

# Recommendations for Updating Selected Practices in Contraceptive Use Volume II:

Female Sterilization  
 Vasectomy  
 Combined Injectable Contraceptives  
 Levonorgestrel-Releasing Intrauterine Device  
 Lactational Amenorrhea Method  
 Natural Family Planning  
 Withdrawal  
 Progestin-Only Pills during Breastfeeding  
 Barrier Methods  
 Oral Contraceptives as Emergency Contraceptive Pills  
 Selected Questions on NORPLANT® Implants  
 (not covered in Volume I)  
 Selected Questions on IUDs, COCs and DMPA  
 (not covered in Volume I)  
 COC CBS Checklist  
 DMPA (or NET-EN) CBS Checklist  
 Guide for Using COC and DMPA (or NET-EN) Checklists  
 Client-Provider Interaction in Family Planning Services  
 Contraceptive Effectiveness  
 STD Risk Assessment  
 Dual Method Use  
 Chart of Family Planning Methods and STD Protection  
 Cervical Cancer Prevention



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# Recommendations for Updating Selected Practices in Contraceptive Use

## Volume II

Produced by the Technical Guidance/Competence Working Group (TG/CWG)  
Results of a Technical Meeting and Other Technical Review

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## FOREWORD

The Family Planning and Population Unit, Division of Reproductive Health of the World Health Organization (WHO) and the Office of Population of the U.S. Agency for International Development (USAID) are pleased to have collaborated with the Technical Guidance/Competence Working Group in the process which led to the production of this document. The recommendations contained in this document are intended to help national (and other) reproductive health teams to revise their family planning service delivery guidelines, on the basis of the latest clinical, epidemiological and programmatic experience.

This document acknowledges that despite many significant advances made over the past thirty years in the development of new contraceptive methods and in improving effectiveness and safety of the older techniques, there is still a huge gap between this knowledge and its application for improving family planning care. In many regions of the world, current policies and delivery practices continue to be based on the older contraceptive products that are no longer in wide use, and/or on long standing theoretical concerns that have never been scientifically substantiated. The full range of modern family planning methods remains inaccessible to millions of couples and individuals who wish to space or prevent pregnancies.

A first step in redressing the situation was taken by the World Health Organization with the issuance of its document "Improving Access to Quality Care in Family Planning: Medical Eligibility Criteria for Contraceptive Use" in 1996. The Organization undertook, in 1994 and 1995, an in-depth review and analysis of all the clinical, epidemiological and acceptability research that had been carried out over the past ten years on all the contraceptive methods that are widely available around the world. A new approach and classification system was then devised by the participants of two scientific expert group meetings convened by WHO for defining the medical conditions or life situations that are relevant for consideration with the use of each contraceptive method. New medical eligibility criteria were proposed based on this approach which ensures that each contraceptive method is "prescribed" with an adequate margin of safety for the user and that no one is unnecessarily denied the method of his or her choice.

The present document takes the process of improving access to quality family planning care one step further by *defining the service delivery implications* complementary to the new medical eligibility criteria developed by WHO. It proposes recommendations for appropriate screening procedures, provision of methods and follow-up care/procedures that are essential for high quality services. For each recommendation, a scientific basis has been formulated along with relevant references. The question/answer format utilized is particularly useful and reader-friendly.

This document is a valuable reference and guidance tool for professionals interested in updating their service delivery guidelines for improved quality of family planning care. It answers many of the difficult questions being raised about enhancing access to family planning without sacrificing safety and effectiveness, in a scientifically justified manner. The World Health Organization and USAID encourage this document's widespread use as a major step forward in bridging the gap between current knowledge and its actual application for the benefit of all men and women around the world.

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# Introduction

## A. Purpose of this Document

Volume II of *Recommendations for Updating Selected Practices in Contraceptive Use* supplies recommendations and updated information about specific procedural steps concerning those contraceptive methods not covered in the companion document, Volume I, as well as information concerning other selected reproductive health (RH) services. These recommendations are part of United States Agency for International Development's (USAID) broader efforts to improve quality and access in family planning (FP) programs under the Maximizing Access and Quality (MAQ) Initiative.

As with Volume I, these recommendations have been developed by the Technical Guidance/Competence Working Group (TG/CWG) (see background page 4) in collaboration with World Health Organization (WHO) to help update service delivery guidelines and to make them consistent with current clinical and epidemiological evidence. The intention of this document is to improve both access to and quality of men's and women's FP and related RH services through better use of resources. To help achieve this goal, this document (like Volume I) also provides the underlying scientific rationale for each recommendation.

Neither this document (Volume II) nor its companion (Volume I) should be viewed as constituting actual service delivery guidelines; both are intended to provide **guidance** for the administration of selected FP methods and related RH issues for anyone who is developing, updating, or revising FP and other RH service guidelines.

## B. Content

**Section 1** contains information on select contraceptive methods organized in a question/answer format. The topics discussed include:

- female sterilization, vasectomy, combined (estrogen-progestin) injectable contraceptives (CICs), levonorgestrel-releasing intrauterine devices (LNg IUDs), the Lactational Amenorrhea Method (LAM), natural family planning (NFP), withdrawal, progestin-only pills (POPs) during breastfeeding, barrier methods, and oral contraceptives (OCs) as emergency contraceptive pills (ECPs); and
- some additional recommendations for methods discussed in Volume I including: NORPLANT® Implants, non-hormonal IUDs, COCs and depo-medroxyprogesterone acetate (DMPA).

For each question posed, the document includes:

1. recommendations, and
2. the basic scientific rationale justifying the recommendations, with citations of the most relevant (preferably primary) literature.

In addition to the information included in the question/answer portion, each section includes a table that addresses the relative necessity of selected procedures prior to the initiation of the contraceptive method. The information in the tables indicates which of the procedures fall into the following classes, and provides a rationale and citations for the classification.

The following four classes were established to differentiate the relative necessity of various procedures. **Please note: the definitions of these four classes have been slightly modified (indicated in italics) since the 1994 publication of Volume I, in order to improve accuracy and consistency.**

- Class A** = essential and mandatory *or otherwise important* in all circumstances for safe *and effective* use of the contraceptive method
- Class B** = medically/epidemiologically rational in some circumstances to optimize the safe *and effective* use of the contraceptive method, but may not be appropriate for all clients in all settings
- Class C** = may be appropriate for good preventive health care, but not *materially* related to safe *and effective* use of the contraceptive method
- Class D** = *not materially related to either good routine preventive health care or safe and effective use of the contraceptive method*

The following procedures are addressed for each contraceptive method since these procedures are the most commonly used in programs to screen clients before providing contraceptive methods:

1. Pelvic examination
2. Blood pressure
3. Breast examination
4. STD screening by lab tests
5. Cervical cancer screening
6. Routine, mandatory lab tests
7. Proper infection prevention procedures
8. Counseling

**Section 2** contains combined oral contraceptive (COC) and DMPA (or NET-EN) checklists designed to determine whether clients can safely initiate use of these methods. The checklists are intended for use by health care workers in community-based service (CBS) settings. The checklists are followed by guides that provide information to program managers, policymakers, administrators and trainers about adapting and using the checklists.

**Section 3** contains information on a variety of RH issues, including: client-provider interaction, contraceptive method efficacy, sexually transmitted disease (STD) risk assessment, dual method use, FP methods and protection against STDs, and cervical cancer prevention.

**Appendices** contain a variety of information including:

- guidelines for determining with reasonable certainty that a woman is not pregnant (applicable to all of the contraceptive methods)
- a key to abbreviations used in this document
- lists of: participants' and reviewers' organizations, participants in the May 23, 1996 meeting, and reviewers

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\* World Health Organization. *Improving Access to Quality Care in Family Planning: Medical Eligibility Criteria for Contraceptive Use*. Geneva, WHO, March 1996.

- acknowledgments, including the list of volunteer resource persons- persons who helped substantially with the chapters (e.g. drafting the initial version of a chapter)
- information about how to access Volume I on the Internet
- a summary of the WHO 1996 medical eligibility criteria for initiating use of contraceptives\*

### C. Two Related Quality of Care Concepts

It is important to note **two related quality of care concepts which should also be addressed**, but are **not the focus** of the guidance given in this document:

1. **Appropriate medical eligibility criteria for use of each contraceptive method should be followed.** Neither Volume I nor II of *Recommendations for Updating Selected Practices in Contraceptive Use* address all of the questions that deal with medical eligibility for initiation and re-administration of these methods. Therefore, it is recommended that the medical eligibility criteria compiled by the World Health Organization (WHO) be consulted for this information.\* (Please note the WHO 1996 medical eligibility recommendations have been summarized and are included in Appendix F.)
2. **Service providers should be appropriately trained, adequately equipped, and properly supervised in order to competently deliver specific contraceptive methods, according to relevant national or institutional standards** and the performance requirements for each cadre of service provider.

### D. Limitations of the Scope of This Document

The goal of this document is **NOT** to produce a set of “generic” guidelines, but rather to produce a reference for service providers involved in developing and updating FP service delivery guidelines.

The participants of the May 1996 meeting, members of the USAID TG/CWG and other FP/RH experts, did not attempt to comprehensively cover aspects of policy, program, social, economic, and other types of barriers to FP and related RH service access and quality. Participants also did not address certain quality issues and other technical aspects of contraceptive methods not covered in this document. Such issues merit attention by policymakers, program directors, and client groups, but neither this volume nor Volume I have attempted to deal comprehensively with these concerns. Other USAID-supported activities address training, communication research, policy and service delivery initiatives necessary to improve the quality of and access to FP and RH care.

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\* World Health Organization. *Improving Access to Quality Care in Family Planning: Medical Eligibility Criteria for Contraceptive Use*. Geneva, WHO, March 1996.

## E. Background and Contributors

The TG/CWG of the MAQ Initiative was established with USAID support in August 1992 to provide leadership and guidance on updating selected procedures and practices in FP and other selected RH service guidelines. Since 1992, the TG/CWG has addressed the challenge of maximizing FP/RH service quality and access, through the improvement of FP/RH guidelines. This document, *Recommendations for Updating Selected Practices in Contraceptive Use: Volume II* is the second product of the TG/CWG.

In November 1992, the USAID MAQ Initiative's TG/CWG convened a meeting of representatives of many of the Cooperating Agencies (CAs) of USAID. From that meeting, Volume I of *Recommendations for Updating Selected Practices in Contraceptive Use* was initiated. Volume I was published in 1994 supplying information on four contraceptive methods: COCs, progestin-only injectables, NORPLANT® Implants and IUDs. In 1995, plans for the second volume were implemented: numerous experts in FP and related RH subjects were invited to submit questions for Volume II, and volunteer resource persons from several agencies refined the recommendations and rationales (see Appendix D for a complete list of Volunteer Resource Persons).

Volume II complements Volume I by including those FP methods not previously covered. This volume also includes some additional recommendations for methods that were included in Volume I. The working group also included information on other RH issues that they thought would be of interest to the users of these documents.

At the TG/CWG meeting in May 1996, material for Volume II was reviewed and augmented by the FP/RH experts in attendance at the meeting. Volume II was then reviewed again in September 1996 by a larger group of experts in RH and FP (see Appendix C for a complete list of participants at the May 1996 TG/CWG meeting and participants of the review process). The documents in Section 3 were reviewed after the May 1996 meeting by some members of the TG/CWG and by other reviewers.

# SECTION 1

## Contraceptive Methods:

- 1.1 Female Sterilization
- 1.2 Vasectomy
- 1.3 Combined Injectable Contraceptives (CICs)
- 1.4 Levonorgestrel-Releasing Intrauterine Devices (LNg IUDs)
- 1.5 Lactational Amenorrhea Method (LAM)
- 1.6 Natural Family Planning (NFP)
- 1.7 Withdrawal (coitus interruptus)
- 1.8 Progestin-Only Pills (POPs) During Breastfeeding
- 1.9 Barrier Methods
- 1.10 Oral Contraceptives as Emergency Contraceptive Pills (ECPs)
- 1.11 Selected Questions on NORPLANT® Implants  
(not covered in Volume I)
- 1.12 Selected Questions on IUDs, COCs and DMPA  
(not covered in Volume I)

## 1.1 Female Sterilization (Tubal Occlusion)

This section outlines recommendations on the following selected procedural questions for Female Sterilization:

1. **When** can female sterilization be performed?
  - a) interval?
  - b) postpartum?
  - c) post-cesarean section?
  - d) postabortion?
2. Are there any medical restrictions by **client's age** or **number of living children** for a woman to undergo female sterilization?
3. Is the **husband's consent** necessary before a woman undergoes female sterilization?
4. What is the principal variable associated with **requests for reversal** after female sterilization?
5. Should there be a **required waiting period** before female sterilization for a woman who has been counseled and has chosen female sterilization?
6. Does **post-female sterilization syndrome** exist?
7. Are **back-up contraceptive methods** necessary after female sterilization?
8. What is the **long-term risk of pregnancy** following female sterilization?
9. **Who** can provide female sterilization?
10. What is the appropriate **follow-up schedule** after female sterilization?
11. Should female sterilization be considered **permanent**?

## Q.1. When can female sterilization be performed?

Recommendations	Rationale
<p>a) <b>Interval?</b></p> <p>Female sterilization can be performed any time the provider is reasonably sure a woman is not pregnant (see Appendix A), for example, during the seven days which begin with the onset of menses (days one through seven of the menstrual cycle).</p> <p>b) <b>Postpartum?</b></p> <p><b>(early postpartum)</b></p> <p>Sterilization can be performed within the first seven days postpartum, preferably within 48 hours after delivery.</p> <p>The procedure should be delayed in the presence of certain conditions (see WHO Medical Eligibility Criteria).</p> <p><b>(late postpartum)</b></p> <p>Sterilization can also be performed postpartum once the uterus is fully involuted.</p>	<p>a) Pregnancy is considered a category D (delay the procedure until the condition is corrected) by WHO for performing female sterilization. While medically there does not exist contraindications for performing a female sterilization during early pregnancy, the perception is that the sterilization procedure has failed. Clients should be refused sterilization if an early pregnancy cannot be ruled out.</p> <p>1) World Health Organization. Improving access to quality care in family planning: medical eligibility criteria for contraceptive use. Geneva: WHO, 1996.</p> <p>b-d) From the surgical perspective, minilaparotomy performed within 48 hours after vaginal or cesarean delivery is easier than and as safe and effective as interval sterilization. Because the uterus is enlarged immediately postpartum, the fallopian tubes are nearer the abdominal wall, and can be reached easily during the first 48 hours after delivery. Approximately two days postpartum the uterus begins to involute and by two weeks is within the true pelvis. Thus, after 48 hours postpartum, more care is required if sterilization is to be performed as the uterus becomes less accessible from the subumbilical incision and its position in the abdomen may be difficult to ascertain. The uterus is still accessible for up to seven days, but may require a slightly lower incision.</p> <p>1) World Health Organization, Task Force on Female Sterilization, Special Programme of Research, Development and Research Training in Human Reproduction. Mini-incision for post-partum sterilization of women: a multicenter, multinational prospective study. <i>Contraception</i> 1982;26:495-503.</p> <p>2) Cunningham FG, MacDonald PC, Leveno KJ, Gant NF, Gilstrap LC. The puerperium. In: <i>Williams Obstetrics</i>. 19th ed. Norwalk, CT: Appleton and Lange, 1993:459-73.</p>

(continued on next page)

**Q.1. When?** (continued)

Recommendations	Rationale
<p><b>c) Post cesarean-section?</b></p> <p>Female sterilization can be performed at the same time as a cesarean section, or within seven days (preferably within 48 hours) post-cesarean, as long as the woman is stable.</p> <p>The procedure should be delayed in the presence of certain conditions (see WHO Eligibility Criteria).</p> <p>Sterilization can also be performed postpartum once the uterus is fully involuted.</p>	<p><b>b-d)</b> It has been recent practice to avoid doing female sterilization after 48 hours postpartum because of a concern about increased infection. Because bacteria are present in the endometrial cavity and fallopian tubes, prophylactic antibiotics are recommended when female sterilization is performed beyond postpartum day three.</p> <p>1) Laros RK Jr., Zatulni GI, Andros GJ. Puerperal tubal ligation morbidity, histology, and bacteriology. <i>Obstetrics and Gynecology</i> 1973;41:397-403.</p>
<p><b>d) Postabortion?</b></p> <p>Sterilization can be performed concurrently with a medically safe induced abortion, or within seven days postabortion, if you are sure the woman is free of infection.</p> <p>In the context of postabortion care, where it is possible that an unsafe abortion has occurred, female sterilization should not be performed unless the provider is sure the woman is free from infection.</p>	<p>Severe pre-eclampsia/eclampsia, premature rupture of membranes, sepsis or indication of infection, severe hemorrhage, and severe trauma to the genital tract or uterine rupture or perforation are contraindications to female sterilization and the procedure should be delayed until the condition is resolved.</p> <p>1) World Health Organization. Improving access to quality care in family planning: medical eligibility criteria for contraceptive use. Geneva: WHO, 1996.</p>
<p><b>Note:</b></p> <p>If the woman intends to breastfeed her infant, <b>local anesthesia</b> is preferred over general anesthesia to minimize interruption of the early breastfeeding pattern and infant exposure to the anesthetic agent.</p>	<p>The uterus is usually fully involuted four weeks after delivery, although it may take six weeks or longer in some cases. For women who are not breastfeeding and are therefore at some risk of pregnancy before six weeks postpartum, if the uterus is fully involuted, female sterilization at four weeks postpartum can be safely provided. If the uterus is not fully involuted, this may be a sign of infection or incomplete resolution of postpartum healing and female sterilization should be delayed.</p> <p>1) Hatcher RA, Kowal D, Guest F, Trussell J, Stewart F, Stewart G, et al. Voluntary Surgical Contraception. In: <i>Contraceptive Technology International</i>. Atlanta: Printed Matter, 1989:59-64.</p> <p>In the absence of complications, female sterilization can be performed at the same time as the abortion.</p> <p>1) World Health Organization. Improving access to quality care in family planning: medical eligibility criteria for contraceptive use. Geneva: WHO, 1996.</p> <p>General anesthesia may affect lactation by delaying the start of breastfeeding, because of the mother's recuperation from the anesthesia and by hampering the infant's attempts to feed if the infant has ingested some of the anesthetic agent in the milk. These negative effects on breastfeeding are more pronounced when the sterilization is not performed immediately after delivery.</p> <p>1) Kennedy KI. Fertility, sexuality and contraception during lactation. In: Riordan J, Auerback K, editors. <i>Breastfeeding and human lactation</i>. Boston: Jones and Bartlett Publishing, 1993.</p> <p>2) Kennedy KI. Postpartum contraception. <i>Contraception</i> 1996;10(1):25-42.</p>

## Q.2. Are there any medical restrictions by client's age or number of living children for a woman to undergo female sterilization?

### Recommendations

No. In terms of safety, there are no age and parity medical restrictions for a woman to undergo sterilization, but age and parity must be considered during the counseling process to minimize the potential for regret.

While the client's wishes should be paramount, she should understand that young age and possibly low parity are risk factors for regret.

### Rationale

Age at time of sterilization has been found to be a risk factor for regret in both women and men. Wilcox et al., in a prospective study based on 7,590 U.S. women followed-up for five years, found that women less than 30 years of age at sterilization were two to three times more likely to report regret than those sterilized between 30 and 35 years of age. This effect was independent of number of living children or marital status at the time of sterilization. Young age has also been found to be a major factor in other U.S. studies and in studies of women in Canada and Puerto Rico.

- 1) Wilcox LS, Chu SY, Eaker ED, Zeger SL, Peterson HB. Risk factors for regret after tubal sterilization: 5 years of follow-up in a prospective study. *Fertility and Sterility* 1991;55:927-33.
- 2) Henshaw SK, Singh S. Sterilization regret among U.S. couples. *Family Planning Perspectives* 1986;18:238-40.
- 3) Marcil-Gratton N. Sterilization regret among women in metropolitan Montreal. *Family Planning Perspectives* 1988;20:222-7.
- 4) Boring CC, Rochat RW, Becerra J. Sterilization regret among Puerto Rican women. *Fertility and Sterility* 1988;49:973-81.

Parity has often been discussed as a risk factor for regret in women. Several major studies have not found parity to be a significant predictor of regret. However, some experts suspect that parity may still be an important predictor of regret in some cultures.

- 1) Pitaktepsombati P, Janowitz B. Sterilization acceptance and regret in Thailand. *Contraception* 1991;44:623-37.
- 2) Leader A, Galan N, George R, Taylor P. A comparison of definable traits in women requesting reversal of sterilization and women satisfied with sterilization. *American Journal of Obstetrics and Gynecology* 1983;145:198-202.
- 3) Wilcox LS, Chu SY, Eaker ED, Zeger SL, Peterson HB. Risk factors for regret after tubal sterilization: 5 years of follow-up in a prospective study. *Fertility and Sterility* 1991;55:927-33.
- 4) Boring CC, Rochat RW, Becerra J. Sterilization regret among Puerto Rican women. *Fertility and Sterility* 1988;49:973-81.
- 5) Henshaw SK, Singh S. Sterilization regret among U.S. couples. *Family Planning Perspectives* 1986;18:238-40.
- 6) Marcil-Gratton N. Sterilization regret among women in metropolitan Montreal. *Family Planning Perspectives* 1988;20:222-7.

### Q.3. Is the husband's consent necessary before a woman undergoes female sterilization?

Recommendations	Rationale
<p>No. A husband's consent should not be mandatory for a woman to have a sterilization. However, the woman may wish to discuss the decision with her husband and family.</p>	<p>Control over the decision to undergo sterilization is a significant factor in regret. Two studies reported that women who decided alone or with their husbands showed markedly less regret than those cases in which the decision was made solely by the husband.</p> <ol style="list-style-type: none"> <li>1) Boring CC, Rochat RW, Becerra J. Sterilization regret among Puerto Rican women. <i>Fertility and Sterility</i> 1988;49:973-81.</li> <li>2) Shain RN, Miller WB, Holden AEC. Married women's dissatisfaction with tubal sterilization and vasectomy at first-year follow-up: effects of perceived spousal dominance. <i>Fertility and Sterility</i> 1986;45:808-19.</li> </ol>

### Q.4. What is the principal variable associated with requests for reversal after female sterilization?

Recommendations	Rationale
<ol style="list-style-type: none"> <li>a) The factor most strongly associated with regret is <b>young age</b>.</li> <li>b) Other factors which may increase regret are changes in marital status or partners, the death of a child, low parity, decision made by partner, sterilization for medical reasons, post-cesarean section sterilization and perhaps, postpartum sterilization.</li> </ol> <p>However, the incidence of regret even with these factors remains low. Counseling is important to minimize the incidence of regret.</p>	<p>a-b) Age at time of sterilization has been found to be a risk factor for regret in both women and men. A large prospective study of U.S. women followed-up for five years found that women less than 30 years of age at sterilization were two to three times more likely to report regret than those sterilized between 30 and 35 years of age. This effect was independent of number of living children or marital status at the time of sterilization. Young age has also been found to be a major factor in other U.S. studies and in studies of women in Canada and Puerto Rico.</p> <ol style="list-style-type: none"> <li>1) Wilcox LS, Chu SY, Eaker ED, Zeger SL, Peterson HB. Risk factors for regret after tubal sterilization: 5 years of follow-up in a prospective study. <i>Fertility and Sterility</i> 1991;55:927-33.</li> <li>2) Henshaw SK, Singh S. Sterilization regret among U.S. couples. <i>Family Planning Perspectives</i> 1986;18:238-40.</li> <li>3) Marcil-Gratton N. Sterilization regret among women in metropolitan Montreal. <i>Family Planning Perspectives</i> 1988;20:222-7.</li> <li>4) Boring CC, Rochat RW, Becerra J. Sterilization regret among Puerto Rican women. <i>Fertility and Sterility</i> 1988;49:973-81.</li> <li>5) Peterson HB, Xia Z, Hughes JM, Wilcox LS, Tylor LR, Trussell J. The risk of pregnancy after tubal sterilization: findings from the U.S. collaborative review of sterilization. <i>American Journal of Obstetrics and Gynecology</i> 1996; 174:1161-70.</li> </ol>

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**Q.4. Requests for reversal?** (continued)

Recommendations	Rationale
	<p>a-b) Parity has often been discussed as a risk factor for regret in women. Several major studies have not found parity to be a significant predictor of regret. However, some experts suspect that parity may still be an important predictor of regret in some cultures.</p> <p>Timing of procedure has also been reported as a possible risk factor for regret in women. Clients who underwent each type of postpartum procedure have been compared to interval clients in a range of studies. An increase in regret in women who had female sterilization concurrent with cesarean section was found in some studies when compared to a group having interval procedures. Likewise, women who had a vaginal delivery followed by postpartum sterilization had an increased incidence of regret in some data sets, but not in others.</p> <ol style="list-style-type: none"><li>1) Pitaktepsombati P, Janowitz B. Sterilization acceptance and regret in Thailand. <i>Contraception</i> 1991;44:623-37.</li><li>2) Leader A, Galan N, George R, Taylor P. A comparison of definable traits in women requesting reversal of sterilization and women satisfied with sterilization. <i>American Journal of Obstetrics and Gynecology</i> 1983;145:198-202.</li><li>3) Wilcox LS, Chu SY, Eaker ED, Zeger SL, Peterson HB. Risk factors for regret after tubal sterilization: 5 years of follow-up in a prospective study. <i>Fertility and Sterility</i> 1991;55:927-33.</li><li>4) Boring CC, Rochat RW, Becerra J. Sterilization regret among Puerto Rican women. <i>Fertility and Sterility</i> 1988;49:973-81.</li><li>5) Peterson HB, Xia Z, Hughes JM, Wilcox LS, Tylor LR, Trussell J. The risk of pregnancy after tubal sterilization: findings from the U.S. collaborative review of sterilization. <i>American Journal of Obstetrics and Gynecology</i> 1996;174:1161-70.</li></ol>

**Q.5. Should there be a required waiting period before female sterilization for a woman who has been counseled and has chosen female sterilization?**

Recommendations	Rationale
<p>No. If a woman has been counseled and has made an informed choice of female sterilization, no waiting period should be required. However, if it does not pose a barrier to access and the woman is using another contraceptive method so that she is not at risk of pregnancy, it is often beneficial for the woman to have time to think about her decision.</p> <p>For cases associated with delivery (post-vaginal delivery, postpartum or concurrent with cesarean section), it is recommended that counseling occur well in advance of delivery, wherever possible, to minimize the chances of regret following the decision. If counseling cannot be provided in the antenatal period, it may be provided in the immediate postpartum period once the woman is past the major stress of labor and delivery and has no residual effects of anesthesia or sedatives.</p>	<p>For postpartum minilaparotomy, counseling should take place well in advance of delivery, at a time when the woman is under minimal stress. During counseling, the woman should be told that if she changes her mind or if the condition of the baby is unstable, she can choose not to have the sterilization after giving birth. If she will give birth away from the hospital, she should be counseled that she must come to the hospital within seven days (preferably within 48 hours) or wait until at least four to six weeks after delivery for an interval procedure. If FP counseling has not been provided during the antepartum period, it should be included in postpartum services.</p> <p>1) Neamatalla GS, Harper PB. Family planning counseling and voluntary sterilization. New York: AVSC International, 1990.</p>

