DMPA, 62.6% received it prior to hospital discharge,<sup>27</sup> indicating that early postpartum use is common in some settings. This study team quantified the association between postpartum DMPA and early breastfeeding cessation among 183 women and concluded that if there is a causal effect of DMPA on breastfeeding duration, it is minimal. A prospective case control study of 150 women receiving DMPA after initiation of lactation but prior to hospital discharge (Days 2–10) compared with 100 women not receiving hormonal contraception followed up for 6 months found no difference in satisfaction with their breastfeeding experience or infant growth, although it is unclear how the breastfeeding patterns compared.<sup>28</sup>

A study by Brito et al.<sup>29</sup> compared either insertion of an etonogestrel-releasing implant within 1–2 days after delivery or DMPA given at 6 weeks postpartum. Forty women were then followed up through 12 weeks postpartum. Newborns of those in the implant group had a trend toward more weight gain in the first 6 weeks, but the overall duration of exclusive breastfeeding was not statistically different. Gurtcheff et al.<sup>30</sup> similarly studied early (1–3 days) versus delayed (4–8 weeks) insertion of the contraceptive implant. This noninferiority study found no difference in breastfeeding failure rates with early insertion compared with the delayed group.

#### Estrogen-containing combined hormonal options

Estrogen-containing options include combination oral contraceptive (COC) pills (taken daily using monthly cyclic, extended cyclic, or continuous options), transdermal patch (weekly), or combined contraceptive vaginal rings (monthly). Estrogen-containing options are not ideal for early postpartum breastfeeding mothers because of the potential adverse impact on milk supply. The potential for estrogen to cause milk suppression is exemplified by the historical use of large estrogen doses immediately postpartum for lactation suppression prior to our understanding of the elevated thrombogenic risk during that time period. A Cochrane review on methods of lactation suppression noted seven trials using four different estrogen preparations and found a significant reduction in lactation within 7 days postpartum; of note is that the doses and estrogen preparations used differ from those currently used in hormonal contraceptives.<sup>31</sup>

A 2010 systematic review on COCs and breastfeeding found only three randomized controlled trials and four observational studies; the three randomized controlled trials found a decreased mean breastfeeding duration in COC users and an increased use of supplement.<sup>32</sup> No other documented adverse effects on infant health were noted.

If an estrogen-containing contraceptive is chosen, it is prudent to start the lowest estrogen-containing options as late as possible and after milk supply and lactation are well established (III). Additionally, estrogen-containing options should not be initiated in the first few weeks postpartum because of the elevated risk of deep venous thrombosis and pulmonary embolism. Absolute and relative contraindications are otherwise the same for lactating women as for nonlactating women.

Contemporary COCs have estrogen doses ranging from 10 to 35  $\mu$ g daily. No significant difference in contraceptive efficacy has been found in a Cochrane review of COCs containing  $< 20 \,\mu$ g of estrogen compared with those with  $> 20 \,\mu$ g.<sup>33</sup> This information should provide reassurance regarding anticipated efficacy when choosing lower estrogen dose options in a breastfeeding mother in order to minimize potential adverse effects.

#### Direct comparison of progestin-only pills and COCs

A WHO task force study done in the 1980s found a 41.9% decrease in supply in women using COCs within 6 weeks of initiation.<sup>21</sup> However, a recent randomized controlled trial compared 63 women using a 35- $\mu$ g progestin-only pill (POP) with 64 women using a COC containing 35  $\mu$ g of ethinyl-estradiol from 2 through 8 weeks postpartum; the authors found no difference in continued breastfeeding at 8 weeks (63.5% POP vs. 64.1% COC).<sup>34</sup> Forty-four percent of those in the POP group stopped breastfeeding because of perceived insufficient milk supply compared with 55% in the COC group. Twenty-three percent of women who stopped their pills in the POP group and 21% in the COC groups reported that they did so because of a perceived negative impact on milk supply.