## Q.6. Does post-female sterilization syndrome exist?

Recommendations	Rationale
<p>No, based on the weight of the evidence. The existence of post-female sterilization syndrome, in which women report having menstrual changes following female sterilization, has not been confirmed in large studies.</p> <p>The changes reported by these women seem to be related to aging or stopping the use of oral contraceptives, not to the procedure.</p>	<p>For many years there has been controversy over whether or not a "post-female sterilization syndrome" truly exists. The varying definitions of post-female sterilization syndrome usually refer to menstrual symptoms such as dysmenorrhea, heavy bleeding or spotting and changes in cycle length or regularity. It has also been suggested that those methods of occlusion resulting in more extensive damage to the fallopian tubes and mesosalpinx may be more likely to cause subsequent changes in menstrual function.</p> <p>Some criticism faulted early studies on menstrual irregularities following sterilization for a failure to account for other factors leading to a change in menstrual function following sterilization such as pre-sterilization use of oral contraceptives possibly masking underlying menstrual dysfunction. Recent prospective studies that accounted for these confounding factors have failed to find a significant difference in the change in menstrual function between sterilized and non-sterilized women over time.</p> <p>Most studies of menstrual change following sterilization have had periods of follow-up for one to two years, and have found no increase in risk of menstrual change. Studies with follow-up periods longer than one year have been inconsistent in their findings.</p> <ol style="list-style-type: none"><li>1) Rulin MC, Davidson AR, Philliber SG, Graves WL, Cushman LF. Changes in menstrual symptoms among sterilized and comparison women: a prospective study. <i>Obstetrics and Gynecology</i> 1989;74:149-54.</li><li>2) DeStefano F, Perlman JA, Peterson HB, Diamond EL. Long-term risk of menstrual disturbances after tubal sterilization. <i>American Journal of Obstetrics and Gynecology</i> 1985;152:835-41.</li></ol>

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## Q.6. Post-female sterilization syndrome (continued)

Recommendations	Rationale
	<p>Studies looking at laboratory determinations of hormone levels as a possible mechanism for the post-female sterilization syndrome have yielded little useful information. Many studies compare women undergoing sterilization to controls but do not measure the subjects' hormone levels preoperatively. Studies that did measure such levels preoperatively found no changes following sterilization (but these studies contained small numbers of women).</p> <ol style="list-style-type: none"><li>1) Alvarez F, Faundes A, Brache V, Tejada AS, Segal S. Prospective study of the pituitary-ovarian function after tubal sterilization by the Pomeroy or Uchida techniques. <i>Fertility and Sterility</i> 1989;51:604-8.</li><li>2) Rivera R, Gaitan J, Ruiz R, Hurley D, Arenas M, Flores C, et al. Menstrual patterns and progesterone circulating levels following different procedures of tubal occlusion. <i>Contraception</i> 1989; 40(2):157-69.</li><li>3) Garza-Flores J, Vazquez-Estrada L, Reyes A, Valero A, Morales Del Olmo A, Alba V, et al. Assessment of luteal function after surgical tubal sterilization. <i>Advances in Contraception</i> 1991;7:371-7.</li></ol>

## Q.7. Are back-up contraceptive methods necessary after female sterilization?

Recommendations	Rationale
<p>No. There is no need to use a back-up method for contraceptive purposes.</p> <p>However, female sterilization offers no protection against STDs and HIV. For women who are at risk of STDs following a sterilization, protection should be recommended.</p>	<p>Sterilization is immediately effective. Women may resume having intercourse a week after the procedure, or when it is comfortable, without the need for a contraceptive.</p> <p>Clients should be encouraged to use barrier methods (e.g., condoms) when they are at risk for these diseases. Two studies conducted in the U.S. found poor use of condoms by sterilized women with potential risk factors for STDs/HIV. Both studies point out the need for counseling about client and partner behaviors associated with STD/HIV infection, and the use of condoms for prevention of infection, not just as a contraceptive.</p> <ol style="list-style-type: none"><li>1) Santelli JS, Burwell LG, Rozsenich C, Augustyn M, Celentano DD, et al. Surgical sterilization among women and use of condoms-Baltimore, 1989-1990. <i>MMWR</i> 1992;41:568-75.</li><li>2) Armstrong KA, Samost L, Tavis DR. HIV-risk behaviors of sterilized and nonsterilized women in drug treatment programs-Philadelphia, 1989-1991. <i>MMWR</i> 1992;41:149-51.</li></ol>

## Q.8. What is the long-term risk of pregnancy following female sterilization?

Recommendations	Rationale
<p>a) The <u>cumulative</u> probability of becoming pregnant in <u>10 years</u> is estimated to be <u>0.8%</u> following partial removal of the tube for <u>postpartum sterilization</u>, and <u>2.0%</u> following <u>interval sterilization</u> (based on U.S. data).</p> <p>Female sterilization is the most effective long-term FP method, other than vasectomy. Female sterilization is particularly effective when performed by <u>partial removal of the tube</u>, as with minilaparotomy, either:</p> <ul style="list-style-type: none"> <li>• immediately postpartum, or</li> <li>• at six or more weeks after delivery (interval sterilization).</li> </ul> <p>In general, women sterilized at young ages have higher failure rates than women sterilized at older ages.</p>	<p>a) Female sterilization is the only permanent female FP method. Annual pregnancy rates for minilaparotomy using partial salpingectomy, commonly the Pomeroy and Parkland techniques, are very low, but when failure occurs it is more often in the first or second years after surgery. Rarely do pregnancies occur after five years.</p> <p>The best data come from a long-term US study. This study reports that the cumulative pregnancy rates <u>during the first five years</u> and <u>for years six through ten</u> are:</p> <ul style="list-style-type: none"> <li>• for postpartum partial salpingectomy, 0.6 and 0.1 per 100 women, respectively;</li> <li>• for laparoscopic silicone bands, 1.0 and 0.8 per 100 women; and</li> <li>• for interval partial salpingectomy, the study does not have good, unbiased data. However, it may be reasonable to estimate the rates for interval partial salpingectomy as similar to the postpartum rates because studies in the past have demonstrated the interval procedure to be as or more effective than when performed postpartum.</li> </ul> <p>Experts assume that the extremely low pregnancy rates in years six through ten will continue through years 11-20, which is very important for women wanting no more children. Because pregnancies are rare events following female sterilization, accurate pregnancy rates are difficult to determine from international data sources such as the <i>Demographic and Health Surveys (DHS)</i>, and therefore are not routinely reported with pregnancy rates for other methods.</p> <ol style="list-style-type: none"> <li>1) Peterson HB, Xia Z, Hughes JM, Wilcox LS, Tylor LR, Trussell J. The risk of pregnancy after tubal sterilization: findings from the U.S. collaborative review of sterilization. <i>American Journal of Obstetrics and Gynecology</i> 1996;174:1161-70.</li> <li>2) Female sterilization: a guide to provision of services. Geneva: WHO, 1992.</li> <li>3) Moreno L, Goldman N. Contraceptive failure rates in developing countries: evidence from the demographic and health surveys. <i>International Family Planning Perspectives</i> 1991;17:44-9.</li> </ol>

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## Q.8. Long-term risk of pregnancy (continued)

Recommendations	Rationale
<p>b) The <u>10 year cumulative pregnancy rate is 1.8%</u> for tubal sterilization by laparoscopy using <u>silicone bands</u>. Silicone bands are the most common laparoscopic female sterilization method outside North America and Western Europe. Female sterilization by laparoscopy using silicone bands is equally effective as interval minilaparotomy techniques.</p> <p>c) The <u>10 year cumulative ectopic pregnancy rate is 0.73%</u> for all methods of tubal sterilization combined.</p>	<p>b) Laparoscopic female sterilization by spring clip and bipolar electrocoagulation result in higher cumulative 10 year pregnancy rates, 3.7 and 2.5 per 100 women (whereas the 10 year pregnancy rate for a postpartum partial salpingectomy is 0.8 per 100 women). However, these laparoscopic occlusion techniques are used infrequently outside North America and Western Europe.</p> <p>1) Peterson HB, Xia Z, Hughes JM, Wilcox LS, Tylor LR, Trussell J. The risk of pregnancy after tubal sterilization: findings from the U.S. collaborative review of sterilization. <i>American Journal of Obstetrics and Gynecology</i> 1996;174:1161-70.</p> <p>c) The 10 year cumulative ectopic pregnancy rates were higher in women who were younger than 30 at the time of the sterilization compared to women who were 30 or older at the time of the procedure, and in women who were sterilized by bipolar coagulation compared to women sterilized by any other method.</p> <p>1) Peterson HB, Xia Z, Hughes JM, Wilcox LS, Tylor LR, Trussell J. The risk of ectopic pregnancy after tubal sterilization. <i>New England Journal of Medicine</i> 1997;336:762-7.</p>

## Q.9. Who can provide female sterilization?

Recommendations	Rationale
<p>Female sterilization can be provided by any health professional who has been appropriately trained to perform a minilaparotomy (interval or postpartum). Minilaparotomy can be successfully performed by properly trained doctors, medical officers, nurses, nurse midwives, and other health personnel with surgical experience.</p>	<p>Various types of doctors, including general medical practitioners, general surgeons, and other specialists (such as obstetrician-gynecologists), can receive training to perform minilaparotomy, as can paramedical professionals (such as midwives) who routinely perform surgery in a country. It is important that candidates selected for training be interested in and supportive of voluntary sterilization as a FP choice. In addition, trainees who have demonstrated their surgical ability and who have prior experience in abdominal surgery are suitable to be trained in minilaparotomy and management of surgical complications. Those with no or minimal previous abdominal surgery experience may be safely trained to competently perform minilaparotomy in settings where surgical backup is available on site or by referral.</p> <ol style="list-style-type: none"><li data-bbox="826 1030 1349 1073">1) Minilaparotomy under local anesthesia: service delivery guidelines. New York: AVSC International, May 1996</li><li data-bbox="826 1073 1422 1112">2) AVSC International. Safe and voluntary surgical contraception. New York: AVSC International, 1988.</li></ol>

## Q.10. What is the appropriate follow-up schedule after female sterilization?

Recommendations	Rationale
<p>One follow-up visit seven days following sterilization or within 14 days is strongly recommended to check on the healing of the wound and to remove any sutures.</p> <p>The woman should be encouraged to come back promptly if she has any problems (such as fever, pain, bleeding, or pus) or at any time if she has questions or concerns.</p>	<p>The follow-up examination should take place between seven and 14 days after surgery. If nonabsorbable sutures were used, removal after seven days increases the risk of infection.</p> <p>1) World Health Organization. Female sterilization: a guide to provision of services. Geneva: WHO, 1992.</p> <p>There is no medical benefit to routine long term follow-up, although women should be encouraged to seek medical care for general health reasons. In addition, women should receive counseling on warning signs that would necessitate a return to the provider.</p>

## Q.11. Should female sterilization be considered permanent?

Recommendations	Rationale
<p>Yes. Although there are procedures to reverse a female sterilization, the operation is complex and expensive and the success rate depends on several factors (such as the surgeon's experience with the reversal procedure, age of the client, the type of sterilization the client received, average tubal length, and site of anastomosis).</p> <p>Although some studies have reported high success rates, the live birth rates are lower than the "success" rates reported because "success" is often defined as an intrauterine pregnancy and includes both births and miscarriages. Only a small fraction of the total number of women who request removal are likely to have a successful reversal procedure.</p>	<p>Reversing sterilization is a complex and expensive procedure.</p> <p>Rouzi et al. found that age and average tubal length were significant factors in predicting success of sterilization reversals. Other predictive factors are the type of sterilization procedure and surgeon's experience.</p> <p>Siegler et al. reviewed the literature and found that although the overall pregnancy rate from seven studies was 67.7%, the live birth rate was only 54.4%. Glock et al. looked at sterilization reversals in women over age 40 and found a live birth rate of 14.3% and a spontaneous abortion rate of 23.8%.</p> <p>1) Ross J, Hong S, Huber D. Voluntary sterilization: an international fact book. New York: AVSC International, 1985.</p> <p>2) Rouzi A, Mackinnon M, McComb P. Predictors of success of reversal of sterilization. <i>Fertility and Sterility</i> 1995;64(1):29-36.</p> <p>3) Siegler A, Hulka J, Peretz A. Reversibility of female sterilization. <i>Fertility and Sterility</i> 1985; 43(4):499-510.</p> <p>4) Dubuisson J, Chapron C, Nos C, Morice P, Aubriot F, Garnier P. Sterilization reversal: fertility results. <i>Human Reproduction</i> 1995;10(5):1145-51.</p> <p>5) Glock J, Kim A, Hulka J, Hunt R, Trad F, Brumsted J. Reproductive outcomes after tubal reversal in women 40 years of age or older. <i>Fertility and Sterility</i> 1996;65(4):863-5.</p>

## Classification of Selected Procedures for Female Sterilization (continued)

Procedure	Class GENERAL ANESTHESIA	Class LOCAL ANESTHESIA	Rationale
Pelvic examination (speculum and bimanual)	A	A	A pelvic exam is required to assess the size, position and mobility of the uterus prior to surgery.
Blood pressure	A	B	Hypertension increases the anesthesia risks associated with female sterilization procedures. Postural hypotension increases the risk of the procedure <sup>1</sup> .
Breast examination	C	C	A breast exam is not necessary to ensure a safe female sterilization procedure.
STD screening by lab tests (for asymptomatic persons)	C	C	STD screening by lab tests is not necessary for a female sterilization.
Cervical cancer screening	C	C	Cervical cancer screening is unrelated to the female sterilization procedure.
Routine, mandatory lab tests (e.g., cholesterol, glucose, liver function tests)	C	C	Cholesterol levels, glucose levels and liver function do not affect the female sterilization procedure.
Hemoglobin level testing	B	B	<ul style="list-style-type: none"> <li>• A hemoglobin level is recommended before female sterilization. If a woman has symptomatic anemia, delay the procedure and treat the anemia<sup>1</sup>.</li> <li>• If hemoglobin testing cannot be done, clinical assessment of anemia is satisfactory, particularly when using local anesthesia with light sedation.</li> </ul>
Urine sugar testing	B	B	Undetected diabetes may delay wound healing or increase risk of post-operative infection <sup>1</sup> .

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**KEY:**

**Class A** = essential and mandatory or otherwise important in all circumstances, for safe and effective use of the contraceptive method

**Class B** = medically/epidemiologically rational in some circumstances to optimize the safe and effective use of the contraceptive method, but may not be appropriate for all clients in all settings

**Class C** = may be appropriate for good preventive health care, but not materially related to safe and effective use of the contraceptive method

**Class D** = not materially related to either good routine preventive health care or to the safe and effective use of the contraceptive method

## Classification of Selected Procedures for Female Sterilization (continued)

Procedure	Class GENERAL ANESTHESIA	Class LOCAL ANESTHESIA	Rationale
Proper infection prevention procedures	A	A	Proper infection prevention procedures are important to minimize the risk of infection to clients and providers.
Specific counseling points for female sterilization: <ul style="list-style-type: none"> <li>• irreversibility of method</li> <li>• efficacy</li> <li>• common side effects</li> <li>• signs and symptoms for which to see a health provider</li> <li>• STD protection (when/as appropriate)</li> <li>• pre-operation instructions</li> <li>• recovery/post-operation instructions</li> </ul>	A	A	<ul style="list-style-type: none"> <li>• Proper counseling is important to ensure informed consent prior to having a sterilization operation.</li> <li>• Proper counseling may also minimize future regret.</li> <li>• Female sterilization should be considered a permanent contraceptive method.</li> </ul>

### Citations for Procedures Table:

- 1) World Health Organization. Improving access to quality care in family planning: medical eligibility criteria for contraceptive use. Geneva: WHO, 1996.

### KEY:

- Class A** = essential and mandatory or otherwise important in all circumstances, for safe and effective use of the contraceptive method
- Class B** = medically/epidemiologically rational in some circumstances to optimize the safe and effective use of the contraceptive method, but may not be appropriate for all clients in all settings
- Class C** = may be appropriate for good preventive health care, but not materially related to safe and effective use of the contraceptive method
- Class D** = not materially related to either good routine preventive health care or to the safe and effective use of the contraceptive method

## 1.2 Vasectomy

This section outlines recommendations on the following selected procedural questions for Vasectomy:

1. Are there any medical restrictions by **client's age, number of living children, or required waiting period** for a man to undergo vasectomy?
2. Is a **wife's consent** necessary before a man undergoes vasectomy?
3. **Who** can provide vasectomies?
4. Are **back-up contraceptive methods** necessary after a vasectomy?
5. What is the appropriate **follow-up schedule** after a vasectomy?
6. Does vasectomy cause **adverse long term health effects**?
7. Should a vasectomy be considered **permanent**?

**Q.1. Are there any medical restrictions by client's age, number of living children or required waiting period for a man to undergo vasectomy?**

Recommendations	Rationale
<p>a) <b>Age or number of living children?</b>            No. In terms of safety, there are no age or number of living children medical restrictions for a man to undergo sterilization, but both must be considered during the counseling process to minimize the potential for regret.</p> <p>While the client's wishes should be paramount, he should understand that young age is a risk factor for regret.</p> <p>b) <b>Waiting period?</b>            No. If a man has been counseled and has chosen a vasectomy, no waiting period should be required. However, it is often beneficial for the man to have time to think about his decision.</p> <p>However, the incidence of regret, even with young age at time of vasectomy, remains low. Counseling is important to minimize the potential for regret.</p>	<p>a-b) Age and number of living children are not medical reasons to restrict access to vasectomy according to WHO Medical Eligibility Criteria. However, age and number of living children are important considerations for the counseling process. Clarke and Gregson found that men who requested vasectomy reversal were younger at the time of sterilization than controls.</p> <ol style="list-style-type: none"> <li>1) World Health Organization. Improving access to quality care in family planning: medical eligibility criteria for contraceptive use. Geneva: WHO, 1996.</li> <li>2) Clarke L, Gregson S. Who has a vasectomy reversal? Journal of Biosocial Science 1986;18:253-69.</li> </ol> <p>Other factors that have been associated with vasectomy regret are remarriage or a change in partner, death of one or more children after the procedure, improvement in financial status, and more rarely, psychological problems with infertility or other physical problems. However, vasectomy has not been shown to physically cause adverse health effects (see Question 6).</p> <ol style="list-style-type: none"> <li>1) Male sterilization. Population Reports 1983;Series D(4):61-100.</li> </ol>

## Q.2. Is a wife's consent necessary before a man undergoes vasectomy?

Recommendations	Rationale
<p>No. A wife's consent should not be mandatory for a man to have a vasectomy. However, the man may wish to discuss the decision with his wife and family.</p>	<p>There are no studies on male regret based on the influence of the wife's consent on the decision for a vasectomy. In general, the literature supports the finding that couples that reach a decision together are more satisfied with their decision.</p> <ol style="list-style-type: none"><li data-bbox="834 619 1419 666">1) Boring CC, Rochat RW, Becerra J. Sterilization regret among Puerto Rican women. <i>Fertility and Sterility</i> 1988;49:973-81.</li><li data-bbox="834 666 1446 749">2) Shain RN, Miller WB, Holden AEC. Married women's dissatisfaction with tubal sterilization and vasectomy at first-year follow-up: effects of perceived spousal dominance. <i>Fertility and Sterility</i> 1986;45:808-19.</li></ol>

## Q.3. Who can provide vasectomies?

Recommendations	Rationale
<p>Vasectomies can be provided by any health professional who has been properly trained to perform a vasectomy. Properly trained doctors, medical officers, nurses, nurse midwives, and other medical personnel with surgical experience can successfully perform vasectomies.</p>	<p>Various types of doctors, including general medical practitioners, general surgeons, other specialists (such as obstetrician-gynecologists) and paramedical professionals can receive training to perform vasectomy.</p> <ol style="list-style-type: none"><li data-bbox="846 1538 1459 1613">1) AVSC International. No-scalpel vasectomy: a training course for vasectomy providers and assistants. New York: AVSC International, 1997. In press.</li></ol>

## Q.4. Are back-up contraceptive methods necessary after a vasectomy?

Recommendations	Rationale
<p>Yes. Although a man may have intercourse two or three days after the procedure if it is comfortable, a vasectomy is not immediately effective. The recommendations are for back-up methods to be used for 12 weeks following vasectomy or at least 20 ejaculations. Where programmatically feasible, a semen analysis should be performed at that time to check that the semen no longer contains sperm.</p> <p>It is important to recognize that a vasectomized man may still be at risk of acquiring or transmitting STDs and may need to use a back-up method (e.g., condoms) to protect himself and his partner(s).</p>	<p>It may take several months for the vas to clear the sperm contained in it at the time of vasectomy. This time varies from man to man. Therefore a back-up method for pregnancy prevention (e.g., condoms, DMPA for partner) will need to be used for at least 12 weeks or 20 ejaculations.</p> <p>1) Brownlee H, Tibbels C. Vasectomy. <i>Journal of Family Practice</i> 1983;16(2):279-84.</p>

## Q.5. What is the appropriate follow-up schedule following a vasectomy?

Recommendations	Rationale
<p>One follow-up visit within 7 to 14 days following a vasectomy is recommended to check incision sites, remove any sutures, and look for signs of complications. If feasible, a semen analysis can be performed after 20 ejaculations or 12 weeks to verify that azoospermia has been achieved.</p> <p>The client should be encouraged to return promptly if he has any problems (e.g., bleeding, swelling, fever, pain) or at any time he has questions or concerns.</p>	<p>The follow-up examination should take place between 7 and 14 days after surgery. Clients should receive counseling for warning signs and reasons to return for follow-up.</p>

## Q.6. Does vasectomy cause adverse long-term health effects?

Recommendations	Rationale
<p>a) No, based on the weight of available evidence. Studies have not been conclusive as to a possible increased risk of prostate cancer. Although several studies found no association, two studies found a slight increase in risk.</p> <p>A large study also found no association between vasectomy and other health effects including cardiovascular disease.</p> <p>b) Vasectomy does not affect normal sexual function. After a vasectomy, the man's body continues to produce male hormones which help the man to have erections, sex drive/feeling, and ejaculation. A man may even feel his sex drive is increased because he no longer worries about getting his partner pregnant.</p>	<p>a) Based on biological and epidemiological evidence, it is unlikely that vasectomy causes prostate cancer or any other long-term health effects such as cardiovascular disease.</p> <p>A recent study and two earlier studies also examined the association between vasectomy and prostate cancer. Zhu et al. used a population-based case-control design in a population where vasectomy was common. No association was found. Massey et al. and Sidney et al. both used a cohort study design. The former used a retrospective cohort of 10,590 vasectomized men while the later used a prospective cohort with a mean follow-up period of 6.8 years among 5119 vasectomized men. Neither study found an association between prostate cancer and vasectomy. Giovannucci et al. found odds ratios of 1.56 and 1.66, respectively, in two separate cohort studies. However, the biological explanation for the association has not been accepted by experts as likely.</p> <ol style="list-style-type: none"> <li>1) Healy B. From the National Institutes of Health: does vasectomy cause prostate cancer? <i>Journal of the American Medical Association</i> 1993;269:2620.</li> <li>2) Zhu K, Stanford JL, Daling JR, McKnight B, Stergachis, Brawer MK, Weiss NS. Vasectomy and prostate cancer: a case-control study in a health maintenance organization. <i>American Journal of Epidemiology</i> 1996;144:717-22.</li> <li>3) Massey FJ Jr., Bernstein GS, O'Fallon WM, Schuman LM, Coulson AH, Crozier R, et al. Vasectomy and health: results from a large cohort study. <i>Journal of the American Medical Association</i> 1984;252:1023-9.</li> <li>4) Sidney S, Quesenberry CP, Sadler MC, Guess HA, Lydick EG, Cattolica EV. Vasectomy and the risk of prostate cancer in a cohort of multiphasic health-checkup examinees: second report. <i>Cancer Causes and Control</i> 1991;2:113-6.</li> <li>5) Giovannucci E, Tosteson TD, Speizer FE, Ascherio A, Vessey MP, Colditz GA. A retrospective cohort study of vasectomy and prostate cancer in US men. <i>Journal of the American Medical Association</i> 1993;269:878-82.</li> <li>6) Giovannucci E, Ascherio A, Rimm EB, Colditz GA, Stampfer MJ, Willett WC. A prospective cohort study of vasectomy and prostate cancer in US men. <i>Journal of the American Medical Association</i> 1993;269:873-7.</li> </ol> <p>b) Vasectomy only involves the occlusion of two small ducts, not the removal of any glands or organs. Therefore, it does not interfere with the functions of the testes- testosterone production and spermatogenesis.</p> <ol style="list-style-type: none"> <li>1) Dias P. The long-term effects of vasectomy on sexual behaviour. <i>Acta Psychiatrica Scandinavia</i> 1983;67(5):333-8.</li> </ol>

## Q.7. Should a vasectomy be considered permanent?

Recommendations	Rationale
<p>Yes. Although there are procedures to reverse a vasectomy, the operation is very complex and expensive and the success rate depends on several factors, such as, type of reversal procedure, the physician's experience with the reversal procedure, time since the vasectomy was performed, the client's sperm quality and quantity, the anatomical effects of the original vasectomy, the presence of sperm antibodies, and the client's partner's fertility.</p> <p>Although reports have found sperm in the ejaculate in more than 67% of the men who had undergone vasectomy reversal, the percent of successes, as measured by pregnancies among their partners, ranged from 16 to 85 percent, with over half of the studies reporting that less than 50% of the wives achieved an intrauterine pregnancy.</p>	<p>A vasectomy reversal is an extremely complex operation that should be performed by highly trained and experienced surgeons. Microsurgical techniques require approximately 40 hours of intensive training in addition to frequent practice before a surgeon is proficient. Vasectomy reversal may be performed using micro- or macrosurgical techniques, each with its own advantages and disadvantages.</p> <p>Belker et al. and Fox found that the fertility rate after the vasectomy reversal decreased as the time between the reversal and the original vasectomy increased. The fertility rate can also be affected by postoperative scarring of the lumen, a lack of sperm in the ejaculate, and possibly the presence of sperm antibodies.</p> <ol style="list-style-type: none"> <li>1) Male Sterilization. Population Reports 1983;Series D(4):61-100.</li> <li>2) Ross J, Hong S, Huber D. Voluntary sterilization: an international fact book. New York : AVSC, 1985.</li> <li>3) Marmar J. The status of vasectomy reversals. International Journal of Fertility 1991;36(6):352-7.</li> <li>4) Belker A, Thomas A, Fuchs E, Konnak J, Sharlip I. Results of 1,469 microsurgical vasectomy reversals by the vasovasotomy study group. Journal of Urology 1991;145:505-11.</li> <li>5) Fox M. Vasectomy reversal - microsurgery for best results. British Journal of Urology 1994;73:449-53.</li> </ol>

## Classification of Selected Procedures for Vasectomy

Procedure	Class	Rationale
Genital examination	A	Required to rule out scrotal pathology.
Blood pressure	C	Blood pressure not related to safe use of vasectomy <sup>1</sup> .
STD screening by lab tests (for asymptomatic persons)	C	There are no required lab exams for vasectomy in asymptomatic persons <sup>1</sup> .
Routine, mandatory lab tests (e.g., cholesterol, glucose, liver function tests)	D	There are no required lab exams for vasectomy.
Proper infection prevention procedures	A	Proper infection prevention procedures are important to minimize the risk of infection to clients and providers.
Specific counseling points for male sterilization: <ul style="list-style-type: none"> <li>• efficacy</li> <li>• use of a back-up method (See Question 4)</li> <li>• irreversibility of method</li> <li>• common side effects</li> <li>• signs and symptoms for which to see a health provider</li> <li>• STD protection (when/as appropriate)</li> <li>• Post-operation counseling</li> </ul>	A	<ul style="list-style-type: none"> <li>• Proper counseling is important to ensure informed consent prior to having a sterilization operation.</li> <li>• Proper counseling may also minimize future regret.</li> <li>• Vasectomy should be considered a permanent contraceptive method.</li> </ul>

### Citations for Procedures Table:

- 1) World Health Organization. Improving access to quality care in family planning: medical eligibility criteria for contraceptive use. Geneva: WHO, 1996.

### KEY:

- Class A** = essential and mandatory or otherwise important in all circumstances, for safe and effective use of the contraceptive method
- Class B** = medically/epidemiologically rational in some circumstances to optimize the safe and effective use of the contraceptive method, but may not be appropriate for all clients in all settings
- Class C** = may be appropriate for good preventive health care, but not materially related to safe and effective use of the contraceptive method
- Class D** = not materially related to either good routine preventive health care or to the safe and effective use of the contraceptive method

## 1.3 Combined Injectable Contraceptives

This section outlines recommendations on the following selected procedural questions for Combined Injectable Contraceptives (CICs):

1. When is the **best time to start CICs**?
  - a) in general?
  - b) postpartum (breastfeeding and non-breastfeeding)?
  - c) postabortion?
2. In what **site(s)** can the injection of CICs be safely given?
3. **When** can the **next injection** be provided?
4. Is it appropriate for CICs to be provided if **infection prevention** measures cannot be followed?
5. Should CICs be discontinued because of **extended amenorrhea**?
6. If a woman complains of **heavier menses and/or prolonged bleeding**, is there a medical basis for discontinuing CICs?
7. Who can safely **initiate and re-supply** CICs?
8. Are there some **drugs that may decrease the effectiveness** of CICs?
9. What is the recommendation for the once-a-month injectable contraceptive with **10 mg of estradiol enanthate and 150 mg of dihydroxyprogesterone acetophenide (Deladroxate)**?

## Combined Injectable Contraceptives

The name of Combined Injectable Contraceptives (CICs) is given to a group of hormonal contraceptives administered by intramuscular injection. The term "combined" indicates that these injectables contain both a progestin and an estrogen. At present there are 3 main types of CICs on the market:

Progestin	Natural Estrogen	Brand Names
depo-medroxyprogesterone acetate (DMPA) 25 mg	estradiol cypionate 5 mg	Cyclofem
norethisterone enanthate (NET-EN) 50 mg	estradiol valerate 5 mg	Mesigyna
dihydroxyprogesterone acetophenide 150 mg	estradiol enanthate 10 mg	Deladroxate, Perlutal, Patector, Topasel, and others

The first 2 are new products approved by World Health Organization (WHO), which are becoming more widely used throughout the world; the latter is mostly used in some Latin American countries. The 3 formulations provide very effective pregnancy protection for a 30-day period, therefore, they are also referred to as "monthly injectables".

CICs have some similarities with progestin-only injectables: the 2 new CICs contain precisely the same progestin as the 2 most widely used progestin-only injectables (Depo Provera® and Noristerat); however, the progestin dose received over time is much lower with the new CICs. The basic difference between CICs and progestin-only injectables is the presence of estrogen in the CICs; the estrogen was incorporated mostly to improve the regularity of the menstrual cycle.

Although CICs and combined oral contraceptives (COCs) are combined hormonal contraceptives, they have several differences. Besides the different route of administration, from a safety point of view, the most important difference is the presence of a "natural" estrogen in the CICs versus a "synthetic" estrogen in the COCs. It is now recognized that natural estrogens have very favorable effects on lipid metabolism and cardiovascular function. The use of natural estrogens in post-menopausal women has actually shown to have a protective effect against cardiovascular disease, including both cerebrovascular and cardiac problems. Estradiol has direct effects on the arterial wall and on various stages of the atherosclerotic plaque formation, resulting in an increase in tissue blood flow, and in an anti-atherosclerotic effect. The addition of a progestin to the estradiol (in CICs) has not been shown to lessen these beneficial effects.

Based on the above evidence, CICs might actually be considered safer than COCs. However, due to the recent introduction of the 2 new CICs, no long-term safety information on the use of these CICs is available yet. Therefore, the current medical criteria for CIC use are mostly derived from the information existing on COC use.

### Citations:

- 1) World Health Organization, Task Force on Long-acting Systemic Agenda for Fertility Regulation, Special Programme of Research, Development and Research Training in Human Reproduction. A multicentered phase III comparative study of 2 hormonal contraceptive preparations given once-a-month by intramuscular injection: I. contraceptive efficacy and side-effects. *Contraception* 1988;37:1-20.
- 2) Garza-Flores J. Pharmacokinetics of once-a-month injectable contraceptives. *Contraception* 1994;49(4):347-59.
- 3) Lobo RA, Speroff L. International consensus conference on post menopausal hormone therapy and the cardiovascular system. *Fertility and Sterility* 1994;61(4):592-5.
- 4) Chester AH, Jiang C, Borland JA, Yacoub MH, Collins P. Oestrogen relaxes human epicardial coronary arteries through non-endothelium-dependent mechanisms. *Coronary Artery Disease* 1995;6(5):417-22.

## Q.1. When is the best time to start CICs?

Recommendations	Rationale
<p>a) <b>In general?</b></p> <p>CICs can be started anytime the provider can be reasonably sure the woman is not pregnant (see Appendix A).</p> <p>There are two views on when Cyclofem and Mesigyna should be initiated, one based on the initiation period of the clinical trials studying the efficacy of these CICs, and the other on the analogy between the two lower dose CICs and COCs (and on the analogy between an older CIC and COCs).</p> <p>WHO and other experts recommend that Cyclofem and Mesigyna (Norigynon) are given within the first 5 days of the menstrual cycle. If this is done, no back-up method is required. If the provider is reasonably sure that the woman has not been exposed to the risk of pregnancy during that cycle, CICs can be started after the first 5 days, provided that a back-up method is used for 7 days.</p> <p>Other experts recommend that if these CICs are given within the first 7 days of the menstrual cycle, no back-up method is necessary. If CICs are started after the first 7 days of a cycle and the provider is reasonably sure that the woman has not been exposed to the risk of pregnancy since her last menstrual period, or if the woman does not have menstrual cycles, a back-up method is recommended to be used for 7 days.</p>	<p>a) Since lower dose CICs are only now becoming more widely available, current WHO recommendations are based on the results of clinical trials. For Cyclofem and Mesigyna (two newer, lower dose formulations of CICs), all clinical trials have used the first 5 days of the cycle as the period for initiation. But the possibility of extending the window for the first injection to day 7 of a menstrual cycle is under investigation.</p> <p>However, some experts believe that the lower dose CICs are effective at least as promptly as COCs, and could be safely initiated within the first 7 days of the menstrual cycle. These CICs have slightly less of an estrogen effect and more of a progestin effect than COCs, and it is presumed that their effect on cervical mucus is at least as prompt as the effect of COCs. In addition, starting within the first 7 days of the menstrual cycle lowers the possibility of beginning CICs while the client is already pregnant.</p> <p>Analogous to COCs, the higher dose CIC, Deladroxate, is begun within the first 7 days of the cycle: Koetsawang states that Deladroxate should be given within the first 7 days of the cycle (and notes that in his review of 19 efficacy studies, no pregnancies occurred in more than 30,000 woman-months of use).</p> <ol style="list-style-type: none"> <li>1) Koetsawang S. Once-a-month injectable contraceptives: efficacy and reasons for discontinuation. <i>Contraception</i> 1994;49(4):387-98.</li> <li>2) Coutinho EM, Spinola P, Barbosa I, Gatto M, Tomaz G, Morais K, et al. Multicenter, double-blind, comparative clinical study on the efficacy and acceptability of a monthly injectable contraceptive combination of 150 mg dihydroxyprogesterone acetophenide and 10 mg estradiol enanthate compared to a monthly injectable contraceptive combination of 90 mg dihydroxyprogesterone acetophenide and 6 mg estradiol enanthate. <i>Contraception</i> 1997;55:175-81.</li> </ol>

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**Q.1. Best time to start?** (continued)

Recommendations	Rationale
<p><b>b) Postpartum for breastfeeding women?</b></p> <p>CICs can be started 6 months postpartum. Because they contain estrogen, WHO considers the health risks from using CICs during breastfeeding from 6 weeks to 6 months postpartum to generally outweigh the benefits (Category 3), unless other methods are not available or acceptable. Before 6 weeks postpartum, the risks are considered to be unacceptable (Category 4).</p> <p><b>Postpartum for non-breastfeeding women?</b></p> <p>CICs can be started in the third week postpartum or at the first postpartum menstruation.</p> <p><b>c) Postabortion?</b></p> <p>CICs can be initiated anytime within the first week after an abortion.</p>	<p><b>b) There are no data on the effects of combined injectables used during lactation. The following rationale is based on what is known about COCs.</b></p> <p>Even low dose (30 mcg) COCs decrease breastmilk production; it may be that estrogen-containing injectables, although they have a lower estrogen dose than COCs, will have a similar effect but this has not been studied.</p> <ol style="list-style-type: none"> <li>1) WHO Task Force on Oral Contraceptives. Effects of hormonal contraceptives on milk volume and infant growth. <i>Contraception</i> 1984;30(6):505-21.</li> <li>2) World Health Organization. Improving access to quality care in family planning: medical eligibility criteria for contraceptive use. Geneva: WHO, 1996.</li> </ol> <p>Blood coagulation and fibrinolysis are essentially normalized by 3 weeks postpartum (and are close to normal at 2 weeks postpartum). Although CICs have minor effects on blood coagulation, in the immediate postpartum period there may be an increased risk of venous thromboembolism, though less than that associated with COCs in this period.</p> <ol style="list-style-type: none"> <li>1) Dahllman T, Hellgren M, Blomback M. Changes in blood coagulation and fibrinolysis in the normal puerperium. <i>Gynecologic and Obstetric Investigation</i> 1985;20(1):37-44.</li> <li>2) Giwa-Osagie O, WHO Task Force on Long-Acting Systemic Agents for Fertility Regulation. Metabolic effects of once-a-month combined injectable contraceptives. <i>Contraception</i> 1994;49(5):421-33.</li> <li>3) World Health Organization. Improving access to quality care in family planning: medical eligibility criteria for contraceptive use. Geneva: WHO, 1996.</li> </ol> <p><b>c) CICs may be initiated anytime after a first or second trimester abortion, or post-septic abortion.</b></p> <ol style="list-style-type: none"> <li>1) World Health Organization. Improving access to quality care in family planning: medical eligibility criteria for contraceptive use. Geneva: WHO, 1996.</li> </ol>

## Q.2. In what site(s) can the injection of CICs be safely given?

Recommendations	Rationale
<p>Both the arm (deltoid) and the gluteal muscle are acceptable. The choice should be made by client preference. Injection should be deep intramuscular and should not be massaged.</p>	<p>The deltoid generally has greater acceptability and easier access for service providers.</p> <p>1) <i>Injectable Contraceptives: their role in family planning care.</i> Geneva: World Health Organization, 1990.</p> <p>Massaging at the site of injection is not recommended because massaging increases immediate absorption.</p>

## Q.3. When can the next injection be provided?

Recommendations	Rationale
<p>a) The best time to provide the next injection is on the same date each month (or a 4 week schedule may be practical for some programs). This should be emphasized when training the personnel and counseling the clients.</p> <p>The grace period of CICs is officially 3 days. If a client comes in after the grace period (33 days after the previous injection), advise her that delays in obtaining injections increase the risk of pregnancy. Offering re-injection for a woman who comes in after the grace period is reasonable for a woman who states that, once beyond the grace period, she has been abstaining or consistently using a back-up method, or if the provider can be reasonably sure that the woman is not pregnant (see Appendix A). Some programs will advise the woman to use a back-up method for 7 days.</p> <p>b) The fetus will be exposed to the injectable's hormones if the woman is pregnant when she receives the next injection.</p> <p>However, there is no evidence that fetal exposure to CICs will be harmful</p>	<p>a) Clinical trials have studied the efficacy of CICs given 27 to 33 days after the previous injection and found the efficacy to be very high. Some studies have found that the risk of ovulation is low up to 60 days after the previous Cyclofem or Mesigyna injection.</p> <p>1) Sang G. Pharmacodynamic effects of once-a-month combined injectable contraceptives. <i>Contraception</i> 1994;49(4):361-85.</p> <p>2) Aedo AR, Landgren BM, Jolannisson E, Diezfalusy E. Pharmacokinetic and pharmacodynamic investigations with monthly injectable contraceptive preparations. <i>Contraception</i> 1985;31(5):453-69.</p> <p>3) Bassol S, Garza-Flores J. Review of ovulation return upon discontinuation of once-a-month injectable contraceptives. <i>Contraception</i> 1994;49(5):441-53.</p> <p>b) Although the estrogens and progestins in CICs have no known teratogenic effects, avoiding fetal exposure is preferable on general principles.</p>

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**Q.3. When to provide next injection?** (continued)

Recommendations	Rationale
<p>c) It is acceptable to give the injection if you can be reasonably sure she is not pregnant (see Appendix A).</p>	<p>b) (continued)</p> <ol style="list-style-type: none"> <li>1) Simpson JL, Phillips OP. Spermicides, hormonal contraception and congenital malformations. <i>Advances in Contraception</i> 1990;6:141-67.</li> <li>2) Bracken MB. Oral contraception and congenital malformations in offspring: a review and meta-analysis of the prospective studies. <i>Obstetrics and Gynecology</i> 1990;76:552-7.</li> </ol>

**Q.4. Is it appropriate for CICs to be provided if infection prevention measures cannot be followed?**

Recommendations	Rationale
<p>No. All sites providing injectable contraceptives should follow basic infection prevention measures, including:</p> <ul style="list-style-type: none"> <li>• sterilizing needles and syringes (single use, disposable needles and syringes are preferred);</li> <li>• taking precautions to avoid sticking oneself or others with a used needle;</li> <li>• cleaning injection site; and</li> <li>• decontaminating reusable needles/syringes, and safely disposing of single-use needles/syringes.</li> </ul>	<p>Administering an injectable steroid contraceptive is an invasive procedure. Because an injection penetrates the protective skin barrier, the skin should be clean and the needle preferably sterile (high-level disinfection is acceptable).</p> <p>A major concern is the increasing problem of transmission of hepatitis and human immunodeficiency virus (HIV) to clients, health care providers and clinic staff, especially cleaning and housekeeping personnel. To minimize this risk, whenever possible, single-use (disposable) needles and syringes should be used. If reusable needles and syringes must be used, they should be decontaminated immediately after use by soaking in 0.5% chlorine solution or other locally available and approved disinfectant, then sterilized. If sterilization of reusable needles and syringes is impossible, high-level disinfection (HLD) – if correctly executed – may be used. These practices, when combined with the proper disposal of single-use needles and syringes, protect clinic staff, especially cleaning and housekeeping personnel, from contracting hepatitis B or HIV following accidental needle sticks.</p> <ol style="list-style-type: none"> <li>1) Tietjen L, Cronin W, McIntosh N. <i>Infection prevention for family planning service programs: a problem-solving reference manual.</i> Durant, OK: Essential Medical Information Systems, Inc., 1992.</li> </ol>

## Q.5. Should CICs be discontinued because of extended amenorrhea?

Recommendations	Rationale
<p>No. Amenorrhea is unusual in CIC users. Also, amenorrhea is not a contraindication to continuing use of CICs, even in the case of extended amenorrhea. However, some women may choose to stop CICs and their wishes should be respected.</p> <p>Emphasis should be on counseling, including reassurance that amenorrhea with combined injectables is safe.</p> <p>If symptoms or other reasons to suspect pregnancy exist, evaluate accordingly.</p>	<p>Amenorrhea is expected to occur in up to 3% of CIC users.</p> <p>Even when amenorrhea is present, pregnancy is an unlikely possibility provided that the injections have been given at the appropriate interval. In Latin America, the experience with Cyclofem showed no pregnancies in more than 10,000 women-months of use, and only 2 pregnancies in more than 10,000 women-months of use with Mesigyna. In Egypt, there were 2 and 4 pregnancies in over 10,000 women-months of use in women using Cyclofem and Mesigyna, respectively.</p> <p>Bleeding variations tend to decrease with time. Approximately 70% of combined injectables users experience regular monthly vaginal bleeding by the end of 1 year of use.</p> <ol style="list-style-type: none"><li>1) Fraser I. Vaginal bleeding patterns in women using once-a-month injectable contraceptives. <i>Contraception</i> 1994;49(4):399-420.</li><li>2) World Health Organization, Task Force on Long-acting Systemic Agents for Fertility Regulation, Special Programme of Research, Development and Research Training in Human Reproduction. A multicentred phase III comparative study of 2 hormonal contraceptive preparations given once-a-month by intramuscular injection: I. contraceptive efficacy and side effects. <i>Contraception</i> 1988;37:1-20.</li><li>3) Koetsawang S. Once-a-month injectable contraceptives: efficacy and reasons for discontinuation. <i>Contraception</i> 1994;49(4):387-98.</li><li>4) World Health Organization. Facts about once-a-month injectable contraceptives: memorandum from a WHO meeting. <i>Bulletin of the World Health Organization</i> 1993;71(6):677-89.</li></ol>

**Q.6. If a woman complains of heavier menses and/or prolonged bleeding, is there a medical basis for discontinuing CICs?**

Recommendations	Rationale
<p>a) Not usually. Heavy bleeding (greater than normal menstrual bleeding) is common in the first 3 months of use and usually does not require discontinuation.</p>	<p>a) Approximately 20% of CIC users experience frequent or prolonged menstrual bleeding within the first 3 months. However, these variations from normal bleeding patterns tend to decrease with time.</p>
<p>b) If bleeding has stopped and the woman wants to continue using CICs, she should first be reassured by informing her that these effects usually pose no threat to health and tend to improve over time.</p>	<p>b) Compared to women not using any contraceptive method, CIC users experience a significantly increased incidence of frequent, irregular or prolonged bleeding.</p>
<p>c) If a woman is experiencing more days of bleeding than she was prior to starting CICs, the first approach should be counseling to provide information and reassurance.</p> <p>If the bleeding is intolerable to the woman but she wishes to continue CICs, then administration of supplementary short term estrogen (or COCs) or prostaglandin inhibitors may be tried.</p>	<p>c) Little research has been done on the management of heavy bleeding in CIC users. Prolonged or heavy bleeding in users of COCs or progestin-only injectables may be managed by stabilizing the endometrium with increased doses of estrogen, or by ibuprofen (or related non-steroidal anti-inflammatory drugs) which blocks prostaglandin synthesis and thus decreases uterine bleeding.</p>
<p>d) Some women may not be able to tolerate heavy or prolonged bleeding and will discontinue CICs and need another method.</p> <p>Evaluate and address anemia if appropriate. Give nutritional advice on the need to increase the intake of iron-containing foods.</p>	<p>1) <i>Injectable contraceptives: their role in family planning care.</i> Geneva: World Health Organization, 1990.                  2) <i>Speroff L, Darney P. A clinical guide for contraception.</i> Baltimore: Williams &amp; Wilkins, 1996:179.</p>
<p>e) Do not perform uterine evacuation unless another medical condition is suspected (vacuum aspiration is usually the preferred method of uterine evacuation).</p>	

## Q.7. Who can safely initiate and re-supply CICs?

Recommendations	Rationale
<p>a) CICs (including immediate postpartum and postabortion injections) can be safely administered by appropriately trained service providers (e.g., nurses, midwives, pharmacists, community-based service (CBS) workers, and others), provided that infection prevention measures can be assured.</p> <p>b) Under certain circumstances, clients may be provided with the supplies for self-administration or administration by another individual, provided that appropriate storage and infection prevention procedures can be assured and that the woman knows where she can receive supportive services, should she have any problems.</p>	<p>a) Nurses, midwives, and other community health workers can be appropriately trained to initiate and re-supply injectables.</p> <p>1) Injectable contraceptives: their role in family planning care. Geneva: World Health Organization, 1990.</p> <p>b) Self-administration of injectables for family planning (FP) has not been studied in large scale programs, so clinical judgment about individual circumstances is required.</p>

## Q.8. Are there some drugs that may decrease the effectiveness of CICs?

Recommendations	Rationale
<p>Theoretically yes. Commonly used liver enzyme inducers (e.g., rifampin/rifampicin and most anticonvulsants) may reduce the efficacy of CICs. Use of other contraceptives should be encouraged for women who are on long term use of:</p> <ul style="list-style-type: none"> <li>• rifampin/rifampicin (an antibiotic), or</li> <li>• anticonvulsants, such as phenytoin, phenobarbitol, or carbamazepine.</li> </ul> <p>Other antibiotics should not affect the efficacy of CICs.</p>	<p>Little is known about the effects of other drugs on the effectiveness of CICs. However, based on COC data, anticonvulsants, such as phenytoin, phenobarbitol and carbamazepine, the antibiotic rifampin/rifampicin, and possibly the antifungal agent griseofulvin will require use of a back-up method to compensate for hepatic microsomal enzyme induction. Hepatic micro-enzyme induction by rifampin/rifampicin lasts for 4 weeks for short-term use and for 8 weeks for long-term use. Although anecdotal reports of failure to prevent pregnancy in COC users exist for other antibiotics, epidemiological evidence suggests that most antibiotics (except rifampin/rifampicin and griseofulvin) do not require use of a back-up method.</p> <p>1) Orme M, Back DJ. Oral contraceptive steroids – pharmacological issues of interest to the prescribing physician. <i>Advances in Contraception</i> 1991;7:325-31.</p>

**Q.9. What is the recommendation for the once-a-month injectable contraceptive with 10 mg of estradiol enanthate and 150 mg of dihydroxyprogesterone acetophenide (Deladroxate)?**

Recommendations	Rationale
<p>Use of the older injectable (10 mg of estradiol enanthate and 150 mg of dihydroxyprogesterone acetophenide), Deladroxate, is not encouraged due to the availability of newer, lower dose injectables (Mesigyna and Cyclofem). The newer CICs have theoretical advantages (lower estrogen dose) and more clinical trial data demonstrating their safety and efficacy.</p> <p>However, some women may prefer the more reliable menstrual periods produced by the CIC with 10 mg of estradiol enanthate and 150 mg of dihydroxyprogesterone acetophenide (this "menstrual signal" can serve as a reminder for reinjection), or may otherwise have a personal preference. The older CIC may be made available as it may be an appropriate choice for some women.</p>	<p>Both the older and newer CICs have very high efficacy. However, there is a theoretical concern of using 10 mg of estrogen monthly, because of the possible negative effects on blood coagulation. Newer CICs, such as Cyclofem and Mesigyna, have half of the estrogen dosage as the older CICs. The lower dose CICs have, at least theoretically, less risk.</p> <p>In the first year of use, the CICs with 10 mg of estradiol enanthate and 150 mg of dihydroxyprogesterone acetophenide, Deladroxate, cause an average incidence of menstrual irregularities in 22.4% of users, with a range of 7.5% to 24.4%. However, 30% of users of Cyclofem and Mesigyna experienced menstrual irregularities within the first year. The incidence of menstrual irregularities decreased with duration of use.</p> <ol style="list-style-type: none"> <li>1) World Health Organization. Facts about once-a-month injectable contraceptives: memorandum from a WHO meeting. <i>Bulletin of the World Health Organization</i> 1993;71(6):677-89.</li> <li>2) Koetsawang S. Once-a-month injectable contraceptives: efficacy and reasons for discontinuation. <i>Contraception</i> 1994;49(4):387-98.</li> </ol>

## Classification of Selected Procedures for Combined Injectable Contraceptives (CICs)

Procedure	Class	Rationale
Pelvic examination (speculum and bimanual)	C	<ul style="list-style-type: none"> <li>• A pelvic exam is not necessary to ensure safe use of injectables as a contraceptive method.</li> <li>• In some cases, a pelvic exam may help evaluate the question of pregnancy beyond 6 weeks duration. In this case, it is Class A.</li> </ul>
Blood pressure	B	CICs are not known to modify blood pressure, however due to the estrogen content, WHO has included very high blood pressure as an important eligibility criterion <sup>1</sup> .
Breast examination	B	CICs do <b>not</b> cause breast cancer. However, if the client has breast cancer, injectables should not be used. WHO considers current breast cancer to be Category 4 for CICs (use of the method with this condition is an unacceptable health risk) <sup>1</sup> .
STD screening by lab tests (for asymptomatic persons)	C	Presence of an STD will not affect the safe use of injectables.
Cervical cancer screening	C	Cervical screening is not needed for the safe use of injectables.
Routine, mandatory lab tests (e.g., cholesterol, glucose, liver function tests)	D	CICs do not modify cholesterol, glucose or affect the liver function.
Proper infection prevention procedures	A	Proper infection prevention procedures are important to minimize the risk of infection to clients and providers (see Question 4).

(continued on next page)

**KEY:**

- Class A** = essential and mandatory or otherwise important in all circumstances, for safe and effective use of the contraceptive method
- Class B** = medically/epidemiologically rational in some circumstances to optimize the safe and effective use of the contraceptive method, but may not be appropriate for all clients in all settings
- Class C** = may be appropriate for good preventive health care, but not materially related to safe and effective use of the contraceptive method
- Class D** = not materially related to either good routine preventive health care or to the safe and effective use of the contraceptive method

## Classification of Selected Procedures for Combined Injectable Contraceptives (CICs)

Procedure	Class	Rationale
Specific counseling points for CIC use: <ul style="list-style-type: none"> <li>• efficacy</li> <li>• common side effects, including alterations in bleeding patterns (e.g., frequent or irregular bleeding, anemia evaluation with heavy bleeding, extended amenorrhea, breakthrough bleeding)</li> <li>• correct use of method (including date of next injection and instructions for late injections)</li> <li>• signs and symptoms for which to see a health provider</li> <li>• need for STD protection (when/as appropriate)</li> </ul>	A	<ul style="list-style-type: none"> <li>• Proper counseling is important to ensure informed consent.</li> <li>• Appropriate counseling about common contraceptive side effects at the time of method selection can lead to improved client satisfaction and contraceptive continuation.</li> <li>• The woman should be encouraged to return if she has any problems or at any time she has questions or concerns.</li> </ul>

### Citations for Procedures Table:

- 1) World Health Organization. Improving access to quality care in family planning: medical eligibility criteria for contraceptive use. Geneva: WHO, 1996.

### KEY:

- Class A** = essential and mandatory or otherwise important in all circumstances, for safe and effective use of the contraceptive method
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- Class D** = not materially related to either good routine preventive health care or to the safe and effective use of the contraceptive method

## 1.4 Levonorgestrel-Releasing Intrauterine Devices

This section outlines recommendations on the following selected procedural questions for Levonorgestrel-Releasing intrauterine devices (LNg IUDs):

1. **When can an LNg IUD be inserted?**
  - a) in general?
  - b) postpartum (breastfeeding and non-breastfeeding)?
  - c) postabortion?
2. Should the LNg IUD be **discontinued** because of **extended amenorrhea or steroidal effects**?
3. Can an LNg IUD be used as a method of contraception in women with **heavy menstrual bleeding**?
4. **Because LNg IUDs might protect against pelvic inflammatory disease (PID)**, does this change the IUD eligibility of women at risk of sexually transmitted diseases (STDs)?
5. What is the **duration of use** for LNg IUDs?

**NOTE:** Since many questions concerning LNg IUDs have the same answers as for non-hormonal IUDs, please see Volume I of *Recommendations for Updating Selected Practices in Contraceptive Use* for answers to the following questions:

- What is an appropriate follow-up schedule after IUD insertion?
- Is there a need for a routine pre-exam (a separate visit) before IUD insertion?
- Is there a minimum or maximum age to receive IUDs?
- Can nulliparous women receive IUDs?
- Is there a need for a "rest period" with IUDs after a certain period of use?
- If a woman is at low risk of STDs based on history, may IUDs be inserted without any lab tests if there is not mucopurulent endocervical discharge or clinically apparent PID or cervicitis?
- Should an IUD be removed if the partner complains about the string?
- If the cervix is red due to eversion of the squamo-columnar junction (ectopy/ectropion), may the IUD be inserted without further investigation?
- Can IUDs be safely inserted by trained nurses and midwives?
- How much time should elapse between STD treatment and insertion? What about previous STD incidence?
- Should IUDs be provided if infection prevention measures cannot be followed?
- Following removal of an LNg IUD (for reasons of partial expulsion without infection, or expiration of IUD), should one wait to insert another?