#### Emergency contraception

Emergency contraception is most effective when initiated within 72 hours after unprotected sexual intercourse, although it is still useful up to 120 hours. Postcoital copper IUD placement, mifepristone, COC, and progesterone options (LNG) are potentially available choices. Postcoital copper IUD placement would be unlikely to impact lactation (see section on IUDs) and has the advantage of providing continued contraception. LNG options are slightly more effective than the COC and also are less likely to cause significant nausea and vomiting.<sup>35</sup> Furthermore, in theory, LNG options would be less likely to impact lactation. A pharmacologic study of 12 breastfeeding mothers found the estimated infant exposure to the maternal treatment of 1.5 mg of LNG was  $1.6\,\mu g$  on the day of therapy.<sup>36</sup> A single observational study comparing progestin-only with estrogen-containing options for postcoital contraception found that an adverse effect on

breastfeeding was uncommon and similar in both groups.<sup>37</sup> Based on similar efficacy, less propensity to nausea, and the absence of exposure to estrogen, it appears that the use of LNG is likely the preferred option over a COC in a breastfeeding mother. There are limited data on mifepristone and ulipristal in lactation. The use of postcoital mifepristone (an antiprogesterone) is similar to or superior in efficacy to LNG depending on dosage. Based on a small study, mifepristone transfers into milk in low levels (relative infant doses  $\leq 1.5\%$ ) and would not be anticipated to have adverse effects on the breastfeeding infant.<sup>38</sup> Ulipristal is a selective progesterone receptor modulator. There are currently no data available on its use in breastfeeding mothers.

Postcoital contraception has also been evaluated as a backup to lactational amenorrhea. Although this may not be a practical option, one study found a lower pregnancy rate for the group that was provided with a postcoital contraceptive during counseling regarding lactational amenorrhea at the postpartum visit.<sup>39</sup>

#### Barrier methods

There are no known adverse effects on lactation with the use of barrier methods of contraception. Patients should be counseled regarding the reduced efficacy of these methods compared with other hormonal, intrauterine, or permanent options.

#### IUDs

The IUD is one of the most frequently used contraceptives in the world. Prevalence rates range from 6% in the United States and in other countries up to 80% of contraceptive users.<sup>40,41</sup> Hormonal and nonhormonal IUDs are available and have different side effect profiles.

Progestin-releasing IUDs are associated with reduced menstrual blood flow, although around the time of insertion, women frequently experience irregular bleeding. This side effect is most pronounced during the initial 6 months and typically improves with time. Other progestin-related side effects are also possible. The copper IUD is associated with increased dysmenorrhea and menorrhagia.

In a study comparing breastfeeding outcomes in women randomized to receive a copper or progestin IUD at 6–8 weeks postpartum, the authors found no difference in full breastfeeding duration, infant growth, or development through 1 year postpartum.<sup>42</sup> However, in a secondary analysis of a randomized controlled trial comparing women who had an LNG-IUD placed immediately postpartum versus 6–8 weeks postpartum, early LNG-IUD placement was associated with lower breastfeeding rates<sup>43</sup>; in the delayed placement group, four women received DMPA prior to their 6-week visit. Studies of the copper-containing IUD have found no change in milk or serum copper levels.<sup>44</sup>

Complications related to the device itself include uterine perforation, failure (pregnancy), inability to visualize strings, vaginal discharge, infection, pain, the partner feeling the strings, malpositioning (which may require a surgical procedure to remove the IUD), and expulsion (2–10% within the first year). Data do suggest that there is an increased risk of perforation when either IUD is inserted in breastfeeding women.<sup>45</sup> A recent systematic review suggested that IUDs

WHO category	With clinical judgment	With limited clinical judgment
1	Use the method in any circumstances	Use the method
2	Generally use the method	Use the method
3	Use of the method not usually recommended unless other, more appropriate methods are not available or acceptable	Do not use the method
4	Method not to be used	Do not use the method

TABLE 3. MEDICAL ELIGIBILITY CRITERIA

Where a doctor or nurse is not available to make clinical judgments, the four categories can be simplified into a two-category system (third column) by combining World Health Organization (WHO) Categories 1 with 2 and 3 with 4.

remain a long-acting reversible contraceptive option for breastfeeding women with cesarean birth.46

#### Irreversible options (sterilization)

Multiple methods of surgical sterilization are available, including male vasectomy, postpartum tubal ligation, laparoscopic tubal ligation, and hysteroscopic tubal occlusion. These procedures involve different technologies, surgical techniques, anesthesia, and procedural settings.

Important considerations for breastfeeding dyads include the potential to impact early maternal-infant interaction. Ideally, procedures should not be performed during the initial hours postpartum to allow skin-to-skin contact between the mother and infant and initiation of breastfeeding. Early maternal-infant contact should not, however, prevent breastfeeding mothers from undergoing postpartum tubal ligation. To minimize disruption, the infant should be kept skin-toskin with the mother in the preoperative area and be reunited with her as soon as the mother is awake and alert in the recovery room. This interruption should be managed in a breastfeeding-supportive way, and the provider should remain cognizant of the implications of anesthesia and analgesia on the breastfeeding dyad.<sup>4</sup>

Unfortunately, women who do not have the postpartum tubal sterilization procedure performed during their maternity stay are at risk for ultimately not having the procedure performed and subsequent pregnancy.<sup>48-50</sup> This risk should be considered. Such considerations may warrant early maternal-infant separation in order for the procedure to be completed prior to discharge.