## LNg - IUD Levonorgestrel-20 IUDs

The levonorgestrel-20 IUD (LNg IUD) releases about 20 micrograms of levonorgestrel into the uterine cavity daily, leading to:

- highly effective contraception rates (comparable to female sterilization) for five to seven years;
- decreased blood loss compared to other IUDs, and decreased blood loss for women with a history of heavy menses (although the mean number of bleeding days is higher than normal for the first few months, it becomes lower than normal by six to eight months of using the levonorgestrel IUD, with improvement in anemia due to menstrual blood loss);
- improvement in dysmenorrhea in most women;
- decreased risk for ectopic pregnancy; and
- possible use as the progestin necessary for a menopausal woman on estrogen replacement therapy.

The levonorgestrel IUD works in at least three ways:

1. by causing a thick cervical mucus which inhibits the passage of sperm through the cervical canal;
2. by causing anovulation in about 25% women; and
3. by causing high levonorgestrel levels in the uterine cavity, which suppress estradiol receptors and produce an atrophic endometrium, and inhibit passage of sperm through the uterine cavity.

Serum levonorgestrel levels are low, thus reports of hormonal side effects are few; no difference between LNg IUDs versus other IUDs has been reported concerning weight, blood pressure or lipid or carbohydrate metabolism. Because pituitary suppression is not strong, the LNg IUD does not cause a hypoestrogenic state.

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- 1) Luukkainen T, Toivonen J. Levonorgestrel-releasing IUD as a method of contraception with therapeutic properties. *Contraception* 1995;52:269-76.
- 2) Andersson K, Odland V, Rybo G. Levonorgestrel-releasing and copper-releasing (Nova T) IUDs during five years of use: a randomized comparative trial. *Contraception* 1994;49:56-72.
- 3) Intrauterine progestagen for effective contraception. *IPPF Medical Bulletin* 1992;26(4).
- 4) Hatcher RA. The levonorgestrel-20 IUD (monograph). Atlanta: Emory University 1997.

## Q.1. When can an LNG IUD be inserted?

Recommendations	Rationale
<p>a) <b>In general?</b> The LNG IUD may be inserted anytime during the menstrual cycle, at the user's convenience, when one can be reasonably sure the woman is not pregnant (see Appendix A).</p>	<p>a) All IUDs are effective immediately and prevent pregnancy if inserted before implantation.</p> <ol style="list-style-type: none"><li>1) Guillebaud J. Contraception: your questions answered. New York: Churchill Livingstone, 1993:293-366.</li></ol>
<p>b) <b>Postpartum for breastfeeding women?</b> The insertion of the LNG IUD is not usually recommended in the first six weeks postpartum in breastfeeding women (WHO Category 3).</p>	<p>b) The WHO Medical Eligibility Criteria list the use of LNG IUDs prior to four weeks postpartum as a Category 3 classification ("use of the method [is] not usually recommended unless other more appropriate methods are not available or acceptable"). Little research has been done on women initiating IUDs before six weeks. There is concern that breastfeeding infants may be at risk due to exposure to steroid hormones during the first six weeks postpartum. Levonorgestrel in maternal serum is low and infants receive only 0.1% of the maternal daily dose. Since there is virtually no risk of ovulating during the first six weeks postpartum in breastfeeding women, LNG IUDs may safely be begun after six weeks postpartum.</p> <ol style="list-style-type: none"><li>1) World Health Organization. Improving access to quality care: medical eligibility criteria for contraceptive use. Geneva: WHO, 1996.</li><li>2) Heikkila M, Haukkamaa M, Luukkainen T. Levonorgestrel in milk and plasma of breast-feeding women with a levonorgestrel-releasing IUD. Contraception 1982;25(1):41-9.</li><li>3) Heikkila M, Luukkainen T. Duration of breast-feeding and development of children after insertion of a levonorgestrel-releasing intrauterine contraceptive device. Contraception 1982;25(3):279-92.</li><li>4) Shikary ZK, Betrabet SS, Patel ZM, Patel S, Joshi JV, Toddywala VS, et al. Transfer of levonorgestrel (LNg) administered through different drug delivery systems from the maternal circulation into the newborn infant's circulation via breast milk. Contraception 1987;35(5):477-86.</li></ol>
<p><b>Postpartum for non-breastfeeding women?</b> The insertion of the LNG IUD is not usually recommended in the first four weeks postpartum for non-breastfeeding women (WHO Category 3).</p>	<p>There is an increased risk of perforation for IUD insertions done after 48 hours and up to four weeks postpartum. The risk varies by the experience of the provider. There is little data on the local effects of LNG IUD on uterine involution.</p>
<p>The LNG IUD may be inserted at four weeks postpartum or any time beyond that when you can be reasonably sure the woman is not pregnant.</p>	<ol style="list-style-type: none"><li>1) Chi I, Farr G. Postpartum IUD contraception-a review of an international experience. Advances in Contraception 1989;5:127-46.</li><li>2) O'Hanley K, Huber D. Postpartum IUDs: keys for success. Contraception 1992;45:351-61.</li></ol>

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**Q.1. Insert an LNg IUD?** (continued)

Recommendations	Rationale
<p><b>c) Postabortion?</b> The LNg IUD may be inserted immediately after a safe first-trimester abortion, in the absence of infection.</p>	<p>c) Data exists only for first trimester legal abortions with no or treated cervical infections. The LNg IUD may be inserted immediately postabortion; however, as with any IUD insertion, the woman must be evaluated for the presence of infection.</p> <p>1) Heikkila M, Lahteenmaki P, Luukkainen T. Immediate postabortal insertion of a levonorgestrel-releasing IUD. <i>Contraception</i> 1982;26(3):245-59.</p>

## Q.2 Should the LNG IUD be discontinued because of extended amenorrhea or steroidal effects?

Recommendations	Rationale
<p>a) <b>Extended amenorrhea?</b></p> <p>No. Amenorrhea is expected and is not a medical reason for removal. Emphasis should be on counseling, including reassurance that amenorrhea with LNG IUDs is to be expected and is safe, as well as counseling on the benefits of amenorrhea.</p> <p>However, if the woman does wish to have the LNG IUD removed, her wishes should be respected.</p>	<p>a) The intrauterine release of levonorgestrel converts the endometrium to a nonproliferative stage, which is insensitive to ovarian estradiol. The result of this complete suppression of the endometrium is a sharp reduction of the duration of bleeding and menstrual blood loss. The reduction of bleeding is so intensive that in about 20% of women there is no bleeding at all in spite of completely normal ovarian function; therefore, amenorrhea is common and normal for women using LNG IUDs.</p> <p>Women who are well informed about the possibility of amenorrhea may consider it to be a convenience/advantage. Also, hemoglobin levels increase with LNG IUD use, thereby benefiting women with anemia.</p> <ol style="list-style-type: none"> <li>1) Andersson K, Odland V, Rybo G. Levonorgestrel-releasing and copper-releasing (Nova T) IUDs during five years of use: a randomized comparative trial. <i>Contraception</i> 1994;49(1):56-72.</li> <li>2) Xiao B, Zeng T, Wu S, Sun H, Xiao N. Effect of levonorgestrel-releasing intrauterine device on hormonal profile and menstrual pattern after long-term use. <i>Contraception</i> 1995;51(6):359-65.</li> <li>3) Sivin I, Stern J, Coutinho E, Mattos CE, el Mahgoub S, Diaz S, et al. Prolonged intrauterine contraception: a seven-year randomized study of the levonorgestrel 20 mcg/day (LNg 20) and the copper T 380 Ag IUDs. <i>Contraception</i> 1991;44(5):473-80.</li> </ol>
<p>b) <b>Steroidal effects?</b></p> <p>No. However, the LNG IUD should be removed if the client experiences intolerable or unacceptable side effects, attributable either to the IUD or to systemic steroidal effects.</p>	<p>b) Steroidal side effects such as acne, weight change, nausea, headache, have been found to be prevalent in Nordic countries. However, the gross discontinuation rate due to all of these side effects was only 2.7 per 100 women in a European multicenter study.</p> <ol style="list-style-type: none"> <li>1) Luukkainen, T, Allonen H, Haukkamaa M, Holma P, Pyorala T, Terho J, et al. Effective contraception with the levonorgestrel-releasing intrauterine device: a 12-month report of a European multicenter study. <i>Contraception</i> 1987;36(2):169-79.</li> </ol>

### Q.3 Can an LNG IUD be used as a method of contraception for women with heavy menstrual bleeding?

Recommendations	Rationale
<p>Yes. The LNG IUDs can be used for treatment of women with heavy menstrual bleeding.</p>	<p>LNG IUDs decrease the menstrual blood loss (MBL) by about 80% at three months of use and by more than 95% at one year. With correct insertion, the LNG IUD does not cause prolonged or heavy bleeding. However, women should be told that in the first three months of use they may experience many days of spotting and bleeding.</p> <ol style="list-style-type: none"> <li>1) Luukkainen T, Allonen H, Haukkamaa M, Holma P, Pyorala T, Terho J, et al. Effective contraception with the levonorgestrel-releasing intrauterine device: a 12-month report of a European multicenter study. <i>Contraception</i> 1987;36(2):169-79.</li> <li>2) Andersson JK, Rybo G. Levonorgestrel-releasing intrauterine device in the treatment of menorrhagia. <i>British Journal of Obstetrics and Gynaecology</i> 1990;97(8):690-4.</li> <li>3) Milsom I, Andersson K, Andersch B, Rybo G. A comparison of flurbiprofen, tranexamic acid, and a levonorgestrel-releasing intrauterine device in the treatment of idiopathic menorrhagia. <i>American Journal of Obstetrics and Gynecology</i> 1991;164(3):879-83.</li> </ol> <p>The LNG IUD has also been used in treatment of menorrhagia. Reduction of MBL gives clients better iron balance and less anemia. The reduced bleeding can also relieve the symptoms of dysmenorrhea.</p> <ol style="list-style-type: none"> <li>1) Andersson JK, Rybo G. Levonorgestrel-releasing intrauterine device in the treatment of menorrhagia. <i>British Journal of Obstetrics and Gynaecology</i> 1990;97(8):690-4.</li> <li>2) Milsom I, Andersson K, Andersch B, Rybo G. A comparison of flurbiprofen, tranexamic acid, and a levonorgestrel-releasing intrauterine device in the treatment of idiopathic menorrhagia. <i>American Journal of Obstetrics and Gynecology</i> 1991;164(3):879-83.</li> <li>3) Faundes A, Alvarez F, Brache V, Tejada AS. The role of the levonorgestrel intrauterine device in the prevention and treatment of iron deficiency anemia during fertility regulation. <i>International Journal of Gynaecology and Obstetrics</i> 1988;26(3):429-33.</li> </ol>

**Q.4 Because LNG IUDs might protect against pelvic inflammatory disease (PID), does this change the IUD eligibility of women at risk of sexually transmitted diseases (STDs)?**

Recommendations	Rationale
<p>No. The evidence that LNG IUDs may protect against PID is not conclusive.</p> <p>The insertion of the LNG IUD is not usually recommended for women at increased risk of STDs or HIV, unless more appropriate methods are not available or are not acceptable. The LNG IUD should not be used in women with a current (or within the last three months) pelvic or sexually transmitted disease (STD). When there is a risk of STD or HIV, condoms should be recommended.</p>	<p>Evidence is conflicting as to a protective effect. One major study suggests that women using LNG IUDs have a lower risk of progression from STDs to PID, compared to users of copper IUDs. However, other major studies have not demonstrated a significant protection by LNG IUDs against PID. The preventive effect of LNG IUDs against PID is probably similar to the prevention provided by oral contraceptives (OCs).</p> <ol style="list-style-type: none"> <li>1) Toivonen J, Luukkainen T, Allonen H. Protective effect of intrauterine release of levonorgestrel on pelvic infection: three years' comparative experience of levonorgestrel- and copper-releasing intrauterine devices. <i>Obstetrics and Gynecology</i> 1991;77(2):261-4.</li> <li>2) Andersson K, Odland V, Rybo G. Levonorgestrel-releasing and copper-releasing (Nova T) IUDs during five years of use: a randomized comparative trial. <i>Contraception</i> 1994;49(1):56-72.</li> <li>3) Sivin I, Stern J, Coutinho E, Mattos CE, el Mahgoub S, Diaz S, et al. Prolonged intrauterine contraception: A seven-year randomized study of the levonorgestrel 20 mcg/day (LNg 20) and the Copper T380 Ag IUDs. <i>Contraception</i> 1991;44(5):473-80.</li> </ol> <p>No hormonal method prevents the transmission of STDs; however, the possible prevention of the progression of infection is a safety feature of this method of contraception in young women, compared to IUDs without progestin, or to use of no method at all.</p>

**Q.5 What is the duration of use for LNG IUDs?**

Recommendations	Rationale
<p>Currently, the LNG-20 IUD is technically approved for five years of use; however, evidence indicates that it actually will last for seven years.</p>	<p>It has been approved for five years of use in Europe. However, it has been shown to have low pregnancy rates through seven years. Studies are on-going.</p> <ol style="list-style-type: none"> <li>1) Sivin I, Stern J, Coutinho E, Mattos CE, el Mahgoub S, Diaz S, et al. Prolonged intrauterine contraception: a seven-year randomized study of the levonorgestrel 20 mcg/day (LNg 20) and the copper T 380 Ag IUDs. <i>Contraception</i> 1991;44(5):473-80.</li> </ol>

## Classification of Selected Procedures for Levonorgestrel IUDs (LNg IUDs)

Procedure	Class	Rationale
Pelvic examination (speculum and bimanual)	A	<ul style="list-style-type: none"> <li>• Bimanual and speculum exams are essential and mandatory before IUD use, to rule out contraindications (pregnancy, PID and endocervical infection, cervical lesions) and to determine uterine position in order to avoid perforation. If the woman is pregnant, presence of the IUD will lead to spontaneous abortion (miscarriage) in about half of all pregnancies, and there is significant risk of septic abortion<sup>1</sup>.</li> <li>• If a purulent endocervical discharge is present at the time the IUD is inserted through the cervical canal, bacteria in the canal may be introduced into the sterile uterine cavity and lead to PID<sup>2</sup>.</li> </ul>
Blood pressure	C	The use of this method does not affect blood pressure.
Breast examination	C	There is no evidence linking the LNg IUD to breast cancer. The LNg IUD provides a very low dose of progestin.
STD screening by risk assessment	A	Assessment of STD risk by personal history and socio-demographic risk factors is an essential procedure for identifying women at risk of PID.

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**KEY:**

- Class A =** essential and mandatory or otherwise important in all circumstances, for safe and effective use of the contraceptive method
- Class B =** medically/epidemiologically rational in some circumstances to optimize the safe and effective use of the contraceptive method, but may not be appropriate for all clients in all settings
- Class C =** may be appropriate for good preventive health care, but not materially related to safe and effective use of the contraceptive method
- Class D =** not materially related to either good routine preventive health care or safe and effective use of the contraceptive method

**Classification of Selected Procedures for  
Levonorgestrel IUDs (LNg IUDs)**  
(continued)

Procedure	Class	Rationale
STD screening by lab tests (for asymptomatic persons)	B	<ul style="list-style-type: none"> <li>• Assessment of STD risk by personal history and socio-demographic risk factors may be the most practical method of identifying women at risk for PID. The speculum and bimanual exam may also detect some STDs. When feasible, negative test results provide reassurance to corroborate the woman's history.</li> <li>• For those clients with a personal history or with socio-demographic risk factors which suggest high risk, the clients who still make an informed choice of an IUD must understand they may have an STD without any signs or symptoms. While negative STD lab tests would be somewhat reassuring in this circumstance, they will not alter the clients' future STD risk.</li> </ul>
Cervical cancer screening	C	<ul style="list-style-type: none"> <li>• IUD insertions and continued IUD use have no known relation to the risk of acquiring cervical carcinoma<sup>3</sup>.</li> <li>• Although WHO considers cervical cancer for IUD insertion to be Class 4 (a condition which represents an unacceptable health risk), clinically apparent cervical lesions are detectable from observation during a pelvic exam<sup>1</sup>.</li> </ul>
Routine, mandatory lab tests (e.g., cholesterol, glucose, liver function tests)	C	These tests are not necessary to perform before insertion.
Proper infection prevention procedures.	A	Proper infection prevention procedures are essential and mandatory to minimize the risk of infection to clients and providers.

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**KEY:**

- Class A** = essential and mandatory or otherwise important in all circumstances, for safe and effective use of the contraceptive method
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**Classification of Selected Procedures for  
Levonorgestrel IUDs (LNg IUDs)**  
(continued)

Procedure	Class	Rationale
<p>Specific counseling points for LNg IUDs:</p> <ul style="list-style-type: none"> <li>• efficacy</li> <li>• common side effects, including change in menses (irregular or absent menstrual bleeding)</li> <li>• correct use of method</li> <li>• signs and symptoms for which to see a health provider</li> <li>• STD protection (when/as appropriate), and counseling about condom use for women who are at high risk for STDs.</li> </ul> <p><i>NOTE: Women currently at high risk for STDs, in general, should not receive IUDs.</i></p> <ul style="list-style-type: none"> <li>• benefits (anemia and dysmenorrhea improved)</li> </ul>	A	<ul style="list-style-type: none"> <li>• Accurate client education is essential for maximum quality of family planning (FP) services.</li> <li>• Appropriate counseling about common contraceptive side effects at the time of method selection can lead to improved client satisfaction and contraceptive continuation.</li> <li>• Women at risk should be counseled on high risk behavior for contracting STDs and potential complications from IUD use.</li> <li>• The woman should be encouraged to return if she has any problems or at any time she has questions or concerns.</li> </ul>

**Citations for Procedures Table:**

- 1) World Health Organization. Improving access to quality care in family planning: medical eligibility criteria for contraceptive use. Geneva: WHO, 1996.
- 2) Mishell DR, Jr. Contraception, sterilization and pregnancy termination. In: Herbst AL, Mishell DR Jr., Stenchever MA, Droegemueller W, editors. Comprehensive Gynecology, second edition. St. Louis: Mosby Year Book, 1992: 295-362.
- 3) Lasse DL, Savitz DA, Hamman RF, Baron AE, Brinton LA, Levines RS. Invasive cervical cancer and intrauterine device use. International Journal of Epidemiology 1991;20(4):865-70

**KEY:**

- Class A** = essential and mandatory or otherwise important in all circumstances, for safe and effective use of the contraceptive method
- Class B** = medically/epidemiologically rational in some circumstances to optimize the safe and effective use of the contraceptive method, but may not be appropriate for all clients in all settings
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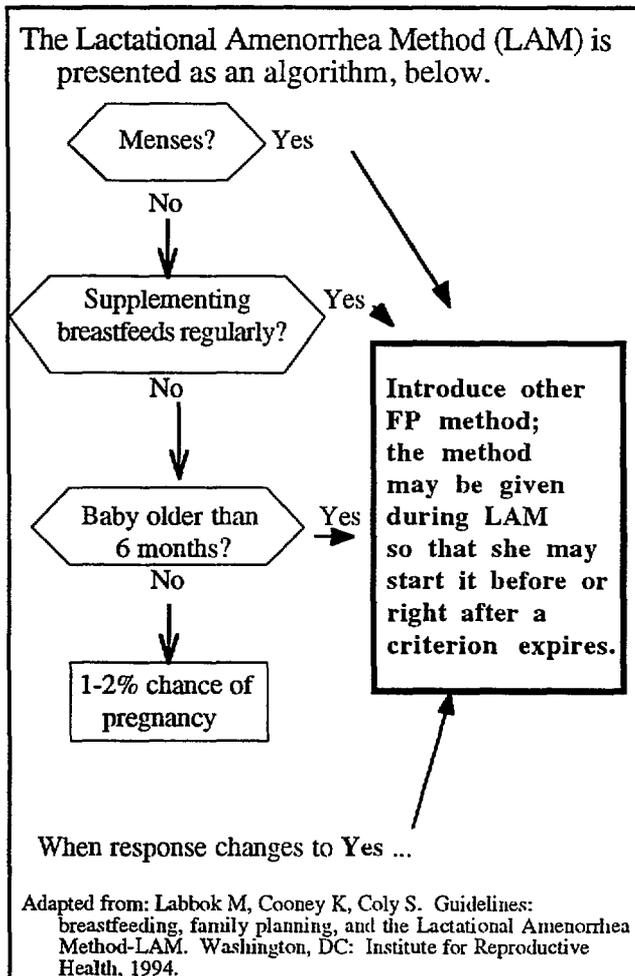
## 1.5 Lactational Amenorrhea Method

This section outlines recommendations on the following selected procedural questions for Lactational Amenorrhea Method (LAM):

1. When should LAM users **begin another method**?
2. Is **exclusive breastfeeding for the first six months** of a baby's life **safe** for the health of the mother and the baby?
3. Can LAM use be **extended beyond six months**?

## Lactational Amenorrhea Method

The Lactational Amenorrhea Method (LAM) was codified at a meeting in Washington, DC in 1989, based on research, program work, and the findings of the Bellagio Consensus Meeting of 1988. It was recently reassessed at a 1995 meeting in Bellagio, and is now considered an appropriate method for programmatic use.



LAM has three criteria:

1. **Amenorrhea**, defined as the absence of the menses.

Menses return is defined as the first two sequential days of bleeding or spotting which may occur **after** two months postpartum.

2. **Fully or nearly fully breastfeeding**, includes exclusive breastfeeding, almost exclusive breastfeeding, and nearly fully breastfeeding, day and night, on demand by the infant.

Efficacy and duration of LAM are enhanced with more intense breastfeeding patterns, especially during the earlier weeks and months.

3. **Less than six months postpartum.**

The effectiveness of LAM has been demonstrated in clinical trials and in programmatic use. As long as all three criteria are met, the method is about 98%-99% effective (perfect use). If any one of the criteria is unmet, the use of another method which is appropriate for use during breastfeeding should be recommended for continued high pregnancy protection.

The method allows deviation from the three criteria without a sudden increase in risk of unplanned pregnancy. Menses return is the least flexible. If a woman is no longer amenorrheic, she cannot use LAM.

If a woman has deviated only slightly from the fully or nearly fully breastfeeding criterion, she should be re-counseled about appropriate breastfeeding and may use LAM thereafter if she returns to nearly fully breastfeeding. Small amounts of other food or liquid which do not replace breastfeeds do not have a substantial effect on the woman's fertility. However, lowered frequencies of breastfeeding and regular supplementation to the infant's diet are associated with an increased risk of menses return and a higher probability that ovulation will precede that menses.

If an amenorrheic woman is separated from her infant and expresses milk, she may still use LAM. Milk expression by hand or pump may produce sufficient breast stimulation to prevent ovulatory activity. However, her risk of pregnancy is increased to 5 to 6%.

LAM can be taught during the prenatal, perinatal, or postnatal periods. Counseling on use of the method is very important. In order for LAM to provide effective protection against pregnancy, the method must be used consistently and correctly with another method started very soon after any of the LAM criteria no longer apply, particularly amenorrhea. It is recommended that the LAM user be provided with another method for self-initiation prior to menses return (See Question 1).

There are no medical contraindications to using LAM. However, there are a few conditions under which it is preferable not to breastfeed (e.g., if the mother is using a few specific drugs or has some infectious conditions, or if the infant has certain metabolic disorders). These conditions are discussed more fully in the WHO *Medical Eligibility Criteria for Contraceptive Use*.

The follow-up schedule for LAM should be similar to the follow-up schedule used for all temporary methods, with the understanding that before any one of the three criteria will no longer apply, the client should return for counseling and another method of family planning (FP).

#### Citations:

- 1) Kennedy KI, Rivera R, McNeilly AS. Consensus statement on the use of breastfeeding as a family planning method. *Contraception* 1989;39:477-96.
- 2) Kennedy KI, Labbok MH, Van Look PFA. Consensus statement on the Lactational Amenorrhea Method for family planning. *International Journal of Gynecology and Obstetrics* 1996;54:55-7.
- 3) Labbok M, Cooney K, Coyle S. Guidelines: breastfeeding, family planning, and the Lactational Amenorrhea Method-LAM. Washington, DC: Institute for Reproductive Health, 1994.
- 4) Perez A, Labbok ML, Queenan JT. Clinical study of the Lactational Amenorrhea Method for family planning. *Lancet* 1992;339:968-70.
- 5) Kazi A, Kennedy KI, Visness CM, Khan T. Effectiveness of the Lactational Amenorrhea Method in Pakistan. *Fertility and Sterility* 1995;64:717-23.
- 6) Labbok M, Perez A, Valdes V, Sevilla F, Wade K, Laukaran V, et al. The Lactational Amenorrhea Method: a new postpartum introductory family planning method. *Advances in Contraception* 1994;10:93-109.
- 7) Pugin E, Valdes V, Labbok M, Perez A, Aravena R. Does prenatal education contribute to the duration of full breastfeeding in a comprehensive breastfeeding promotion program? *Journal of Human Lactation* 1996;12:15-20.
- 8) Gray R, Campbell O, Eslanu S, Zaccur H, Labbok M, Apelo R. The return of ovarian function during lactation: results of studies from the United States and the Philippines. In Gray R (ed.) *Biomedical and Demographic Determinants of Reproduction*. Oxford: Clarendon Press, 1993.
- 9) Zinaman M, Hughes V, Queenan J, et al. Acute prolactin, oxytocin response and milk yield to infant suckling and artificial methods of expression in lactating women. *Pediatrics* 1992;89:437-40.
- 10) World Health Organization. Improving access to quality care in family planning: medical eligibility criteria for contraceptive use. Geneva: WHO, 1996.

## Q.1. When should LAM users begin another method?

Recommendations	Rationale
<p>a) Backup methods are not necessary while the LAM criteria are met. However, another method can be used during the period of LAM protection if the woman so wishes. Backup methods should be limited to methods that are appropriate for breastfeeding women.</p> <p>According to WHO, progestin-only methods (e.g., POPs, Depo Provera® NORPLANT®) should not be initiated before six weeks postpartum, and estrogen-containing methods (e.g. COCs, CICs) should not be started by breastfeeding women before six months postpartum.</p> <p>b) It is appropriate for a LAM user to have a contraceptive method on hand that she can initiate herself. A woman should have the opportunity to make an informed choice to begin any other method which is appropriate for her while she is still protected by LAM. She can then initiate that method when the LAM criteria no longer hold or she chooses to end reliance on LAM.</p> <p>c) If a woman using LAM becomes at risk for STDs, including HIV/AIDS, she may need to initiate use of condoms or other barrier methods for STD protection, in addition to LAM.</p>	<p>a) While the LAM criteria are met, LAM is a very effective contraceptive method.</p> <p>1) Perez A, Labbok M, Queenan J. Clinical study of the Lactational Amenorrhoea Method for family planning. <i>Lancet</i> 1992;339:968-70.</p> <p>Non-hormonal methods have no effect on lactation or the infant. Progestin-only methods have no known effect but are WHO Category 3 for theoretical concerns. Estrogenic methods should generally not be used by breastfeeding women prior to six months postpartum due to their effects on lactation (WHO Category 3/4).</p> <p>1) World Health Organization. Improving access to quality care in family planning: medical eligibility criteria for contraceptive use. Geneva: WHO, 1996.</p> <p>b) The method a LAM user has on hand (for use after she is no longer relying on LAM) may be a woman's chosen follow-up method, or it may be for use as a temporary complementary method until she has a chance to visit her family planning provider to procure the method she desires. A service provider can be reasonably sure that a LAM user is not pregnant provided that the LAM criteria are met. The provider can then provide the chosen method (as per the protocol for that method) before the end of LAM.</p> <p>1) Perez A, Labbok M, Queenan J. Clinical study of the Lactational Amenorrhoea Method for family planning. <i>Lancet</i> 1992;339:968-70.</p> <p>Having a contraceptive method on hand that the user can initiate herself when LAM expires (or when the woman no longer wishes to rely on LAM) is thought to have the potential of reducing the chance of a gap in protection.</p> <p>c) LAM does not offer protection from STDs or HIV. Clients at risk for these diseases should be encouraged to use barrier methods and counseled about behaviors that can decrease risk.</p>

## Q.2 Is exclusive breastfeeding for the first six months of a baby's life safe for the health of the mother and the baby?

Recommendations	Rationale
<p>a) Yes, with possible rare exceptions, exclusive breastfeeding is safe for the health of the mother. If the mother's nutritional status is very poor, it is generally preferable and less expensive to supplement the mother's diet, rather than the nursing infant's.</p> <p>It is important to address the woman's health and nutritional status. Adequate child spacing and sufficient food will help protect women's health.</p> <p>b) Yes, exclusive breastfeeding for six months is safe for the health of the baby. Giving food or water supplements to the baby introduces a higher risk of disease and death, and has minimal nutritional benefits.</p> <p><b>Note:</b> In some situations where a woman is known to be HIV-positive, WHO does not recommend breastfeeding. Breastfeeding women at risk for HIV should be advised that if they are HIV-positive, or acquire HIV during the course of lactation, there is a risk of transmitting the virus to their infants through their breastmilk. Where safe alternatives to breastmilk are not readily available, known HIV-positive women should still be advised to breastfeed; those women who are known HIV-positive and who can safely bottle-feed should be advised to do so.</p>	<p>a) Most women, even those who are moderately malnourished, are able to produce a sufficient quantity and quality of breastmilk to breastfeed exclusively for up to six months.</p> <ol style="list-style-type: none"> <li>1) Prentice AM, Goldberg GR, Prentice A. Body mass index and lactation performance. <i>European Journal of Clinical Nutrition</i> 1994;48(Suppl):S78-96.</li> <li>2) Krasovec K. The implications of poor maternal nutritional status during pregnancy for future lactational performance. <i>Journal of Tropical Pediatrics</i> 1991;37(Suppl):3-10.</li> <li>3) Huffman SL. Maternal malnutrition and breastfeeding: is there really a choice for policy makers? <i>Journal of Tropical Pediatrics</i> 1991;37(Suppl):19-22.</li> </ol> <p>b) Supplements given to the baby before six months usually displace breastmilk without adding calories or important nutritional benefits. In addition, breastmilk is protective against infant illnesses and deaths due to diarrhea and infectious diseases.</p> <ol style="list-style-type: none"> <li>1) Cohen RJ, Brown KH, Canahuati J, Rivera LL, Dewey KG. Effects of age of introduction of complementary foods on infant breast milk intake, total energy intake, and growth: a randomized intervention study in Honduras. <i>Lancet</i> 1994;343:288-93.</li> <li>2) Victora CG, Smith PG, Vaughan JP, Nobre LC, Lombardi C, Teixeira AMB, et al. Infant feeding and deaths due to diarrhea: a case-control study. <i>American Journal of Epidemiology</i> 1989;129(5):1032-41.</li> <li>3) Howie PW, Forsyth JS, Ogston SA, Clark A, du V Florey C. Protective effect of breast feeding against infection. <i>British Medical Journal</i> 1990;300:11-6.</li> <li>4) Victora CG, Vaughan JP, Lombardi C, Fuchs SM, Gigante LP, Smith PG, et al. Evidence for protection by breast-feeding against infant deaths from infectious diseases in Brazil. <i>Lancet</i> 1987; 2(8554):319-22.</li> </ol> <p>The growth pattern of breastfed infants differs from current reference standards, which are based on the growth pattern of bottlefed infants. This should not be interpreted as growth faltering as long as the infant continues to gain weight. All infants, however they are fed, should be monitored as a part of well-child care to be sure they are growing properly.</p> <ol style="list-style-type: none"> <li>1) Dewey KG, Pearson JM, Brown KH, Krebs NF, Michaelsen KF, Persson LA, et al. Growth of breast-fed infants deviates from current reference data: a pooled analysis of US, Canadian, and European data sets. <i>Pediatrics</i> 1995;96:495-503.</li> </ol>

### Q.3. Can LAM use be extended beyond six months?

Recommendations	Rationale
<p>a) The duration of LAM protection may be extended for a few months in amenorrheic women, in certain country situations, through support for optimal breastfeeding practices.</p>	<p>a) Prenatal breastfeeding education and information on LAM can increase the duration of breastfeeding, lactational amenorrhea, and LAM protection.</p>
<p>b) The extended versions of LAM (e.g., LAM-9, MAMA-9, LAM-12) are based on amenorrhea and maintenance of a high frequency pattern of breastfeeding, with fully or nearly fully breastfeeding, and with breastfeeding before each supplemental feed.</p>	<p>b) The probability of becoming pregnant during lactational amenorrhea is low during the first six months postpartum. While the risk of pregnancy during lactational amenorrhea is higher after six months postpartum, among women with intensive breastfeeding practices the failure rate for lactational amenorrhea up to one year postpartum is comparable to the perfect use failure rates for other reversible methods. However, more research is needed on the efficacy of the extended Lactational Amenorrhea Method.</p>
<p>Lactational amenorrhea beyond six months postpartum conveys a good deal of protection from pregnancy, although it provides less protection than in the first six months.</p>	<ol style="list-style-type: none"> <li>1) Pugin E, Valdez V, Labbok M, Perez A, Aravena R. Does prenatal education contribute to the duration of full breastfeeding in a comprehensive breastfeeding promotion program? <i>Journal of Human Lactation</i> 1996;12:15-20.</li> <li>2) Cooney KA, Nyirabukeye T, Labbok M, Hoser P, Ballard E. Assessment of the nine-month Lactational Amenorrhea Method (MAMA-9) in Rwanda. <i>Studies in Family Planning</i> 1996;24:162-71.</li> <li>1) Kennedy KI, Visness C. Contraceptive efficacy of lactational amenorrhoea. <i>Lancet</i> 1992;339:227-30.</li> <li>2) Kazi A, Kennedy KI, Visness C, Khan T. Effectiveness of the lactational amenorrhea method in Pakistan. <i>Fertility and Sterility</i> 1995;64:717-23.</li> <li>3) Ramos R, Kennedy KI, Visness C. Effectiveness of the Lactational Amenorrhea Method in preventing pregnancy in Manila, the Philippines. <i>British Medical Journal</i> 1996;313:909-12.</li> <li>4) Cooney KA, Nyirabukeye T, Labbok M, Hoser P, Ballard E. Assessment of the nine-month Lactational Amenorrhea Method (MAMA-9) in Rwanda. <i>Studies in Family Planning</i> 1996;24:162-71.</li> </ol>
<p>As with standard LAM, use of another method should be encouraged when menses return. If she is amenorrheic, before the woman ceases to fully or nearly fully breastfeed, she should return for counseling (either to continue relying on extended LAM, or for another contraceptive method if she wishes) (See Question 1).</p>	

## Classification of Selected Procedures for the Lactational Amenorrhea Method (LAM)

Procedure	Class	Rationale
Pelvic examination (speculum and bimanual)	C	<ul style="list-style-type: none"> <li>• A pelvic exam is not necessary to ensure safe use of LAM as a contraceptive method.</li> <li>• A pelvic exam may help evaluate the question of pregnancy. In this case, it is Class A.</li> </ul>
Blood pressure	C	LAM does not affect blood pressure.
Breast examination	C	<ul style="list-style-type: none"> <li>• In certain cases, examination of the breasts and appropriate counseling and/or treatment may assist women to successfully breastfeed. In this case, it is Class B.</li> <li>• LAM does not cause breast cancer. In fact, breastfeeding may reduce the risk of breast cancer<sup>1,2</sup>.</li> </ul>
STD screening by lab tests (for asymptomatic persons)	C	Clients at risk for STDs (by personal history or socio-demographic risk factors) should be offered STD screening, where possible. However, the presence of an STD, other than HIV, will not affect the safe use of LAM.
HIV screening	B	<ul style="list-style-type: none"> <li>• Breastfeeding women at risk for STDs, including HIV, should be advised that if they are HIV-positive or should acquire HIV during the course of lactation, there is a risk of transmitting the virus to their infants through their breastmilk<sup>3</sup>.</li> <li>• Where safe alternatives to breastmilk are not readily available, HIV-positive women should still be advised to breastfeed; those women who are HIV-positive and who can safely bottlefeed should be advised to do so<sup>4,5</sup>.</li> </ul>
Cervical cancer screening	C	Cervical cancer screening is not needed for the safe use of LAM <sup>6</sup> .
Proper infection prevention procedures	C	Infection prevention procedures are not applicable to LAM use.

(continued on next page)

**KEY:**

**Class A** = essential and mandatory or otherwise important in all circumstances, for safe and effective use of the contraceptive method

**Class B** = medically/epidemiologically rational in some circumstances to optimize the safe and effective use of the contraceptive method, but may not be appropriate for all clients in all settings

**Class C** = may be appropriate for good preventive health care, but not materially related to safe and effective use of the contraceptive method

**Class D** = not materially related to either good preventive health care or safe and effective use of the contraceptive method

## Classification of Selected Procedures for the Lactational Amenorrhea Method (LAM)

(continued)

Procedure	Class	Rationale
Specific counseling points for LAM: <ul style="list-style-type: none"> <li>• LAM criteria</li> <li>• efficacy</li> <li>• optimal breastfeeding behaviors</li> <li>• when and where to obtain follow-up method</li> <li>• signs and symptoms for which to see a health provider</li> <li>• STD protection (when/as appropriate)</li> </ul>	A	<ul style="list-style-type: none"> <li>• LAM is an educational method, so appropriate client counseling and education is of the utmost importance. LAM users must learn the three LAM criteria, the importance of using another method before the criteria no longer apply, and where they can receive the method of their choice. Counseling regarding the breastfeeding behaviors which are optimal for maintaining lactational infertility is also important<sup>7</sup>.</li> <li>• Accurate client education is essential for maximum quality of FP services.</li> </ul>

### Citations for Procedures Table:

1. United Kingdom National Case-Control Study Group. Breast feeding and risk of breast cancer in young women. *British Medical Journal* 1993;307:17-20.
2. Thomas DB, Noonan EA and the WHO Collaborative Study of Neoplasia and Steroid Contraceptives. Breast cancer and prolonged lactation. *International Journal of Epidemiology* 1993;22:619-26.
3. Van de Perre P, Simonon A, Msellati P, Hitimana D, Vaira D, Bazubagira A, et al. Postnatal transmission of human immunodeficiency virus type 1 from mother to infant. *New England Journal of Medicine* 1991;325:593-8.
4. Nicoll A, Newell M-L, Van Praag E, Van de Perre P, Peckham C. Infant feeding policy and practice in the presence of HIV-1 infection. *AIDS* 1995;9:107-19.
5. Van de Perre P. Postnatal transmission of human immunodeficiency virus type 1: the breast-feeding dilemma. *American Journal of Obstetrics and Gynecology* 1995;173:483-7.
6. World Health Organization. Improving access to quality care in family planning: medical eligibility criteria for contraceptive use. Geneva: WHO, 1996.
7. Labbok M, Cooney K, Coly S. Guidelines: breastfeeding, family planning, and the Lactational Amenorrhea Method-LAM. Washington, DC: Institute for Reproductive Health, 1994.

### KEY:

- Class A** = essential and mandatory or otherwise important in all circumstances, for safe and effective use of the contraceptive method
- Class B** = medically/epidemiologically rational in some circumstances to optimize the safe and effective use of the contraceptive method, but may not be appropriate for all clients in all settings
- Class C** = may be appropriate for good preventive health care, but not materially related to safe and effective use of the contraceptive method
- Class D** = not materially related to either good preventive health care or safe and effective use of the contraceptive method

## 1.6 Natural Family Planning

This section outlines recommendations on the following selected procedural questions for Natural Family Planning (NFP):

1. How **effective** are NFP methods?
2. **Who can use** NFP?
3. Can women who have **vaginal infections** use NFP?
4. **Who can teach** NFP?
5. How long does it take to **learn** NFP?
6. What **follow-up** schedule is recommended?
7. What client **counseling** is required?
8. Can a woman use NFP if she has **irregular cycles**?
9. Are there any **risks**, or harmful effects, of using NFP?
10. Can NFP be used to **select the sex** of a child?
11. Can NFP be **combined with other methods**?

# Natural Family Planning

The World Health Organization (1988) defines Natural Family Planning (NFP) as “Methods for planning and preventing pregnancies by observation of naturally occurring signs and symptoms of the fertile and infertile phases of the menstrual cycle, with the avoidance of intercourse during the fertile phase if pregnancy is to be avoided.”

NFP methods can be divided into two groups according to how the fertile time is identified:

## 1. *Identification Using Fertile Sign Indicators in the Current Cycle*

In which fertility signs (such as cervical mucus, basal body temperature (BBT), symptothermal methods, and others) are observed in the *current* cycle, and

## 2. *Identification Using a Calculation or Counting Days*

In which a formula is used to predict the fertile time using *past* cycle lengths. This approach is called the Calendar or Rhythm method.

NFP methods are based upon “fertility awareness” which is the basic information about male and female reproduction that helps people understand how and when a woman can become pregnant. NFP methods provide rules to guide couples how to time intercourse to either avoid or achieve a pregnancy, based upon their observations.

### **Lactational Amenorrhea Method (LAM)**

The Lactational Amenorrhea Method (LAM) is a method of family planning (FP) that is based upon the natural postpartum infertility that occurs when a woman is amenorrheic and fully breastfeeding her infant (see section on LAM for definitions and criteria for using LAM). When using LAM, the woman is not cycling normally. Therefore, LAM does not meet the criteria for a NFP method using the strict WHO definition. Nevertheless, LAM is a method based on observing naturally occurring signs (i.e. return of menses) and upon guidelines established with scientific research showing the relationship between LAM criteria and the return to fertility.

### **Combining NFP with other methods**

Methods which combine use of NFP methods and the use of a barrier method or withdrawal during the fertile time are referred to by various names including “Fertility Awareness Methods”, “Combined Methods”, “Mixed Methods”, or “Multi-Index Methods”. By definition, these methods are not considered to be NFP, because couples do not abstain from vaginal intercourse during the fertile time.

### **Citations:**

- 1) World Health Organization. Natural family planning: a guide to provision of services. Geneva: WHO, 1988.

## Q.1. How effective are NFP methods?

Recommendations	Rationale
<p>a) <b>NFP Effectiveness</b> Estimates of NFP effectiveness vary widely.</p> <p>b) <b>Calendar-based methods</b> Estimates from clearly reported trials which state the rule used range from 5% to 14%. A recent re-analysis of calendar method clinical studies found a typical failure rate estimate of about 20%.</p> <p>c) <b>Single indicator methods (basal body temperature (BBT), cervical mucus or ovulation methods)</b> Estimates range from 3% with perfect use to about 20% with typical use.</p>	<p>a) NFP effectiveness depends upon several factors, including:</p> <ul style="list-style-type: none"> <li>• the indicator(s) used,</li> <li>• the validity of the rules used,</li> <li>• the type and quality of teaching,</li> <li>• the ability of the woman to observe and interpret her fertility signs,</li> <li>• the ability of the couple to abstain from vaginal intercourse when indicated by the rules, and</li> <li>• individual characteristics of the couple, such as the age of the woman and her past history of pelvic infection or other determinants of lowered fertility.</li> </ul> <p>b) It is difficult to estimate the effectiveness of the calendar method because very few well-designed studies have been conducted. Many of the estimates are based upon surveys and do not report the requisite information required to calculate effectiveness rates. It is difficult to compare studies on the calendar method because many reports do not state what rule was used to identify the fertile time or if couples understood the basis for the method.</p> <ol style="list-style-type: none"> <li>1) Dicker D, Wachsman Y, Feldberg D. The vaginal contraceptive diaphragm and the condom: a reevaluation and comparison of two barrier methods with the rhythm method. <i>Contraception</i> 1989; 40(4):497-504.</li> <li>2) Laing J. Periodic abstinence in the Philippines: new findings from a national survey. <i>Studies in Family Planning</i> 1987;18(1):32-41.</li> </ol> <p>c) The probability of accidental pregnancy when using single indicator methods is highest when couples do not abstain during the fertile period. For users of the cervical mucus or ovulation methods, having intercourse during periods of stress on the woman also increases the risk of pregnancy by affecting the quality of mucus. Stress, illness, travel or interrupted sleep can disrupt a woman's typical biphasic pattern, thereby making it difficult to identify the fertile period for that cycle using the BBT method.</p> <ol style="list-style-type: none"> <li>1) World Health Organization. A prospective multicentre trial of the ovulation method of natural family planning II. The effectiveness phase. <i>Fertility and Sterility</i> 1981; 35(5):591-8.</li> <li>2) Trussell J, Grummer-Strawn L. Contraceptive failure of the ovulation method of periodic abstinence. <i>Family Planning Perspectives</i> 1990;22:65-75.</li> <li>3) Hatcher RA, Trussell J, Stewart F, Stewart GK, Kowal D, Guest F, et al. <i>Fertility Awareness</i>. In: <i>Contraceptive Technology</i>. New York: Irvington Publishers, 1994:327-40.</li> </ol>

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**Q.1. Effective** (continued)

Recommendations	Rationale
<p>d) <b>Two or more indicator methods (symptothermal methods)</b> Estimates range from about 2% with perfect use to about 15% to 20% with typical use.</p>	<p>d) The use of two or more indicators can be somewhat more effective than the use of a single indicator.</p> <ol style="list-style-type: none"><li>1) Hatcher RA, Trussell J, Stewart F, Stewart GK, Kowal D, Guest F, et al. Fertility Awareness. In: Contraceptive Technology. New York: Irvington Publishers, 1994:327-40.</li><li>2) Frank-Herrmann P, Freundl G, Baur S, Bremme M, Doring G, Godehardt E, et al. Effectiveness and acceptability of the symptothermal method of natural family planning in Germany. American Journal of Obstetrics and Gynecology 1991;165:2052-4.</li></ol>

**Q.2. Who can use NFP?**

Recommendations	Rationale
<p>a) Women in different stages of their reproductive lives can use NFP. However, certain NFP methods are inappropriate during long periods of anovulation, amenorrhea, or irregular cycles, e.g., the calendar method.</p>	<p>a) Most women who are regularly cycling can use NFP. Women who are post-menarche, postpartum, breastfeeding, postabortion, or peri-menopause can also use NFP. However, since the hormonal patterns are altered in these situations, a woman may find it more difficult to interpret her fertility signs and must follow special rules to track her fertility. The specific rules used will depend upon the circumstances and the NFP method chosen. Calendar-based methods are <i>not</i> recommended for women in the situations mentioned above because many of these cycles are not ovulatory and are often very irregular, requiring prolonged required abstinence intervals, which may be difficult for many couples.</p> <ol style="list-style-type: none"><li>1) World Health Organization and BLAT Centre for Health and Medical Education. Family fertility education: a resource package for teachers of Natural Family Planning Methods. Geneva: WHO, 1982.</li></ol>
<p>b) Because of the large range of failure rates of NFP methods, women with conditions that may be seriously affected by pregnancy must be counseled on the degree of risk of an unintended pregnancy.</p>	<p>b) The higher range of failure rates of these methods may expose the user to an unacceptable risk of unintended pregnancy. (See Question 1)</p> <ol style="list-style-type: none"><li>1) World Health Organization. Improving access to quality care in family planning: medical eligibility criteria for contraceptive use. Geneva: WHO, 1996.</li></ol>

### Q.3. Can women who have vaginal infections use NFP?

Recommendations	Rationale
<p>Calendar-based or BBT methods do not depend upon interpretation of cervical secretions and may be used if a woman is unable to interpret cervical mucus patterns.</p> <p>It is not recommended that women rely on the cervical mucus method (CMM) if they have an abnormal vaginal discharge.</p>	<p>Abnormal pathologic discharge interferes with a woman's ability to observe changes in cervical mucus patterns. If a woman has an abnormal discharge she should be referred to a health care provider for appropriate diagnosis and treatment. If possible, couples should abstain until treatment is complete, or be advised to use condoms to prevent re-infection. The male partner should also be treated at the same time, if required. Once the discharge has returned to normal, women can begin using the cervical mucus method.</p>

### Q.4. Who can teach NFP?

Recommendations	Rationale
<p>NFP is best taught by experienced, qualified counselors who preferably have experience in observing their own fertility signs.</p>	<p>NFP counselors must be able to provide accurate information to couples throughout all the stages of a woman's life cycle. They must be able to observe, chart, and correctly interpret fertility indicators (e.g., physical signs, cycle length) and be able to teach this skill to others. Qualified NFP teachers must have good communication skills, and be able to follow-up clients as necessary until a couple becomes autonomous.</p> <p>1) World Health Organization. Natural family planning: a guide to provision of services. Geneva: WHO, 1988.</p>

## Q.5. How long does it take to learn NFP?

Recommendations	Rationale
<p>a) Most women can learn to identify the fertile time within one to three cycles.</p> <p>b) The time required to teach NFP varies depending upon client needs and circumstances. Some programs use less than a week of instruction. Initial instruction in how to use NFP may be spread out over two to six weeks so that couples can practice observing fertility signs and charting over the course of at least an entire cycle.</p>	<p>a) In a study conducted by the World Health Organization, 91% of subjects demonstrated a “good” or “excellent” grasp of the ovulation method after the initial cycle of charting, 94% after two cycles, and over 97% after three cycles.</p> <p>1) World Health Organization. A prospective multicentre trial of the ovulation method of natural family planning. I. The teaching phase. <i>Fertility and Sterility</i> 1981;36(2):152-8.</p> <p>b) Women who are in “special circumstances” – including those who are breastfeeding or postpartum – require more time to learn NFP. Teacher time may be made more efficient by teaching NFP in groups, or using videos to teach some of the material.</p> <p>1) World Health Organization. <i>Natural family planning: a guide to provision of services</i>. Geneva: WHO, 1988.</p> <p>2) Kass-Annese B, Aumack K, Goodman L. <i>Guide for natural family planning trainers</i>. Los Angeles, CA: Institute for International Studies in Natural Family Planning, 1990.</p>

## Q.6. What follow-up schedule is recommended?

Recommendations	Rationale
<p>A fixed follow-up schedule is not necessary. However, close supervision is required in the initial weeks and months of NFP use. Thereafter, less frequent visits are required, depending upon the individual needs of the clients. Most couples can become autonomous NFP users after charting for about four to six cycles.</p>	<p>The goal of NFP training is for couples to reach autonomy – the ability to correctly interpret the woman’s fertility signs and avoid or achieve a pregnancy according to the couple’s wishes. One comparative study shows that poor follow-up of clients leads to fewer couples becoming autonomous, while closer supervision leads to greater numbers of autonomous users. More research is required to determine optimal follow-up schedule in various settings.</p> <p>1) World Health Organization. <i>Natural family planning: a guide to provision of services</i>. Geneva: WHO, 1988.</p> <p>2) Kambic R, Gray R. Factors related to autonomy and discontinuation of use of natural family planning for women in Liberia and Zambia. <i>American Journal of Obstetrics and Gynecology</i> 1991;165:2060-2.</p>

## Q.7. What client counseling is required?

Recommendations	Rationale
a) Commitment by both the man and the woman is required for the effective use of NFP.	a) NFP is a "couple method" and requires good communication and cooperation between partners. NFP is not only a method of FP, but is also a method of self-knowledge and self-control, and mutual respect.
b) NFP requires the ability to observe and interpret fertility indicators accurately.	b) A couple must be willing to monitor the changes in the woman's fertility signs consistently so that the fertile time can be identified accurately.
c) NFP requires abstinence from vaginal intercourse for up to half the days of the menstrual cycle.	c) On average, most NFP methods require 10 to 12 days of abstinence per cycle. The length of abstinence depends upon the NFP method chosen and individual characteristics of the woman's cycle.
d) If the man or the woman abuses drugs or alcohol, the couple should be offered another method of FP.	d) If either the man or the woman abuses alcohol or drugs, it will be difficult for the couple to follow the rules of abstinence.
e) If the male partner is not interested in NFP, then the woman or couple should be informed of alternative methods.	e) NFP will not be effective in preventing unplanned pregnancy if the male partner is unwilling to accept abstinence during the fertile period. Such couples should be informed of other FP options.
f) If the man or the woman is at risk for acquiring or transmitting an STD, the couple should be counseled about risk factors for STD transmission.	f) NFP is not protective against STDs, and couples at risk should be informed that to reduce their risk, they should abstain or use condoms.