#### The Medical Eligibility Criteria

Medical Eligibility Criteria provide guidance on the level of safety of contraception in relation to specific medical conditions and other demographic variables. Risks are divided into four categories as outlined in Table 3, although the categories are sometimes divided into two categories: generally use and generally do not use. The current recommendations from WHO and the Centers for Disease Control and Prevention (CDC) differ. Table 4 shows the categories for the use of several methods during lactation as presented by WHO and revised by CDC. CDC recently revised recommendations to include reducing the postpartum period from 6 weeks to 4 weeks and no longer contraindicating immediate postpartum use of progesterone-only contraception.

There are limited data from well-conducted scientific studies that adequately take into consideration the effect on the infant or exclusive breastfeeding, especially in the immediate postpartum period when the establishment of

TABLE 4. WORLD HEALTH ORGANIZATION AND CENTERS FOR DISEASE CONTROL AND PREVENTION MEDICAL ELIGIBILITY CATEGORIES

	WHO		CDC	
	Timing postpartum	MEC level	Timing postpartum	MEC level
Combined oral contraceptive	0–6 weeks	4	<1 month	3
Ĩ	6 weeks–6 months	3	$\geq 1$ month	2
	>6 months	2		
Progestin only contraceptive	0–6 weeks	3	<1 month	2
(oral and implants)	6 weeks–6 months	1	$\geq 1$ month	1
	>6 months	1		
LNG-IUD	<48 hours	3	< 10 minutes	2
	48 hours-4 weeks	3	10 minutes to $<4$ weeks	2
	>4 weeks	1	$\geq$ 4 weeks	1
Cu-IUD	<48 hours	1	< 10 minutes	1
	48 hours–4 weeks	3	10 minutes to $<4$ weeks	2
	>4 weeks	1	≥4 weeks	1

Adapted from the World Health Organization (WHO) Medical Eligibility Criteria (MEC) and the Centers for Disease Control and Prevention (CDC) Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use Updated June 2012 (www.cdc.gov/ reproductivehealth/unintendedpregnancy/USMEC.htm). See Table 3 for MEC categories.

IUD, intrauterine device; LNG, levonorgestrel.

lactation and adequate milk production is essential. (III) Moreover, exclusively breastfeeding women are very unlikely to become pregnant in the first 6 weeks after birth as described above. In this setting, hormonal contraception has minimal benefit, and early initiation may derail a woman's exclusive breastfeeding intentions. Unless the risk of unplanned pregnancy or loss to follow-up is high, early initiation of hormonal contraception in breastfeeding women is not recommended.

#### **Future Research**

There is need for more detailed prospective research regarding the impact of all hormonal contraception on breastfeeding and on the potential long-term impact on the infant due to exposure to exogenous hormones. Such information will enable women to make informed decisions regarding the risk of unplanned pregnancy versus the risks of disrupted breastfeeding. Prior research has often not adequately accounted for maternal breastfeeding goals, the importance of breastfeeding exclusivity, and amount of supplement used. Until research has addressed these concerns and focused on women's intentions to exclusively breastfeed, it is not possible to exclude adverse potential effects on milk supply, on long-term breastfeeding success, or on the infant, especially if any is a rare occurrence. This is particularly true when initiating hormonal contraception in the initial postpartum period. Research is needed to evaluate the impact of contemporary contraceptive options, which include lower estrogen doses and progestin-only agents, on both breastfeeding in the short term and on the infant in the long term. Further research is also needed on the effectiveness of LAM given the widespread availability of breast pumps and the growing number of mothers who are choosing to exclusively express and feed their infants expressed breastmilk. In sum, rare or long-term adverse outcomes are often not detected, and method efficacy has not been evaluated under a wide variety of conditions. Both of these issues demand study of large populations over time. For the individual breastfeeding family, this lack of sufficient data regarding the impact of hormonal contraception may have significant negative consequences.

### Conclusions

Every woman should be offered full information and support about contraception options so she can make an optimal decision for her individual situation. Physicians and other healthcare providers should not "pre-decide" which method is most appropriate; rather, in discussion with the patient, clinicians should discuss the risks, benefits, availability, and affordability of all methods. This discussion should address contraceptive efficacy and possible impact on breastfeeding outcomes, within the context of each woman's desire to breastfeed, risk of breastfeeding difficulties, and risk of unplanned pregnancy.

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