## Q.8. Can a woman use NFP if she has irregular cycles?

Recommendations	Rationale
<p>a) <b>Using Fertility Indicators?</b> Yes. If the couple uses fertility indicators (such as cervical mucus and BBT to identify the fertile time, then ovulation can be predicted and detected despite irregular menstrual cycles. Past cycle lengths do not influence the length of abstinence in the current cycle.</p> <p>b) <b>Using a Calendar method based on a formula?</b> For a woman with very irregular cycles, a calendar method based on a formula to predict the fertile time may be unacceptable due to the prolonged abstinence required.</p>	<p>a) Women with irregular menstrual cycles can still ovulate and be fertile. The fertile period in such women can only be identified by prospective NFP methods such as cervical mucus and BBT. In the presence of irregular cycles, the period of abstinence may be excessively long and unacceptable to some couples.</p> <p>b) In the absence of relatively regular cycles, it is impossible for a woman to predict the fertile days in her current cycle using the calendar method. As cycle length variation increases, the number of days of abstinence increases. The most common "rule" used to predict the fertile time using a formula is subtracting a certain number of days from the shortest cycle (usually subtract 18 to 20 days) and longest cycle (usually subtract eight to 10 days) lengths in the past 6 to 12 months. If, for example, the longest cycle is 45 days and the shortest cycle is 20 days, a couple would have to abstain for more than 30 days in the woman's current cycle.</p> <p>(NOTE: Cycle length is determined by starting to count on Day 1 of menses, and counting forward until the day before the next menses begins.)</p> <p>Prolonged abstinence may lead to increased risk taking, and greater risk of pregnancy if intercourse occurs during the fertile time.</p> <p>1) Lamprecht V, Grummer-Strawn L. Development of new formulas to identify the fertile time of the menstrual cycle. <i>Contraception</i> 1996;54(6):339-43.</p>

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**Q8. Irregular cycles** (continued)

Recommendations	Rationale
<p>c) <b>Using a Calendar method based on a “blanket” rule?</b></p> <p>Couples using a “blanket” (calendar) rule may be at increased risk for pregnancy if the woman has a very short or very long cycle.</p>	<p>c) When the fertile time is predicted using a “blanket” rule – in which a set number of days each cycle is identified as the fertile time – the length of abstinence is not increased if the woman has irregular cycles. An example of a “blanket” rule is if all couples abstain starting on Day 8 of the woman’s cycle and resume vaginal intercourse on Day 21. Couples using this rule would abstain for 13 days each cycle, regardless of whether the woman has irregular cycles. However, in the presence of long and irregular cycles, it is very likely that the couple will have intercourse on a fertile day as ovulation usually occurs around two weeks before the next menstruation. Thus a woman with a 39 day cycle would resume intercourse on day 21 and probably ovulate around day 25.</p> <p>1) Lamprecht V, Grummer-Strawn L. Development of new formulas to identify the fertile time of the menstrual cycle. <i>Contraception</i> 1996;54(6):339-43.</p>

**Q.9. Are there any risks, or harmful effects, of using NFP?**

Recommendations	Rationale
<p>a) No medical side effects are associated with the use of NFP.</p> <p>b) The best evidence indicates that there is no increased risk to the fetus associated with the use of NFP.</p>	<p>a) No drugs or devices are used with NFP. Fertility awareness-based methods produce no medical side effects. However, periodic abstinence and fear of unplanned pregnancy may create tension and psychological stress in some couples.</p> <p>1) Hatcher RA, Trussell J, Stewart F, Stewart GK, Kowal D, Guest F, et al. <i>Fertility Awareness</i>. In: <i>Contraceptive Technology</i>. New York: Irvington Publishers, 1994:327-40.</p> <p>b) Recent studies show that there is no increased risk of spontaneous abortion, small birth size, low birth weight, or malformation to fetuses among users of NFP.</p> <p>1) Gray R, Simpson J, Kambic R. Timing of conception and the risk of spontaneous abortion among pregnancies occurring during the use of natural family planning. <i>American Journal of Obstetrics and Gynecology</i> 1995;172(5):1567-72.</p> <p>2) Castilla E, Simpson J, Queenan J. Down’s syndrome is not increased in offspring of natural family planning users (case control analysis). <i>American Journal of Medical Genetics</i> 1995; 59(4):525.</p>

## Q.10 Can NFP be used to select the sex of a child?

Recommendations	Rationale
<p>No, timing intercourse according to fertility indicators does not increase the chances of having a boy or a girl.</p>	<p>A few NFP programs suggest that NFP can be used to increase the probability of conceiving a boy or girl. However, review of several scientific studies shows that the sex of a child cannot be reliably determined by timing intercourse.</p> <ol style="list-style-type: none"><li>1) Gray R. Natural Family Planning and Sex Selection: Fact or Fiction? <i>American Journal of Obstetrics and Gynecology</i> 1991; 165(6 Part 2 Suppl):1982-4.</li></ol>

## Q.11. Can NFP be combined with other methods?

Recommendations	Rationale
<p>Yes. By definition, NFP requires that only abstinence during the fertile time be used to avoid pregnancy. However, couples who know how to identify the fertile time may choose to use a barrier method or withdrawal during the fertile time. These alternative approaches are not NFP, but are referred to by different names, such as "fertility-awareness methods" or "mixed methods."</p> <ul style="list-style-type: none"><li>• For example, women who wish to breastfeed can use the Lactational Amenorrhea Method (LAM) in lieu of, or before, using NFP. When the criteria for LAM use (see LAM chapter) are no longer met the woman can use NFP to identify her potentially fertile days.</li></ul>	<p>For couples who are not at risk for STDs, an approach which combines the use of fertility awareness and barrier methods or withdrawal may increase the acceptability and effectiveness of these methods, since the use of other contraceptive methods is needed only when the woman is fertile. Further research is necessary to establish guidelines for combining fertility awareness and barrier method use.</p> <ol style="list-style-type: none"><li>1) European Natural Family Planning Study Group. Prospective European multi-center study of natural family planning (1989-1992): interim results. <i>Advances in Contraception</i> 1993;9:269-83.</li><li>2) Rogow D, Rintoul E, Greenwood S. A year's experience with a fertility awareness program: a report. <i>Advances in Planned Parenthood</i> 1980;15(1):27-33.</li><li>3) Kennedy KI, Gross B, Parenteau-Carreau S, Flynn AM, Brown JB, Visness CM. Breastfeeding and the symptothermal method. <i>Studies in Family Planning</i> 1995; 26(2):107-15.</li></ol>

## Classification of Selected Procedures for Natural Family Planning (NFP)

Procedure	Class	Rationale
Pelvic examination (speculum and bimanual)	C	<ul style="list-style-type: none"> <li>• A pelvic exam would only be indicated if a woman were unable to identify the fertile period after several cycles of NFP use.</li> <li>• If she complains of abnormal vaginal discharge and wishes to use the CMM, a pelvic exam becomes Class A.</li> </ul>
Blood pressure	C	Blood pressure screening is not needed for the safe use of NFP <sup>1</sup> .
Breast examination	C	Breast cancer screening is not needed for the safe use of NFP <sup>1</sup> .
STD screening by lab tests (for asymptomatic persons)	C	Clients at risk for STDs (by personal history or socio-demographic risk factors) should be offered STD screening where possible.
Cervical cancer screening	C	Cervical cancer screening is not needed for the safe use of NFP <sup>1</sup> .
Proper infection prevention procedures	C	Beyond hand washing and personal hygiene, infection prevention procedures are not applicable to NFP use.
Specific counseling points for NFP: <ul style="list-style-type: none"> <li>• instructions for use and teaching points specific to the method</li> <li>• signs and symptoms of fertility</li> <li>• efficacy</li> <li>• importance of partner cooperation</li> <li>• STD protection (when/as appropriate)</li> </ul>	A	Accurate client education (training and counseling) is essential for couples to learn NFP methods and use them effectively (See Question 7).

### Citations for Procedures Table:

- 1) World Health Organization. Improving access to quality care in family planning: medical eligibility criteria for contraceptive use. Geneva: WHO, 1996.

### KEY:

- Class A** = essential and mandatory or otherwise important in all circumstances, for safe and effective use of the contraceptive method
- Class B** = medically/epidemiologically rational in some circumstances to optimize the safe and effective use of the contraceptive method, but may not be appropriate for all clients in all settings
- Class C** = may be appropriate for good preventive health care, but not materially related to safe and effective use of the contraceptive method
- Class D** = not materially related to either good routine preventive health care or safe and effective use of the contraceptive method

## 1.7 Withdrawal (Coitus Interruptus)

This section outlines recommendations on the following selected procedural questions for Withdrawal (Coitus Interruptus):

1. Are couples practicing withdrawal at **risk of pregnancy** from pre-ejaculate fluid?
2. Are couples practicing withdrawal protected from **STDs**?

## Withdrawal

Withdrawal is a method of family planning (FP) in which the man interrupts intercourse and withdraws his penis from his partner's vagina **before** he ejaculates.

To use withdrawal effectively, the man must be able to predict when he is about to ejaculate and be able to pull out his penis in time so that there is no contact between his ejaculate and the woman's vagina or external genitalia where cervical secretions (mucus) may be present. Cervical secretions facilitate the transport of semen into the upper female genital tract. Incomplete withdrawal during the fertile time in a woman's cycle will greatly increase the probability of unplanned pregnancy. However, incomplete withdrawal outside the fertile time will not result in pregnancy. The man (and woman) must be highly motivated to use the withdrawal method because it requires him to pull out and move away from his partner at a time when sexual excitement is near its peak.

### Citations:

- 1) Hatcher R, Trussell J, Stewart F, Stewart G, Kowal D, Guest F, et al. Coitus interruptus (Withdrawal). In: Contraceptive Technology. New York: Irvington, 1994: 341-6.

## Q.1. Are couples practicing withdrawal at risk of pregnancy from pre-ejaculate fluid?

Recommendations	Rationale
<p>a) Probably not. The risk of pregnancy is potentially low if a man is able to “pull out” before ejaculation and makes sure that semen does not have contact with the woman’s genitalia.</p> <p>b) If a second intercourse is anticipated shortly after a first, the man should urinate prior to re-entry and wash off his penis to remove any seminal fluid which may be on the glans or shaft of the penis.</p>	<p>a) Some researchers conclude that the number of sperm required for fertilization is not contained in pre-ejaculatory fluid. Failure of the method to prevent pregnancy is usually related to inadequate withdrawal.</p> <p>1) Rogow D, Horowitz S. Withdrawal: a review of the literature and an agenda for research. <i>Studies in Family Planning</i>. 1995;26(3):140-53.</p> <p>b) Some evidence suggests that after a recent ejaculation, pre-ejaculatory fluid may contain higher levels of viable spermatozoa, and that men should urinate after ejaculating prior to having intercourse a second time, to “flush” or “void” any semen that remains. Washing off the shaft and glans of the penis would prevent any remaining semen external to the man’s urethra from being transported into the vagina during re-entry.</p> <p>1) Rogow D, Horowitz S. Withdrawal: a review of the literature and an agenda for research. <i>Studies in Family Planning</i>. 1995;26(3):140-53.</p> <p>2) Hatcher R, Trussell, J Stewart F, Stewart G, Kowal D, Guest F, et al. Coitus Interruptus (Withdrawal). In: <i>Contraceptive Technology</i>. New York: Irvington, 1994: 341-6.</p>

## Q.2. Are couples practicing withdrawal protected from STDs?

Recommendations	Rationale
No.	<p>Withdrawal has not been proven to protect against STDs. Both partners should be informed that they can transmit STDs to each other whether or not withdrawal is complete. Some researchers speculate that consistent use of withdrawal may partially reduce the risk of transmission of some STDs from men to women when compared to users of no contraceptive method, because there is a reduction in the volume of potentially pathogen-containing fluid to which a woman is exposed. However, the man is still exposed if the woman is infected. More research must be conducted to evaluate if correct and consistent use of withdrawal reduces the risk of STD transmission to either or both partners.</p> <ol style="list-style-type: none"><li data-bbox="803 978 1425 1043">1) Rogow D, Horowitz S. Withdrawal: a review of the literature and an agenda for research. <i>Studies in Family Planning</i>. 1995;26(3):140-53.</li><li data-bbox="803 1043 1425 1086">2) Richters J. Coitus Interruptus: could it reduce the risk of HIV transmission? <i>Reproductive Health Matters</i> 1994;3:105-7.</li></ol>

## Classification of Selected Procedures for Withdrawal (Coitus Interruptus)

Procedure	Class	Rationale
Pelvic examination (speculum and bimanual)	C	A physical exam is not required for the use of withdrawal. A pelvic exam is not required for the man's partner <sup>1</sup> .
Blood pressure	C	Blood pressure screening is not required for use of withdrawal <sup>1</sup> .
Breast examination	C	A breast exam is not required for the use of withdrawal <sup>1</sup> .
STD screening by lab tests (for asymptomatic persons)	C	Clients at risk for STDs (by personal history or socio-demographic risk factors) should be offered STD screening, where possible.
Cervical cancer screening	C	Cervical cancer screening is not needed for the safe use of withdrawal <sup>1</sup> .
Proper infection prevention procedures	C	Proper infection prevention procedures are not applicable to withdrawal.
Specific counseling points for withdrawal (coitus interruptus): <ul style="list-style-type: none"> <li>• efficacy</li> <li>• STD protection (when/as appropriate)</li> <li>• requires high motivation and self-control</li> </ul>	A	<ul style="list-style-type: none"> <li>• Accurate client education is essential for effective use of withdrawal (coitus interruptus).</li> <li>• Many FP programs do not teach withdrawal. Couples choosing withdrawal should be offered information on how to use the method effectively.</li> <li>• Appropriate counseling at the time of method selection can lead to improved client satisfaction and continuation.</li> <li>• Withdrawal can be used if the man can predict when he is going to ejaculate and is able to ensure that his ejaculate does not come in contact with his partner's genitalia.</li> <li>• Withdrawal may be less acceptable if the man is prone to pre-mature ejaculation.</li> <li>• Clients should be informed about the risks of contracting and transmitting STDs.</li> </ul>

### Citations for Procedures Table:

- 1) World Health Organization. Improving access to quality care in family planning: medical eligibility criteria for contraceptive use. Geneva: WHO, 1996.

#### KEY:

- Class A** = essential and mandatory or otherwise important in all circumstances, for safe and effective use of the contraceptive method
- Class B** = medically/epidemiologically rational in some circumstances to optimize the safe and effective use of the contraceptive method, but may not be appropriate for all clients in all settings
- Class C** = may be appropriate for good preventive health care, but not materially related to safe and effective use of the contraceptive method
- Class D** = not materially related to either good routine preventive health care or to the safe and effective use of the contraceptive method

## 1.8 Progestin-Only Pills During Breastfeeding\*

This section outlines recommendations on the following selected procedural questions for Progestin-Only Pills (POPs) during breastfeeding:

1. **When** can POPs be started for **breastfeeding** women?
2. Are there special **considerations** when a **breastfeeding woman is switching** from POPs to other hormonal methods?
3. If a woman is using POPs during breastfeeding, **when should she be advised to switch** to another method?
4. Can POPs be **used when not breastfeeding**?
5. **How many POP cycles** should be given at the first visit for a new user? At subsequent visits?
6. When breastfeeding, is there a **best time of day** to take POPs?
7. Are **back-up methods** advisable in the following situations:
  - a) If a breastfeeding client is taking antibiotics, including anti-tuberculosis medications?
  - b) If a breastfeeding client is taking anticonvulsants?
  - c) If a breastfeeding client is taking anti-malarial medication?
  - d) If it is a breastfeeding client's first cycle of POPs?
  - e) If a breastfeeding client has missed pills?
  - f) If a breastfeeding client has severe diarrhea and/or vomiting?

\* Because the vast majority of POP users are breastfeeding women, this chapter focuses on POPs during breastfeeding. However, POPs are an acceptable contraceptive method for use by women who are not breastfeeding (See Question 4).

## Q.1. When can POPs be started for breastfeeding women?

Recommendations	Rationales
<p>a) If breastfeeding, POPs may be started after six weeks postpartum.</p> <p>POPs are not usually recommended in the first six weeks postpartum in breastfeeding women. The timing of postpartum initiation of POPs should consider a woman's breastfeeding intentions.</p> <p>b) A woman who initially chooses to rely on the Lactational Amenorrhea Method (LAM) is advised to begin POPs, or whichever method she chooses to switch to when one of the following takes place:</p> <ul style="list-style-type: none"> <li>• her menses return, or</li> <li>• she is no longer fully or nearly fully breastfeeding, or</li> <li>• six months postpartum.</li> </ul> <p>Preferably, POP packets are given to the woman before her intended start date to ensure that she is able to begin the method when she needs to. However, if she prefers, POPs can also be started when a woman is still relying on LAM (providing her with dual protection).</p>	<p>a) For breastfeeding women, delaying POP initiation for six weeks after delivery avoids exposing the newborn to exogenous steroids during the time of greatest neuroendocrine development. In breastfeeding women, the risk of ovulating in the first six weeks postpartum is very low. The timing of postpartum initiation of POPs should be dependent on the woman's preference, her previous experience with breastfeeding and her intentions regarding the duration of breastfeeding.</p> <ol style="list-style-type: none"> <li>1) Howie PW, McNeilly AS, Houston MJ, Cook A, Boyle H. Fertility after childbirth: postpartum ovulation and menstruation in bottle and breast feeding mothers. <i>Clinical Endocrinology</i> 1982;17:323-32.</li> <li>2) Diaz S, Rodriguez G, Peralta O, Miranda P, Casado ME, Salvatierra AM, et al. Lactational amenorrhea and the recovery of ovulation and fertility in fully nursing Chilean women. <i>Contraception</i> 1988;38(1):53-67.</li> <li>3) Visness C, Rivera R. Progestin-only pill use and pill switching during breastfeeding. <i>Contraception</i> 1995;51:279-81.</li> </ol> <p>b) While relying on LAM, a postpartum woman has at least 98% protection from pregnancy for six months if she remains amenorrheic and fully or nearly fully breastfeeds (perfect use effectiveness rate). Programs sometimes encourage waiting to initiate POPs until reliance on LAM ends, because it may be more programmatically affordable and because using POPs while breastfeeding may potentially prolong lactational subfertility.</p> <ol style="list-style-type: none"> <li>1) Kennedy K, Rivera R, McNeilly A. Consensus statement on the use of breastfeeding as a family planning method. <i>Contraception</i> 1989;39(5):477-96.</li> <li>2) Chaudhury RR, Chompootawee S, Dusitsin N, Friesen H, Tankeyoon M. The release of prolactin by medroxyprogesterone acetate in human subjects. <i>British Journal of Pharmacology</i> 1977;59:433-4.</li> </ol>

(continued on next page)

**Q.1. When breastfeeding?** (continued)

Recommendations	Rationale
c) After the first six weeks postpartum, POPs can be initiated any time you can be reasonably sure a woman is not pregnant (see Appendix A and POP Question 7d).	c) Based on current literature, including studies with other progestin-only methods, it is unlikely that there is a significant effect on the growth of breastfeeding infants whose mothers initiate POPs after the sixth postpartum week. <ol style="list-style-type: none"><li>1) WHO Task Force on Oral Contraceptives. Effects of hormonal contraceptives on milk volume and infant growth. <i>Contraception</i> 1984;30(6):505-21.</li><li>2) Shaaban M, Salem H, Abdulllah K. Influence of levonorgestrel contraceptive implants, Norplant, initiated early postpartum upon lactation and infant growth. <i>Contraception</i> 1985;32(6):623-35.</li><li>3) Pardthaisong T, Yenchiit C, Gray R. The long-term growth and development of children exposed to Depo-Provera during pregnancy or lactation. <i>Contraception</i> 1992;45:313-24.</li><li>4) McCann MF, Moggia AV, Higgins JE, Potts M, Beeker C. The effects of a progestin-only oral contraceptive (levonorgestrel 0.03 mg) on breastfeeding. <i>Contraception</i> 1989;40(6):635-48.</li></ol>
d) Even if POPs are inadvertently initiated during pregnancy, there is no known risk to the fetus.	d) Epidemiologic studies have found no significant effect on fetal development or malformations due to taking hormonal methods in early pregnancy. <ol style="list-style-type: none"><li>1) Bracken MB. Oral contraception and congenital malformations in offspring: a review and meta-analysis of the prospective studies. <i>Obstetrics and Gynecology</i> 1990;76:552-7.</li><li>2) Wiseman RA, Dodds-Smith IC. Cardiovascular birth defects and antenatal exposure to female sex hormones: a re-evaluation of some base data. <i>Teratology</i> 1984;30(3):359-70.</li><li>3) Simpson JL, Phillips OP. Spermicides, hormonal contraception and congenital malformations. <i>Advances in Contraception</i> 1990;6:141-67.</li></ol>
e) Non-hormonal methods are preferable to hormonal methods during breastfeeding because they have no effect on breastfeeding and the infant is not exposed to exogenous steroids. However, WHO lists POPs as Category 1 after six weeks postpartum, and women should be given a choice of contraceptive methods.	e) Although the amount of exogenous progestins in breastmilk is extremely low, it is prudent to try to minimize infant exposures to any drug. <ol style="list-style-type: none"><li>1) Institute of Reproductive Health. Guidelines for breastfeeding in family planning and child survival programs. Washington, DC: IRH, 1992.</li><li>2) World Health Organization. Improving access to quality care in family planning: medical eligibility criteria for contraceptive use. Geneva: WHO, 1996.</li></ol>

**Q.2. Are there special considerations when a breastfeeding woman is switching from POPs to other hormonal methods?**

Recommendations	Rationale
<p>No. A breastfeeding woman can switch from POPs to another hormonal method any time the new method is appropriate.</p> <p>No back-up method is necessary when the new method is initiated if the woman has been breastfeeding, and has been taking the POPs fairly consistently. Estrogen-containing methods should generally not be used by breastfeeding women prior to six months postpartum or preferably any time during long-term breastfeeding.</p>	<p>As long as the woman is breastfeeding and taking the POPs fairly consistently, she is fully protected through the transition to the new hormonal method.</p> <p>1) McCann MF, Potter LS. Progestin-only oral contraception: a comprehensive review. <i>Contraception</i> 1994;50(6).</p> <p>Clinical trial data indicate that the pregnancy protection conferred by POP use during breastfeeding is high, indicating a synergistic pregnancy prevention effect for breastfeeding while using POPs. In addition, women in lactational amenorrhea have additional protection due to their lowered fecundity.</p> <p>1) Dunson T, McLaurin V, Grubb G, Rosman A. A multicenter clinical trial of a progestin-only oral contraceptive in lactating women. <i>Contraception</i> 1993;47:23-35.</p> <p>2) Kennedy KI, Visness C. Contraceptive efficacy of lactational amenorrhoea. <i>Lancet</i> 1992;339:227-30.</p>

### Q.3. If a woman is using POPs during breastfeeding, when should she be advised to switch to another method?

Recommendations	Rationale
<p>a) Women can rely on POPs after the first six weeks postpartum, and safely use them during the entire duration of breastfeeding.</p>	<p>a) In general, POPs are highly effective, and safe, during breastfeeding.</p>
<p>b) Women can continue using POPs after they stop breastfeeding, provided that they have been informed of the advantages and disadvantages of the method and are willing to use the POPs correctly and consistently.</p>	<p>b) POPs are an effective contraceptive method, even when not breastfeeding, if used correctly and consistently. However, all women should be informed of the advantages and disadvantages of POPs in the absence of breastfeeding, especially that POPs need to be used consistently and correctly to provide effective pregnancy protection (e.g., the pill should be taken at the same time each day), and that they often cause irregular menstrual bleeding.</p>
<p>It is not mandatory for a woman to switch from POPs to another family planning (FP) method after she stops breastfeeding or at six months postpartum.</p>	<p>1) Visness C, Rivera R. Progestin-only pill use and pill switching during breastfeeding. <i>Contraception</i> 1995;51:279-81.                  2) McCann MF, Potter LS. Progestin-only oral contraception: a comprehensive review. <i>Contraception</i> 1994;50(6).                  3) World Health Organization. Improving access to quality care in family planning: medical eligibility criteria for contraceptive use. Geneva: WHO, 1996.</p>
<p>c) Breastfeeding women using POPs should be advised not to switch to combined oral contraceptives (COCs), or other methods containing estrogen, until at least six months postpartum.</p>	<p>c) Even low-dose (30 mcg) COCs decrease breastmilk production and alter its composition.</p>
<p>d) Breastfeeding women can switch to non-hormonal methods at any time, as appropriate.</p>	<p>1) WHO Task Force on Oral Contraceptives. Effects of hormonal contraceptives on milk volume and infant growth. <i>Contraception</i> 1984;30:505-21.                  2) McCann MF, Potter LS. Progestin-only oral contraception: a comprehensive review. <i>Contraception</i> 1994;50(6).                  d) If not inserted with 48 hours of delivery, postpartum IUDs are usually not inserted until uterine involution is complete. Progestin-releasing IUDs are not inserted until six weeks postpartum, even if involution is complete before six weeks, to avoid the theoretical risks of infant steroid exposure. Diaphragms are not fitted until involution is complete.                  1) O'Hanley K, Huber D. Postpartum IUDs: keys for success. <i>Contraception</i> 1992;45:351-61.                  2) Wiley A. The Diaphragm. In: Corson S, Derman R, Tyrer L, editors. <i>Fertility Control</i>. Boston: Little, Brown &amp; Company, 1985:223-32.                  3) World Health Organization. Improving access to quality care in family planning: medical eligibility criteria for contraceptive use. Geneva: WHO, 1996.</p>

## Q.4. Can POPs be used when not breastfeeding?

Recommendations	Rationale
<p>Yes, if taken consistently and correctly. Many women gain experience with and confidence in POPs during breastfeeding and should be allowed to continue POPs after breastfeeding if POPs are the woman's method of choice.</p>	<p>POPs are an effective contraceptive method even when the woman is not breastfeeding if taken consistently and correctly.</p> <p>POPs are a useful alternative for many women who want to use oral contraceptives (OCs) but for whom COCs are not appropriate.</p> <p>Women should be informed of the advantages and disadvantages of POPs, especially that POPs need to be used consistently and correctly to provide effective pregnancy protection (e.g., the pill should be taken at the same time each day) and that POPs often cause irregular menstrual bleeding. Unless a woman is breastfeeding, a back-up method of contraception should be used if a POP is taken more than three hours after her regularly scheduled time (See Question 7e).</p> <p>1) McCann MF, Potter LS. Progestin-only oral contraception: a comprehensive review. <i>Contraception</i> 1994;50(6).</p>

**Q.5. How many POP cycles should be given at the first visit for a new user? At subsequent visits?**

Recommendations	Rationale
<p><b>a) New user?</b></p> <p>Postpartum women who plan to use LAM can be given their pill cycles immediately postpartum, with instructions to begin taking them (see Question 1) when any of the LAM criteria no longer apply. Women who plan to rely on LAM for six months can be given at least a six month supply (to begin when the LAM criteria no longer apply), so they will have contraceptive protection for at least one year.</p> <p>Up to 13 cycles (a full year's supply) can be given, although only three or four may be programmatically feasible. The greatest need is to guarantee continuous, ready access.</p> <p><b>b) Subsequent visits?</b></p> <p>There is no compelling medical reason for a routine return visit concerning POP use, but clients should be encouraged to return at any time with concerns, problems or questions.</p> <p>For first-time users of POPs, programs may encourage a three-month follow-up visit for counseling to assess whether the client is satisfied with the method and is correctly using the method, to reinforce instructions, and to help clients with the management of side effects.</p>	<p><b>a)</b> The woman's convenience is important. To avoid running out of pills, the woman should have ready access to more POP cycles. Ideally, she should be able to obtain plenty of POP cycles at her visit.</p> <p>While some providers suspect that clients who receive multiple pill cycles may "share" these with friends, such "sharing" is likely to be as safe and effective as over-the-counter distribution systems.</p> <p><b>b)</b> The extremely low dose of progestins in POPs make them a very safe method of contraception. The greatest health risk from POPs is pregnancy due to method failure, which is preventable by assuring adequate POP supply and correct, consistent method use.</p> <p>1) McCann MF, Potter LS. Progestin-only oral contraception: a comprehensive review. <i>Contraception</i> 1994;50(6).</p> <p>2) Harlap S, Kost K, Forrest JD. Preventing pregnancy, protecting health: a new look at birth control choices in the United States. Washington, D.C.: The Alan Guttmacher Institute, 1991.</p>

**Q.6. When breastfeeding, is there a best time of day to take POPs?**

Recommendations	Rationale
<p>a) POPs may be taken at any time of the day for effective use during breastfeeding. The client may wish to select a certain time to help her remember to take a pill every day; it may help to link this time to a daily event.</p> <p>b) However, if a woman continues taking POPs <u>after</u> breastfeeding cessation, then it is important to take the POP at the same time every day, preferably late afternoon or four to five hours before the usual time of sexual activity, so that the pill's effect on the cervical mucus is at its maximum by the time sexual activity occurs.</p>	<p>a) Breastfeeding women have additional protection due to their lower fecundity. Clinical trial data indicate that the pregnancy protection conferred by POP use during breastfeeding is extremely high. The synergistic pregnancy protection by POP use in combination with breastfeeding should sufficiently eliminate a client's risk of conception, even if she takes POPs at different times of the day.</p> <ol style="list-style-type: none"> <li>1) Dunson T, McLaurin V, Grubb G, Rosman A. A multicenter clinical trial of a progestin-only oral contraceptive in lactating women. <i>Contraception</i> 1993;47:23-35.</li> <li>2) Wright SW, Fotherby K, Fairweather F. Effect of daily small doses of norgestrel on ovarian function. <i>Journal of Obstetrics and Gynecology of the British Commonwealth</i> 1970; 77:65-8.</li> </ol> <p>b) The most immediate contraceptive effect of POPs is the alteration of cervical mucus. The POP's effect on cervical mucus peaks approximately four to five hours after ingestion of the pill, and is essentially gone by 24 hours after taking one POP.</p> <ol style="list-style-type: none"> <li>1) McCann MF, Potter LS. Progestin-only oral contraception: a comprehensive review. <i>Contraception</i> 1994;50(6).</li> <li>2) Chretien FC, Sureau C, Neau C. Experimental study of cervical blockage induced by continuous low-dose oral progestogens. <i>Contraception</i> 1980;22:445-56.</li> </ol>

## Q.7. Are back-up methods advisable in the following situations?

Recommendations	Rationale
<p>a) <b>If a breastfeeding client is taking <u>antibiotics, including anti-tuberculosis medications</u>?</b></p> <p>Back-up methods are not usually required, unless the woman is taking <b>rifampin/rifampicin</b>.</p> <p>With the exception of rifampin/rifampicin, antibiotics are unlikely to significantly reduce the effectiveness of POPs in breastfeeding women.</p> <p>If the breastfeeding woman is taking rifampin/rifampicin, she should know that rifampin/rifampicin:</p> <ul style="list-style-type: none"> <li>• passes through breastmilk (with potential infant side effects),</li> <li>• may increase breakthrough bleeding, and</li> <li>• lowers progestin levels, possibly significantly reducing the effectiveness of POPs.</li> </ul>	<p>a) Broad-spectrum antibiotics such as ampicillin, erythromycin and tetracycline have <b>not</b> been shown to decrease effectiveness of POPs in careful clinical studies.</p> <p>Rifampin/rifampicin, which is used primarily for treating tuberculosis, induces hepatic enzymes and increases the liver metabolism of progestins, thus decreasing the effectiveness of POPs. The enzyme-inducing effects of rifampin/rifampicin last about four weeks after short-term use and eight weeks after long-term use.</p> <p>Griseofulvin, an anti-fungal antibiotic and another hepatic enzyme inducer, has not been proven to reduce POP effectiveness in humans, but may increase menstrual irregularities.</p> <p>Rifampin/rifampicin is passed in breastmilk (milk:plasma ratio of 0.2 to 0.6). Griseofulvin may also be passed in breastmilk. Infant exposure to rifampin/rifampicin or griseofulvin is appropriate only when the maternal benefits outweigh the potential risks to the infant.</p> <ol style="list-style-type: none"> <li>1) Back DJ, Orme ML. Drug interactions. In: Goldzieher JW, Fotherby K (editors.). <i>Pharmacology of the Contraceptive Steroids</i>. New York: Raven Press, 1994:407-25.</li> <li>2) Fotherby K. Interactions with oral contraceptives. <i>American Journal of Obstetrics and Gynecology</i> 1990;163:2153-9.</li> <li>3) <i>Drug Facts and Comparisons</i>. St. Louis: Facts and Comparisons, June 1996, p. 358 and October 1990, p.387a</li> <li>4) World Health Organization. <i>Improving access to quality care in family planning: medical eligibility criteria for contraceptive use</i>. Geneva: WHO, 1996.</li> <li>5) Baciewicz AM, Self TH, Bekemeer WB. Update on rifampin drug interactions. <i>Archives of Internal Medicine</i> 1987;147(3):565-8.</li> </ol>

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**Q.7. Back-up methods** (continued)

Recommendations	Rationale
<p>b) <b>If a breastfeeding client is taking <u>anticonvulsants</u>?</b></p> <p>Yes, usually. The common anticonvulsants, hydantoin (e.g., phenytoin), barbiturates (e.g., phenobarbital, primidone), and probably carbamazepine significantly decrease the effectiveness of oral contraceptives. POPs are not recommended if using these enzyme-inducing anticonvulsants.</p> <p>Additionally, because anticonvulsants are excreted in breastmilk, and because there is a potential for serious adverse reactions in nursing infants, women taking hydantoin, barbiturates, or carbamazepine for <b>chronic</b> seizure control may be advised to explore safe alternatives to breastfeeding.</p> <p>Injectable contraceptives, such as Depo Provera®, will be effective despite anticonvulsant use, but infant exposure to the anticonvulsants will continue.</p> <p>Non-hormonal methods will continue to be effective despite anticonvulsant use.</p>	<p>b) The hepatic enzyme-inducing effects of most anticonvulsants probably decrease pregnancy protection and increase rates of irregular bleeding among some POP users. It should be noted however that POPs may decrease the probability of seizures among users of anticonvulsants.</p> <p>Because of the dangers of fetal exposure to most anticonvulsants, full protection against pregnancy is essential. Although increased doses of POPs might be effective, they might also further increase bleeding irregularities.</p> <p>1) Mattson RH, Rebar RW. Contraceptive methods for women with neurologic disorders. <i>American Journal of Obstetrics and Gynecology</i> 1993;168:2027-32</p> <p>If a woman ingests hydantoin, barbiturates, or carbamazepine, her breastmilk will contain significant quantities of these substances. In areas where safe alternatives to breastfeeding exist, and where maternal seizures cannot otherwise be controlled, women on long-term anti-seizure medications may be advised to consider safe alternatives to breastfeeding, to avoid chronic infant drug exposure.</p> <p>1) Drug Facts and Comparisons. St. Louis: Facts and Comparisons, July 1996, pp. 282-4.                  2) World Health Organization. Improving access to quality care in family planning: medical eligibility criteria for contraceptive use. Geneva: WHO, 1996.                  3) Anderson GD, Graves NM. Drug interactions with antiepileptic agents. <i>CNS Drugs</i> 1994;2(4):268-79.</p>
<p>c) <b>If a breastfeeding client is taking <u>anti-malarial</u> medication?</b></p> <p>No back-up is needed.</p> <p>There is no evidence that anti-malarial medications reduce the effectiveness of OCs.</p> <p>Chloroquine and related anti-malarials are excreted in breastmilk.</p>	<p>c) Chloroquine, primaquine and tetracycline have not shown any effect on OC hormonal levels, and are not known to reduce the effectiveness of POPs.</p> <p>A nursing infant may consume about half of a mother's 300 mg chloroquine dose over 24 hours; the maternal milk: blood ratio may be about 0.36. Children are especially sensitive to chloroquine and primaquine.</p>

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**Q.7. Back-up methods** (continued)

Recommendations	Rationale
<p>d) <b>If it is a breastfeeding client's <u>first cycle</u> of POPs?</b></p> <p>No back-up is needed.</p> <p>However, if a breastfeeding woman has resumed menstruating and is beginning the pills later than the first seven days of her cycle, some programs recommend that she use a back-up method for seven days after beginning POPs.</p>	<p>c) Weighing the nutritional value of the milk to the child against the effects of the chloroquine, clients are usually not advised to stop breastfeeding while on anti-malarial treatment, unless safe alternatives to breastmilk are available.</p> <p>1) Drug Facts and Comparisons. St. Louis: Facts and Comparisons June 1996, pp. 358 and 387a.</p>
<p>e) <b>If a breastfeeding client has <u>missed pills</u>?</b></p> <p>If the breastfeeding woman is still amenorrheic, missed pills are of minimal consequence.</p> <p>For a breastfeeding woman who has already returned to menses, if two or more pills are missed, the woman should:</p> <ul style="list-style-type: none"> <li>• resume taking a pill as soon as she remembers,</li> <li>• take the next pill at the regular time that day (for added protection), and</li> <li>• use a back-up method or abstinence for 48 hours (some programs recommend use of a back-up method for up to seven days).</li> </ul>	<p>d) The cervical mucus thickens enough to prevent sperm penetration within 24 hours. Also, the synergistic protection against pregnancy conferred by concurrent POP use and breastfeeding should sufficiently eliminate a client's risk of conception. Thus, a back-up method for a full seven days may not be necessary.</p> <p>1) Chretien FC, Sureau C, Neau C. Experimental study of cervical blockage induced by continuous low-dose oral progestogens. <i>Contraception</i> 1980;22:445-56.</p> <p>2) Kessuru-Koos E. Influence of various hormonal contraceptives on sperm migration in vivo. <i>Fertility and Sterility</i> 1971;22:584-603.</p> <p>3) Moghissi KS, Syner FN, McBride LC. Contraceptive mechanism of microdose norethindrone. <i>Obstetrics and Gynecology</i> 1973;41:585-94.</p> <p>e) After missing one pill, breastfeeding women previously taking POPs are estimated to be sufficiently subfertile that the probability of the woman becoming pregnant is extremely low.</p> <p>The most immediate effect of POPs is on cervical mucus, each tablet offering protection for approximately 24 hours. Clinical trial data indicate that the pregnancy protection conferred by POP use during breastfeeding is high, indicating a synergistic pregnancy prevention effect for breastfeeding while using POPs. In addition, women in lactational amenorrhea have additional protection due to their lowered fecundity.</p> <p>1) Kessuru-Koos E. Influence of various hormonal contraceptives on sperm migration in vivo. <i>Fertility and Sterility</i> 1971;22:584-603.</p> <p>2) Dunson T, McLaurin V, Grubb G, Rosman A. A multicenter clinical trial of a progestin-only oral contraceptive in lactating women. <i>Contraception</i> 1993;47:23-35.</p> <p>3) Kennedy KI, Visness C. Contraceptive efficacy of lactational amenorrhoea. <i>Lancet</i> 1992;339:227-30.</p>

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**Q.7. Back-up methods** (continued)

Recommendations	Rationale
<p>f) <b>If a breastfeeding client has <u>severe diarrhea and/or vomiting</u>?</b></p> <p>If a woman is breastfeeding and amenorrheic, no back-up method is needed since the synergistic effect of both breastfeeding and POP use should provide sufficient pregnancy protection.</p> <p>If a breastfeeding woman has resumed menstruating, some programs recommend use of a back-up method for 48 hours or for 7 days after the severe vomiting or diarrhea stops.</p>	<p>f) The synergistic protection conferred by POP use and breastfeeding should sufficiently eliminate a client's risk of conception, because women in lactational amenorrhea have additional protection due to their lowered fecundity.</p> <ol style="list-style-type: none"><li>1) Dunson T, McLaurin V, Grubb G, Rosman A. A multicenter clinical trial of a progestin-only oral contraceptive in lactating women. <i>Contraception</i> 1993;47:23-35.</li><li>2) Orme M, Back DJ, Breckenridge AM. Clinical pharmacokinetics of oral contraceptive steroids. <i>Clinical Pharmacokinetics</i> 1983; 8:95-136.</li><li>3) Kennedy KI, Visness C. Contraceptive efficacy of lactational amenorrhoea. <i>Lancet</i> 1992;339:227-30.</li></ol>

## Classification of Selected Procedures for Progestin-only Pills (POPs) during Breastfeeding

Procedure	Class	Rationale
Pelvic examination (speculum and bimanual)	C	<ul style="list-style-type: none"> <li>• A pelvic exam is not necessary to ensure safe use of POPs as a contraceptive method<sup>1</sup>.</li> <li>• In some cases, a pelvic exam may help evaluate the question of pregnancy if a menstrual history suggests the possibility beyond six weeks duration. In this case it is Class A.</li> <li>• Conditions which would restrict use of POPs should be identified by the client's history before method initiation.</li> </ul>
Blood pressure	C	Current evidence does not demonstrate any notable effect of POPs on blood pressure <sup>2,3</sup> .
Breast examination	C	POPs do not cause breast cancer <sup>4,5</sup> . Lumps that are suspicious as cancer should be evaluated. While any hormonal treatment may in theory cause such lumps to grow, pregnancy causes much higher hormonal levels; therefore, potential malignancies of the breast should not be a reason to delay a woman's access to the use of this contraceptive method.
STD screening by lab tests (for asymptomatic persons)	C	The presence of an STD will not affect the safe use of POPs. Clients at risk of STDs (by personal history or socio-demographic risk factors) should be offered STD screening where possible.
Cervical cancer screening	C	POPs have no known relation to risk of cervical cancer <sup>6</sup> .
Routine, mandatory lab tests (e.g., cholesterol, glucose, liver function tests)	D	The effect of POPs on cholesterol, blood glucose and normal liver function are slight, and of no demonstrated clinical significance <sup>6-8</sup> .
Proper infection prevention procedures	C	Proper infection prevention procedures are not applicable to POP use.

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**KEY:**

- Class A** = essential and mandatory or otherwise important in all circumstances, for safe and effective use of the contraceptive method
- Class B** = medically/epidemiologically rational in some circumstances to optimize the safe and effective use of the contraceptive method, but may not be appropriate for all clients in all settings
- Class C** = may be appropriate for good preventive health care, but not materially related to safe and effective use of the contraceptive method
- Class D** = not materially related to either good routine preventive health care or to the safe and effective use of the contraceptive method

## Classification of Selected Procedures for Progestin-only Pills (POPs) during Breastfeeding

(continued)

Procedure	Class	Rationale
Specific counseling points for POP use: <ul style="list-style-type: none"> <li>• efficacy</li> <li>• common side effects, including alterations in bleeding patterns (e.g. frequent or irregular bleeding, extended amenorrhea)</li> <li>• correct use of method (including instructions for missed pills)</li> <li>• signs and symptoms for which to see a health provider</li> <li>• STD protection (when/as appropriate)</li> </ul>	A	<ul style="list-style-type: none"> <li>• Accurate client education is essential for maximum quality of FP services.</li> <li>• Appropriate counseling about common contraceptive side effects at the time of method selection can lead to improved client satisfaction and contraceptive continuation.</li> <li>• Irregular or absent menstrual bleeding is the single most common side effect of POPs, and the chief complaint leading to discontinuation<sup>9</sup>.</li> <li>• POPs are highly effective if taken correctly and consistently. However, POPs are less effective than COCs after weaning.</li> <li>• The woman should be encouraged to return if she has any problems or at any time she has questions or concerns.</li> </ul>

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**KEY:**

- Class A** = essential and mandatory or otherwise important in all circumstances, for safe and effective use of the contraceptive method
- Class B** = medically/epidemiologically rational in some circumstances to optimize the safe and effective use of the contraceptive method, but may not be appropriate for all clients in all settings
- Class C** = may be appropriate for good preventive health care, but not materially related to safe and effective use of the contraceptive method
- Class D** = not materially related to either good routine preventive health care or to the safe and effective use of the contraceptive method

## Classification of Selected Procedures for Progestin-only Pills (POPs) during Breastfeeding (continued)

### Citations for Procedures Table:

- 1) Huber DH, Huber SC. Screening oral contraceptive candidates and inconsequential pelvic examinations. *Studies in Family Planning* 1975;6(2):49-51.
- 2) Ball MJ, Ashwell E, Gillmer MDG. Progestagen-only oral contraceptives: comparison of the metabolic effects of levonorgestrel and norethisterone. *Contraception* 1991;44(3):223-33.
- 3) Wilson ESB, Cruickshank J, McMaster M, Weir RJ. A prospective controlled study of the effect on blood pressure of contraceptive preparations containing different types and dosages of progestogen. *British Journal of Obstetrics and Gynaecology* 1984;91:1254-60.
- 4) Stanford JL, Thomas DB. Exogenous progestins and breast cancer. *Epidemiologic Reviews* 1993;15(1):98-107.
- 5) UK National Case-Control Study Group. Oral contraceptive use and breast cancer risk in young women. *Lancet* 1989;1:973-82.
- 6) World Health Organization. Improving access to quality care in family planning: medical eligibility criteria for contraceptive use. Geneva: WHO, 1996.
- 7) Miale JB, Kent JW. The effects of oral contraceptives on the results of laboratory tests. *American Journal of Obstetrics and Gynecology* 1974;120(2):264-72.
- 8) Korba VD, Paulson SR. Five years of fertility control with microdose norgestrel: an updated clinical review. *Journal of Reproductive Medicine* 1974;13(2):71-5
- 9) Belsey EM, WHO Task Force on Long-acting Systemic Agents for Fertility Regulation. The association between vaginal bleeding patterns and reasons for discontinuation of contraceptive use. *Contraception* 1988;38(2):207-25.

For further information see McCann MF, Potter LS. Progestin-only oral contraception: a comprehensive review. *Contraception* 1994;50(6).

## 1.9 Barrier Methods

This section outlines recommendations on the following selected procedural questions for Barrier Methods:

### **Spermicides (gels, foam, tablets, and film)**

1. Are there any risks to a fetus conceived while using spermicides or due to spermicide use during pregnancy for sexually transmitted disease (STD) prevention?
2. How often can spermicide be used in a given time period?
3. Do spermicides protect one against: a) pregnancy? b) human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS)? c) other STDs?
4. How soon postpartum or postabortion can spermicides be used?

### **Condoms (male and female)**

1. Do condoms protect against STDs/HIV/AIDS?
2. Where may condoms be made available and how many can be provided?
3. Can condoms (male and female) be re-used?
4. When should the condom be put into place?
5. Does providing condoms in more than one size reduce slippage and breakage?
6. Should latex condoms be used with oil-based lubricants?

### **Diaphragms/Cervical Caps**

1. Does one size of a diaphragm or cervical cap fit all?

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Questions: (continued)

2. Are there any **restrictions** to the use of a diaphragm or cervical cap based on the **number of births** a woman has had?
3. How soon **postpartum** or **postabortion** can a diaphragm or cervical cap be used?
4. Is pregnancy prevented if the diaphragm is **used without spermicide**?
5. How long must a woman **wait after the last act of intercourse** to **remove** the diaphragm or cervical cap?
6. Should a diaphragm user **insert extra spermicide before having a second intercourse**?
7. Does use of a diaphragm or cervical cap **increase the risk of urinary tract infections**?
8. Does a diaphragm or cervical cap **protect against**: a) **HIV/AIDS**?  
b) **other STDs**?

### **General**

1. What should be the **role of barrier methods** in family planning/  
reproductive health programs?

**Q.1. Are there any risks to a fetus conceived while using spermicides or due to spermicide use during pregnancy for STD prevention?**

Recommendations	Rationale
<p>The weight of the evidence is that there is no risk to the fetus from spermicide exposure.</p>	<p>The active ingredient in most spermicide products, nonoxynol-9 (N-9), is absorbed in small quantities from the vagina during use. No adverse systemic effects from N-9 have ever been shown in women. One study found that users of spermicide products containing nonoxynol-9 or octoxynol had a higher risk of congenital malformations in pregnancies conceived during use than did non-users. But several subsequent studies on spermicide use and birth defects have not shown any association, and researchers do not believe that spermicide use has any adverse effects on the fetus.</p> <ol style="list-style-type: none"><li>1) Jick H, Walker AM, Rothman KJ, Hunter JR, Holmes LB, Watkins RN, et al. Vaginal spermicides and congenital disorders. <i>Journal of the American Medical Association</i> 1981;245:1329-32.</li><li>2) Stimpson J, Phillips O. Spermicides, hormonal contraception and congenital malformations. <i>Advances in Contraception</i> 1990;6(3):141-67.</li><li>3) Einarson TR, Koren G, Mattice D, Schechter-Tsafirri O. Maternal spermicide use and adverse reproductive outcome: a meta-analysis. <i>American Journal of Obstetrics and Gynecology</i> 1990;162:655-60.</li></ol>

## Q.2. How often can spermicide be used in a given time period?

Recommendations	Rationale
<p>a) Continued spermicide use as frequently as once or twice a day may cause some tiny breaks in the vaginal lining, whereas use every other day does not cause significant irritation. If irritation is detected upon examination and if a reasonable alternative is available, then the client should be advised to discontinue the spermicidal product until healing is complete.</p>	<p>a) The active ingredients of most spermicide products are surfactants that disrupt cell membranes of spermatozoa, pathogens and genital epithelium. In one study of frequent N-9 insertion, erythema and microscopic epithelial lesions were equally frequent among women inserting N-9 every other day as among placebo users. The rate of irritation was twice as high among women inserting N-9 once or twice daily, and five times higher among women inserting four N-9 suppositories daily than among placebo users. Similar findings have been reported in a World Health Organization (WHO) sponsored study of the spermicide menfegol.</p>
<p>b) Discomfort with spermicide use is uncommon when used at typical family planning (FP) frequencies of once per day or less. If discomfort is reported, a different spermicide product with different ingredients may solve the problem. If discomfort persists, a different contraceptive method is indicated.</p>	<p>Experts fear that the epithelial lesions of spermicide-associated irritation may increase the risk of contracting HIV infection if exposure to HIV occurs. This has not been demonstrated in a human study, but it is plausible, and local irritation should be avoided.</p> <p>1) Roddy RE, Cordero M, Cordero C, Fortney JA. A dosing study of nonoxynol-9 and genital irritation. <i>International Journal of STDs and AIDS</i> 1993;4:165-70.</p> <p>2) Goeman J, Ndoye I, Sakho LM, Mboup S, Piot P, Karam M, et al. Frequent use of menfegol spermicidal vaginal foaming tablets associated with a high incidence of genital lesions. <i>Journal of Infectious Diseases</i> 1995;171:1611-4.</p> <p>b) In studies of spermicide use (approximately one to two times per day) for FP purposes, roughly 5% to 10% of women have symptoms of discomfort after use. The clinical significance of discomfort is unclear, because discomfort is a self-perceived problem and it may not be correlated with signs of vaginal or cervical irritation detected during examination.</p> <p>1) Roddy RE, Cordero M, Cordero C, Fortney JA. A dosing study of nonoxynol-9 and genital irritation. <i>International Journal STD &amp; AIDS</i> 1993;4:165-70.</p> <p>2) Feldblum P, Morrison C, Roddy R, Cates W Jr. The effectiveness of barrier methods of contraception in preventing the spread of HIV. <i>AIDS</i> 1995;9(Suppl A):S85-S93.</p>

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**Q.2. How often?** (continued)

Recommendations	Rationale
<p>c) A woman should insert a new dose of her spermicide product before each act of intercourse. Furthermore, a woman should insert a new dose of spermicide if intercourse takes place an hour or more after initial insertion.</p>	<p>c) In order to be effective, the spermicide must be high in the vagina near the cervix, with a sufficient concentration of the active ingredient. Due to different delivery formulations, some products leak down toward the vulva more quickly than others; some spread better than others. Manufacturers of suppositories, gels and film generally claim that their product is effective for up to one hour after insertion, but the period of effectiveness might be longer. Since spermicides are typically less effective in preventing pregnancy than other methods, it is prudent to insert a new dose for each intercourse.</p> <p>1) Hatcher RA, Trussell J, Stewart F, Stewart GK, Kowal D, Guest F, et al. Vaginal spermicides. In: <i>Contraceptive Technology</i>. New York: Irvington Publishers, 1994:179-90.</p>

**Q.3. Do spermicides protect one against:**  
**a) pregnancy? b) HIV/AIDS? c) other STDs?**

Recommendations	Rationale
<p>a) <b>Against pregnancy?</b>                      Yes. Spermicides can be fairly protective for pregnancy prevention as long as they are used correctly and consistently. However, with typical use, spermicides provide much less protection against pregnancy than with perfect use.</p>	<p>a) The failure rates of spermicides in the first year of use range from 6% with perfect use to 21% with typical use. These rates are similar to those for the diaphragm and female condom.</p> <p>1) Trussell J, Kost K. Contraceptive failure in the United States: a critical review of the literature. <i>Studies in Family Planning</i> 1987;18(5):237-83.</p>

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**Q.3. Protect from pregnancy, HIV/AIDS, other STDs? (continued)**

Recommendations	Rationale
<p><b>b) Against HIV/AIDS?</b></p> <p>Possibly. Spermicides are not generally recommended for HIV prevention.</p> <p>However, for sexually active women who cannot use male or female condoms, a spermicide product may be preferable to unprotected intercourse, unless there are multiple acts of intercourse per day.</p>	<p>b) Little research has been done on spermicide use and HIV risk, and the findings of the only two published studies conflict. In one study, nonoxynol-9 contraceptive sponge users had a higher incidence of HIV infection. In the second study, N-9 suppository users had a lower incidence of HIV. Until large randomized studies currently under way can resolve the controversy, spermicide alone cannot currently be recommended for HIV prevention.</p> <p>Theoretically, spermicides may reduce the incidence of HIV indirectly by preventing bacterial STD co-factors. Spermicides have also been shown to have direct effects on HIV in vitro.</p> <ol style="list-style-type: none"><li>1) Kreiss J, Ngugi E, Holmes K, Ndinya-Achola J, Waiyaki P, Roberts PL, et al. Efficacy of nonoxynol-9 contraceptive sponge use in preventing heterosexual acquisition of HIV in Nairobi prostitutes. <i>Journal of the American Medical Association</i> 1992;268:477-82.</li><li>2) Zekeng L, Feldblum PJ, Godwin SE, Oliver RM, Kaptue L. HIV infection and barrier contraceptive use among high-risk women in Cameroon. <i>AIDS</i> 1993;7:725-31.</li><li>3) Feldblum PJ, Weir SS. The protective effect of nonoxynol-9 against HIV infection (letter). <i>American Journal of Public Health</i> 1994;84:1032-4.</li><li>4) Centers for Disease Control. Update: barrier protection against HIV infection and other sexually transmitted diseases. <i>MMWR</i> 1993;42:589-91 and 597.</li><li>5) Feldblum PJ, Morrison CS, Rowdy RE, Cates W Jr. The effectiveness of barrier methods of contraception in preventing the spread of HIV. <i>AIDS</i> 1995;9(Suppl A):S85-S93.</li><li>6) Jennings R, Clegg A. The inhibitory effect of spermicidal agents on replication of HSV-2 and HIV-1 in vitro. <i>Journal of Antimicrobial Chemotherapy</i> 1993;32:71-82.</li></ol> <p>The highest risk of sexually acquired HIV infection is associated with unprotected intercourse. Women need methods to protect themselves against HIV and other STDs, even if protection is only partial.</p> <ol style="list-style-type: none"><li>1) Rosenberg MJ, Gollub EL. Methods women can use that may prevent sexually transmitted disease, including HIV (commentary). <i>American Journal of Public Health</i> 1992;82:1473-8.</li><li>2) Elias CJ, Heise LL. Challenges for the development of female-controlled vaginal microbicides. <i>AIDS</i> 1994;8:1-9.</li></ol>

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**Q.3. Protect from pregnancy, HIV/AIDS, other STDs? (continued)**

Recommendations	Rationale
<p>c) <b>Against other STDs?</b></p> <p>Yes, spermicides are modestly protective against cervical gonorrhea and chlamydia, compared to users of no method. While the level of protection may not be great, it may offer some protection that women can themselves control.</p> <p>The effectiveness of any coital-dependent method (i.e., one that must be applied at or around the time of intercourse) depends on the consistency and correctness of use. For these methods, acceptability and compliance are as important, if not more so, as their effectiveness during perfect use. Even if a female method is less efficacious than the male condom during perfect use, it may have a greater impact on disease rates if it is used more consistently. Consistent condom with spermicide use may be more effective.</p>	<p>c) Spermicides have been shown to provide protection against some bacterial STDs. Studies with different kinds of participants and different study designs have consistently demonstrated that spermicide use reduces the number of new gonorrheal and chlamydial infections. One study found an overall reduction in gonorrhea of about 50% in nonoxynol-9 users, but that figure includes both consistent and correct users as well as inconsistent users. A greater reduction was found in the most consistent users of the spermicide. Another study found a 25% reduction overall in nonoxynol-9 users. In studies that have compared bacterial STD risk among women relying on male condoms to those using a spermicidal method, the risks were about the same for infections. Most likely, the spermicides were used more consistently than were male condoms.</p> <ol style="list-style-type: none"><li>1 Niruthisard S, Roddy RE, Chutivongse S. Use of nonoxynol-9 and reduction in rate of gonococcal and chlamydial cervical infections. <i>Lancet</i> 1992;339:1371-5.</li><li>2 Weir SS, Feldblum PJ, Zekeng L, Roddy RE. The use of nonoxynol-9 for protection against cervical gonorrhea. <i>American Journal of Public Health</i> 1994;84:910-4.</li><li>3 Louv W, Austin H, Alexander W, Stagno S, Cheeks J. A clinical trial of nonoxynol-9 for preventing gonococcal and chlamydial infections. <i>The Journal of Infectious Diseases</i> 1988;158(3):518-22.</li><li>4 Rosenberg M, Rojanapithayakorn W, Feldblum P, Higgins J. Effect of the contraceptive sponge on chlamydial infection, gonorrhea, and candidiasis: a comparative clinical trial. <i>Journal of the American Medical Association</i> 1987;257:2308-12.</li></ol>

**Q.4. How soon postpartum or postabortion can spermicides be used?**

Recommendations	Rationale
<p>According to the WHO Eligibility Criteria, spermicides can be used any time postpartum or postabortion.</p> <p>Although some providers recommend that spermicide should not be used until six weeks after delivery or abortion, and after healing and uterine involution are complete, there is no evidence to support this practice.</p>	<p>Use of a spermicide by breastfeeding women both prior to and after six weeks postpartum and use after a first, second or post septic-abortion are WHO Category 1. Thus, the WHO recommends the use of spermicides in any of these circumstances. By extrapolation, nonbreastfeeding women can use spermicides any time postpartum as well.</p> <ol style="list-style-type: none"><li>1) World Health Organization. Improving access to quality care in family planning: medical eligibility criteria for contraceptive use. Geneva: WHO, 1996.</li></ol>

## **Q.1. Do condoms protect against STDs/HIV/AIDS?**

<b>Recommendations</b>	<b>Rationale</b>
<p>a) <b>Male condoms?</b></p> <p>Yes, couples who use the male latex condom correctly and consistently have a lower risk of acquiring all STDs, including HIV, compared to non-users. The average reduction is about 50%, although recent studies of HIV show that protection with consistent condom use can be close to 100%.</p>	<p>a) All studies have found that male latex condom users have a lower risk of STD than non-users. The overall risk reduction appears to be about 50%, but that figure is a gross estimate that includes consistent and correct users as well as inconsistent users. In Thailand, a condom-only campaign in brothels is associated with population-based reductions in gonorrhea and HIV rates.</p> <p>Full-time latex condom users may reduce their risk to near-zero. A multi-center Italian study followed seronegative female sexual partners of HIV-infected men for a median of 24 months. The HIV incidence rate was reduced by 90% in women whose partners always used condoms compared with women whose partners used them inconsistently or never; women whose partners were inconsistent condom users did not benefit.</p> <p>In a multi-country European collaborative study, about half of 343 couples used condoms at every coital act, and no new HIV infections occurred among the consistent users. For the couples who used condoms inconsistently, new HIV infections occurred at the rate of 4.8 per 100 per year, even though 50% of the inconsistent users reported using condoms at least half the time. These two studies show that consistent condom use is highly effective protection against HIV transmission, but that inconsistent use carries considerable risks of HIV infection.</p> <ol style="list-style-type: none"><li>1) Feldblum PJ, Morrison CS, Roddy RE, Cates W Jr. The effectiveness of barrier methods of contraception in preventing the spread of HIV. <i>AIDS</i> 1995;9(Suppl A):S85-S93.</li><li>2) Cates W Jr, Stone KM. Family planning, sexually transmitted diseases and contraceptive choice: a literature update-part 1. <i>Family Planning Perspectives</i> 1992;24:75-84.</li><li>3) Hanenberg RS, Rojanapithayakorn W, Kunasol P, Sokal DS. Impact of Thailand's HIV-control programme as indicated by the decline of sexually transmitted diseases. <i>Lancet</i> 1994;344:243-5.</li><li>4) Saracco A, Musicco M, Nicolosi A, Angarano G, Arici C, Gavazzeni G, et al. Man-to-woman sexual transmission of HIV: longitudinal study of 343 steady partners of infected men. <i>Journal of Acquired Immune Deficiency Syndrome</i> 1993;6:497-502.</li><li>5) de Vincenzi I, for the European Study Group on Heterosexual Transmission of HIV. A longitudinal study of human immunodeficiency virus transmission by heterosexual partners. <i>New England Journal of Medicine</i> 1994;331(6):341-6.</li></ol>

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**Q.1. Condoms: Protect against STDs/HIV/AIDS?** (continued)

Recommendations	Rationale
<p>b) <b>Female condoms?</b></p> <p>If used correctly and consistently, the female condom should be very effective in preventing STDs (including HIV), but this has not been confirmed in human use studies.</p>	<p>b) Only one cross-sectional study of the female condom and STD re-occurrence has been done. Women with trichomoniasis were treated, enrolled and followed for 45 days. Consistent users had no re-infections, while 14% of inconsistent users and non-users were re-infected. The plastic membrane of the female condom is impermeable to HIV and other STD organisms, so the device may reduce the risk of HIV and other STDs in consistent users.</p> <ol style="list-style-type: none"><li>1) Soper DE, Shoupe D, Shangold GA, Shangold MM, Gutmann J, Mercer L. Prevention of vaginal trichomoniasis by compliant use of the female condom. <i>Sexually Transmitted Diseases</i> 1993;20:137-9.</li><li>2) Drew WL, Blair M, Miner RC, Conant M. Evaluation of the virus permeability of a new condom for women. <i>Sexually Transmitted Diseases</i> 1990;17:110-2.</li></ol>

**Q.2. Where may condoms be made available and how many can be provided?**

Recommendations	Rationale
<p>Condoms may be made available anywhere. The greater the number of condom distribution outlets- e.g., clinics, pharmacies, street kiosks, community-based services (CBS) programs- the more accessible the devices will be.</p> <p>In clinic contexts, it may be best to allow the client to determine how many condoms the client needs. If the clinic's supply is limited, the number of condoms given should be based on client's projected need and distance from the clinic.</p>	<p>Condoms are generally not abused or used for anything besides sexual intercourse. If in doubt, a clinic should offer too many condoms rather than too few. Even if some devices are re-sold or otherwise distributed, they promote public health.</p>

### **Q.3. Can condoms (male and female) be re-used?**

<b>Recommendations</b>	<b>Rationale</b>
<p>a) Male condoms should not be re-used.</p> <p>b) Studies are underway, but currently re-use of female condoms is not recommended.</p>	<p>a) The re-use of male condoms cannot be recommended until further research is completed. Anecdotal reports suggest that re-use of male condoms is associated with higher breakage rates. The latex membranes are generally not strong enough to withstand repeated stretching, friction and cleaning.</p> <p>1) Steiner M, Piedrahita C, Glover L, Joanis C. Can condom users likely to experience condom failure be identified? <i>Family Planning Perspectives</i> 1993;25:220-3,226.</p> <p>b) The re-use of female condoms is not currently recommended, pending further research. However, anecdotal reports from acceptability studies show that a minority of women use female condoms more than once. Re-use has not been associated with higher breakage rates; female condom breakage is rare in general. Research is currently under way to determine whether re-use reduces the structural strength of the device (increases breakage) and/or increases the risk of communicating STDs.</p>

### **Q.4. When should the condom be put into place?**

<b>Recommendations</b>	<b>Rationale</b>
<p>a) Male condoms should be put on after erection and before genital and/or anal contact.</p> <p>b) The female condom should be put into place any time before the penis touches the vagina in order to prevent exposure to pre-ejaculate and semen.</p>	<p>a-b) Although viable sperm are generally absent from pre-ejaculatory fluid, HIV is present in the pre-ejaculate of HIV-positive men. Thus the pre-ejaculate may transmit disease, and the condom should be in place before genital contact occurs.</p> <p>1) Ilaria G, Jacobs JL, Polsky B, Koll B, Baron P, MacLow C, et al. Detection of HIV-1 DNA sequences in pre-ejaculatory fluid (letter). <i>Lancet</i> 1992;340:1469.</p> <p>2) Pudney J, Oneta M, Mayer K, Seage G III, Anderson D. Pre-ejaculatory fluid as potential vector for sexual transmission of HIV-1 (letter). <i>Lancet</i> 1992;340:1470.</p>

### **Q.5. Does providing condoms in more than one size reduce slippage and breakage?**

Recommendations	Rationale
<p>No. There is no evidence that different sizes will reduce breakage and slippage.</p> <p>There is no need to provide more than one size latex condoms.</p>	<p>Some condom users complain of condoms being too small or too large, and some researchers have presumed that breakage could be minimized if condoms were made in different sizes. One study evaluated breakage rates and acceptability of larger (55 mm flat diameter) and smaller (49 mm) condoms against the industry standard condom (52 mm). In three countries, breakage rates were 5.5% and 7.4% for the standard and larger devices, respectively. In three other countries, breakage rates were under 5% and similar for the standard and smaller condoms; slippage rates were also similar. Further, condom size had a minimal impact on device acceptability. Certain individuals might benefit from different condom sizes, but the impact has not been demonstrated, and it is not justified for a program to invest in multiple condom sizes.</p> <p>1) Feldblum P, Joanis C. Modern barrier methods: effective contraception and disease prevention. Research Triangle Park, NC: Family Health International, 1994.</p>

## Q.6. Should latex condoms be used with oil-based lubricants?

Recommendations	Rationale
<p>a) No. Latex condoms should not be used with oil-based lubricants or products that have an oil as a major ingredient. Oils weaken condoms and can increase the risk of breakage.</p> <p>Clients who use condoms should be counseled on what locally available non-oil-based lubricants are appropriate with condom use.</p> <p>Some substances which cause deterioration of latex condoms within an hour of exposure are mineral oil, baby oil, petroleum jelly, suntan oil, olive oil, peanut oil, corn oil, sunflower oil, palm oil, margarine, coconut oil, dairy butter, insect repellents, burn and hemorrhoidal ointments, rubbing alcohol, cod oil and shark oil. Lubricants which contain these products should not be recommended for use with latex condoms.</p> <p>Other products that weaken latex condoms are specific vaginal creams, vaginal spermicides and sexual lubricants. Some of the brands that were identified as harmful to condoms are:</p> <ul style="list-style-type: none"><li>• vaginal creams (Monistat, Estrace, Femstat, Vagisil, and Premarin);</li><li>• vaginal spermicides (Rendell's Cone and Pharmatex Ovule); and</li><li>• sexual lubricants (Elbow Grease, Hot Elbow Grease, and Shaft).</li></ul> <p>b) Products that are considered water-based have not been shown to be harmful to condoms. Water-based lubricants may reduce the risk of condom failure.</p>	<p>a) Mineral oil has been shown to weaken latex condoms significantly with an exposure time of 60 seconds.</p> <p>Studies have found that some condom users think products which wash off easily with water are water-based and therefore, acceptable to use with condoms. However, several of the lotions that clients labeled as water-based contained mineral oil as a main ingredient.</p> <ol style="list-style-type: none"><li>1) Voeller B, Coulson A, Bernstein G, Nakamura R. Mineral oil lubricants cause rapid deterioration of latex condoms. <i>Contraception</i> 1989;39(1):95-102.</li><li>2) Tests show commonly used substances harm latex condoms. <i>Contraceptive Technology Update</i> 1989;10(2):20-21.</li><li>3) Hatcher RA, Trussell J, Stewart F, Stewart G, Kowal D, Guest F, et al. Condoms. In: <i>Contraceptive Technology</i>. New York: Irvington Publishers, 1994:145-78.</li></ol> <p>b) One study found lower condom failure rates when condoms were used with water-based lubricants. However, more research is needed.</p> <ol style="list-style-type: none"><li>1) Gabbay M, Gibbs A. Does additional lubrication reduce condom failure? <i>Contraception</i> 1996;53:155-8.</li></ol>

## Q.1. Does one size of a diaphragm or cervical cap fit all?

Recommendations	Rationale
<p>a) <b>Diaphragms?</b> No, diaphragms have to be fitted, and a variety of sizes need to be available where this method is offered.</p> <p>b) <b>Cervical caps?</b> No, currently available cervical caps must be fitted, and a variety of sizes need to be available where this method is offered.</p>	<p>a) Two studies of a Nonspermicidal Fit-Free Diaphragm (60 mm) have been done. The first report, an analysis of past diaphragm use, found the Pearl pregnancy rate to be 1 per 100 woman-years. In the second, a prospective non-randomized trial, the 12-month life table pregnancy rate was 24.1 per 100 women, and the high failure rate led to early termination of the study. The effectiveness of this modified approach to diaphragm use has not been confirmed.</p> <ol style="list-style-type: none"><li>1) Stum EM. The nonspermicide fit-free diaphragm: a new contraceptive method. <i>Advances in Planned Parenthood</i> 1980;15(3):88-98.</li><li>2) Smith C, Farr MG, Feldblum PJ, Spence A. Effectiveness of the non-spermicidal fit-free diaphragm. <i>Contraception</i> 1995;51:289-91.</li></ol> <p>b) Until one-size-fits-all caps are available, fitting caps to each client is recommended. New cervical barrier devices have been devised, at least one of which is one-size-fits-all, and human use studies are under way.</p> <ol style="list-style-type: none"><li>1) Hunt WL, Gabbay L, Potts M. Lea's Shield, a new barrier contraceptive preliminary clinical evaluations three-day tolerance study. <i>Contraception</i> 1994;50:551-61.</li><li>2) Mauck C, Glover L, Miller E, Allen S, Archer D, Blumenthal P, et al. Lea's Shield: a study of the safety and efficacy of a new vaginal barrier contraceptive used with and without spermicide. <i>Contraception</i> 1996;53:329-35.</li></ol>

## Q.2. Are there any restrictions to use of a diaphragm or cervical cap based on the number of births a woman has had?

Recommendations	Rationale
<p>a) <b>Diaphragms?</b> No. Women with any number of births can use the diaphragm. The fit of the device should be checked after delivery or second trimester abortion, however.</p>	<p>a) Since the diaphragm comes in sizes from 50 mm to 105 mm in different models, almost all vaginas can be accommodated. The size and muscle tone of the upper vagina can change after pregnancy, though, so a new device may be needed.</p>
<p>b) <b>Cervical caps?</b> No. Women of any parity can use the cervical cap, but the fit of the device should be checked after delivery or second trimester abortion. Parous women who use cervical caps tend to have a much higher pregnancy rate than nulliparous women users.</p>	<p>It is unclear whether the effectiveness of the diaphragm varies according to parity. In one large study of diaphragm users, parous women had a lower pregnancy rate than nulliparous women; in another, the rate among parous women was higher than that in nulliparous women. Parous women do not need to be advised that they are at higher risk of pregnancy.</p> <ol style="list-style-type: none"><li>1) Hatcher RA, Trussell J, Stewart F, Stewart GK, Kowal D, Guest F, et al. The diaphragm, contraceptive sponge, cervical cap and female condom. In: <i>Contraceptive Technology</i>. New York: Irvington Publishers, 1994:191-222.</li><li>2) Trussell J, Strickler J, Vaughan B. Contraceptive efficacy of the diaphragm, the sponge and the cervical cap. <i>Family Planning Perspectives</i> 1993;25:100-5, 135.</li></ol> <p>b) The cervical cap comes in four sizes: 22, 25, 28 and 31 mm. Most women can be fitted properly, but perhaps 10% of prospective users cannot be fit and must use a different method.</p> <p>In a large clinical trial, the pregnancy rate was substantially higher among parous women than nulliparous women for both typical and perfect use.</p> <ol style="list-style-type: none"><li>1) Secor RMC. The cervical cap. <i>NAACOG's Clinical Issues</i> 1992;3(2):236-45.</li><li>2) Hatcher RA, Trussell J, Stewart F, Stewart GK, Kowal D, Guest F, et al. The diaphragm, contraceptive sponge, cervical cap and female condom. In: <i>Contraceptive Technology</i>. New York: Irvington Publishers, 1994:191-222.</li><li>3) Trussell J, Strickler J, Vaughan B. Contraceptive efficacy of the diaphragm, the sponge and the cervical cap. <i>Family Planning Perspectives</i> 1993;25:100-5, 135.</li></ol>

### **Q.3. How soon postpartum or postabortion can a diaphragm or cervical cap be used?**

<b>Recommendations</b>	<b>Rationale</b>
<p>The diaphragm and the cervical cap should not be used until six weeks after delivery (vaginal or cesarean) or second trimester abortion and healing is complete. Re-fitting may be necessary at that time (re-fitting is not necessary after a first trimester abortion).</p> <p>If intercourse occurs prior to six weeks, the use of another appropriate method (i.e., condom) should be recommended.</p>	<p>The shape of the cervix, the size of the vaginal vault, and vaginal muscle tone may change after pregnancy and delivery or after second trimester abortion. It takes four to six weeks for the uterine involution to be complete, and bleeding/spotting can continue for up to eight weeks as well (cap use is contraindicated during bleeding).</p> <p>Additionally, there is marked weight loss after delivery, and many providers recommend re-fitting after a weight loss of more than seven kilograms.</p> <ol style="list-style-type: none"><li>1) Hatcher RA, Trussell J, Stewart F, Stewart GK, Kowal D, Guest F, et al. The diaphragm, contraceptive sponge, cervical cap and female condom. In: <i>Contraceptive Technology</i>. New York: Irvington Publishers, 1994:191-222.</li><li>2) World Health Organization. <i>Improving access to quality care in family planning: medical eligibility criteria for contraceptive use</i>. Geneva: WHO, 1996.</li><li>3) Wiley A. The diaphragm. In: Corson S, Derman R, Tyrer L, editors. <i>Fertility Control</i>. Boston: Little, Brown &amp; Company, 1985:223-32.</li><li>4) Secor RMC. The cervical cap. <i>NAACOG's Clinical Issues</i> 1992;3(2):236-45.</li></ol>

## **Q.4. Is pregnancy prevented if the diaphragm is used without spermicide?**

<b>Recommendations</b>	<b>Rationale</b>
<p>Yes, but not as effectively as with spermicide.</p> <p>Until better data on contraceptive effectiveness refute the traditional recommendations, users should be advised to add spermicide to fitted diaphragms.</p>	<p>Two studies of non-fitted diaphragms without spermicide had conflicting results. Research on fitted diaphragm use without spermicide are also conflicting. In a retrospective review of patient records, women using fitted diaphragms continuously (removing them only to wash) without spermicide had a lower pregnancy rate than did women following the traditional instructions. In a randomized trial comparing fitted diaphragm use with versus without spermicide, the typical use and perfect use pregnancy rates were lower in the diaphragm with spermicide group, but the study was small and the difference was not statistically significant.</p> <p>Some providers believe that spermicide cost, messiness and potential for irritation have resulted in poor compliance, and recommend diaphragm use without spermicide in an effort to enhance acceptability. But another important attribute of the diaphragm is that diaphragms used with spermicide protect against cervical infections and that spermicide use may reduce the risk of HIV infection. If spermicide use is partly responsible for reducing the risk of STD infection in women using diaphragms, it would be a disservice to instruct women to omit spermicide.</p> <ol style="list-style-type: none"><li>1) Ferreira AE, Araujo MJ, Regina CH, Diniz SG, Faundes A. Effectiveness of the diaphragm, used continuously, without spermicide. <i>Contraception</i> 1993;48:29-35.</li><li>2) Stum EM. The nonspermicide fit-free diaphragm: a new contraceptive method. <i>Advances in Planned Parenthood</i> 1980;15(3):88-98.</li><li>3) Smith C, Farr G, Fekilblum PJ, Spence A. Effectiveness of the non-spermicidal fit-free diaphragm. <i>Contraception</i> 1995;51:289-91.</li><li>4) Bounds W, Guillebaud J, Dominik R, Dalberth BT. The diaphragm with and without spermicide: a randomized, comparative efficacy trial. <i>Journal of Reproductive Medicine</i> 1995;40:764-74.</li><li>5) Roddy RE, Cordero M, Cordero C, Fortney JA. A dosing study of nonoxynol-9 and genital irritation. <i>International Journal of STD &amp; AIDS</i> 1993;4:165-70.</li><li>6) Cates W Jr, Stone KM. Family planning, sexually transmitted diseases and contraceptive choice: a literature update-part 1. <i>Family Planning Perspectives</i> 1992;24:75-84.</li></ol>

**Q.5. How long must a woman wait after the last act of intercourse to remove the diaphragm or cervical cap?**

<b>Recommendations</b>	<b>Rationale</b>
<p>Diaphragm and cervical cap users should wait at least six hours after intercourse before removing the device or douching.</p> <p>Upon removal, diaphragms should be washed (and dried prior to storing).</p>	<p>Spermatozoa remain viable in the vagina for several hours, but the great majority of sperm cells that are capable of entering the cervix do so within two hours post-ejaculation. N-9 spermicide can retain its contraceptive effect for a longer time: more than a day inside a cervical cap, and 12 hours inside a diaphragm. The optimum time that diaphragms and caps should remain in place has not been tested, and in the absence of evidence to the contrary, the traditional six-hour recommendation is a sensible compromise.</p> <ol style="list-style-type: none"><li>1) Overstreet JW, Katz DF, Yanagimachi R. Sperm transport and capacitation. In Sciarra JJ (editor). <i>Gynecology and Obstetrics</i>. Philadelphia: J.B. Lippincott Co., 1994.</li><li>2) Leitch WS. Longevity of Gynol II and Ortho Creme in the Prentif cervical cap. <i>Contraception</i> 1986;34(4):363-79.</li><li>3) Leitch WS. Longevity of Ortho Creme and Gynol II in the contraceptive diaphragm. <i>Contraception</i> 1986;34(4):381-93.</li><li>4) Hatcher RA, Trussell J, Stewart F, Stewart GK, Kowal D, Guest F, et al. The diaphragm, contraceptive sponge, cervical cap and female condom. In: <i>Contraceptive Technology</i>. New York: Irvington Publishers, 1994:191-222.</li></ol>

**Q.6. Should a diaphragm user insert extra spermicide before having a second intercourse?**

Recommendations	Rationale
<p>Yes, a diaphragm user should insert a new dose of spermicide before each episode of intercourse. A woman should insert a new dose of spermicide if intercourse takes place six hours or more after diaphragm insertion.</p>	<p>No research has been done to compare diaphragm users who insert more spermicide before a second episode of intercourse, and those who do not. N-9 spermicide may retain its contraceptive effect for more than a day inside a cervical cap, and for 12 hours inside a diaphragm, but the impact of multiple ejaculations on N-9 potency is not known. In the absence of concrete data, it is prudent to insert a new dose of spermicide for each intercourse.</p> <ol style="list-style-type: none"><li>1) Leitch WS. Longevity of Gynol II and Ortho Creme in the Prentif cervical cap. <i>Contraception</i> 1986;34(4) 363-79</li><li>2) Leitch WS. Longevity of Ortho Creme and Gynol II in the contraceptive diaphragm. <i>Contraception</i> 1986;34(4) 381-93.</li><li>3) Hatcher RA, Trussell J, Stewart F, Stewart GK, Kowal D, Guest F, et al. The diaphragm, contraceptive sponge, cervical cap and female condom. In: <i>Contraceptive Technology</i>. New York: Irvington Publishers, 1994:191-222.</li></ol>

## **Q.7. Does use of a diaphragm or cervical cap increase the risk of urinary tract infections?**

<b>Recommendations</b>	<b>Rationale</b>
a) Yes, diaphragm use increases the risk of urinary tract infections (UTI).	<p>a) Most studies have found that diaphragm users develop UTI at a rate two to three times higher than non-diaphragm users. However, it is not understood why this is the case. Foreplay and intercourse seem to introduce <i>E. coli</i> bacteria into the vagina. The spermicide, and probably the diaphragm itself, encourages vaginal and urethral colonization of the <i>E. coli</i>.</p>
b) There is no evidence that the cervical cap increases the risk of UTI, although it may do so.	<p>Several approaches may solve the UTI problem. Urination just before and just after intercourse may offer some protection. Wearing the diaphragm for less time may help. A smaller device, or a different rim style, may relieve pressure on the urethra. Switching to a cervical cap may be an option that retains many of the same advantages as the diaphragm.</p> <ol style="list-style-type: none"><li>1) Foxman B, Chi J-W. Health behavior and urinary tract infection in college-aged women. <i>Journal of Clinical Epidemiology</i> 1990;43(4):329-37.</li><li>2) Hooton TM, Hillier S, Johnson C, Roberts PL, Stamm WE. <i>Escherichia coli</i> bacteriuria and contraceptive method. <i>Journal of the American Medical Association</i> 1991;265(1):64-9.</li><li>3) Hatcher RA, Trussell J, Stewart F, Stewart GK, Kowal D, Guest F, et al. The diaphragm, contraceptive sponge, cervical cap and female condom. In: <i>Contraceptive Technology</i>. New York: Irvington Publishers, 1994:191-222.</li></ol> <p>b) Since there are relatively few cervical cap users, it is difficult to study side effects of cap use. Since the cervical cap shares with the diaphragm the feature of extended spermicide exposure, it is possible that cap use will increase the risk of UTI to a similar extent.</p> <ol style="list-style-type: none"><li>1) Hooton TM, Hillier S, Johnson C, Roberts PL, Stamm WE. <i>Escherichia coli</i> bacteriuria and contraceptive method. <i>Journal of the American Medical Association</i> 1991;265:64-9.</li></ol>

**Q.8. Diaphragm or cervical cap protect against: a) HIV/AIDS? b) other STDs?**

Recommendations	Rationale
<p>a) <b>Against HIV/AIDS?</b></p> <p>Possibly. Diaphragms and caps, even with spermicides, cannot be currently recommended for HIV prevention. Diaphragm use may indirectly reduce the incidence of HIV, however, by preventing bacterial STD co-factors which increase the risk of HIV transmission.</p> <p>For sexually active women who cannot use male or female condoms, a diaphragm, cap with spermicide, or spermicide alone, is unlikely to be riskier than completely unprotected intercourse and may help prevent upper reproductive tract infections (RTI).</p>	<p>a) The effectiveness of the diaphragm and cap against HIV is not known. Much depends on the site of infection; if the portal of virus entry is the cervix, the diaphragm and cap should confer good protection. Until the effectiveness of N-9 spermicide is established, diaphragm or cap use with N-9 spermicide cannot be recommended for HIV prevention.</p> <ol style="list-style-type: none"><li>1) Stein ZA. More on women and the prevention of HIV infection (editorial). <i>American Journal of Public Health</i> 1995;85(11):1485-8.</li><li>2) Centers for Disease Control. Update: barrier protection against HIV infection and other sexually transmitted diseases. <i>Morbidity and Mortality Weekly Report</i> 1993;42:589-91, 597.</li></ol> <p>The highest risk of sexually acquired HIV infection is associated with unprotected intercourse. Women need methods to protect themselves against HIV and other STDs, even if protection is only partial.</p> <ol style="list-style-type: none"><li>1) Feldblum PJ, Weir SS. The protective effect of nonoxynol-9 against HIV infection (letter). <i>American Journal of Public Health</i> 1994;84:1032-4.</li><li>2) Rosenberg MJ, Gollub EL. Methods women can use that may prevent sexually transmitted disease, including HIV (commentary). <i>American Journal of Public Health</i> 1992;82:1473-8.</li><li>3) Elias CJ, Heise LL. Challenges for the development of female-controlled vaginal microbicides. <i>AIDS</i> 1994;8:1-9.</li></ol>

(continued on next page)

**Q.8. Diaphragm/Cap: Protect against HIV/AIDS, other STDs?**  
(continued)

Recommendations	Rationale
<p><b>b) Against other STDs?</b></p> <p>Probably. Users of diaphragms (and probably cervical caps) with spermicides probably have a modestly lower risk of gonorrhea and chlamydia than non-users.</p>	<p><b>b) Diaphragm use has been found to reduce the risk of bacterial STD and pelvic inflammatory disease (PID). One study found a 60% reduction in the risk of PID in diaphragm users compared to women using no contraceptive method. The overall reduction of bacterial cervical infections from spermicide use alone is about 25-50%, but that figure is a gross estimate that includes consistent and correct users as well as inconsistent users. Thus, use of spermicides with diaphragms or cap may reduce the risk of cervical infections. In studies of bacterial STDs among diaphragm users and women whose partners used male condoms, diaphragm users had lower STD risk than women depending on their partners' use of a male condom. The effectiveness of any coital-dependent method (i.e., one that must be applied at or around the time of intercourse) depends on the consistency and correctness of use. For these methods, acceptability and compliance are as important, if not more so, as their efficacy in preventing disease. Even if a female method is less efficacious than the male condom, it may have a greater impact on disease rates if it is used more consistently. Since the diaphragm is a method that combines a physical barrier (the latex or silicon device) and a chemical barrier (the spermicide), it may be more effective than spermicide alone, although there are no data to confirm this.</b></p> <ol style="list-style-type: none"> <li>1) Cates W Jr, Stone KM. Family planning, sexually transmitted diseases and contraceptive choice: a literature update-part 1. <i>Family Planning Perspectives</i> 1992;24:75-84.</li> <li>2) Kelaghan J, Rubin GL, Ory HW, Layde PM. Barrier-method contraceptives and pelvic inflammatory disease. <i>Journal of the American Medical Association</i> 1982;248(2):184-7.</li> <li>3) Austin H, Louv WC, Alexander WJ. A case-control study of spermicides and gonorrhea. <i>Journal of the American Medical Association</i> 1984;251:2822-4.</li> <li>4) Feldblum PJ, Morrison CS, Roddy RE, Cates W Jr. The effectiveness of barrier methods of contraception in preventing the spread of HIV. <i>AIDS</i> 1995;9(Suppl A):S85-S93.</li> <li>5) Cates W Jr, Hinman AR. AIDS and absolutism--the demand for perfection in prevention (sounding board). <i>New England Journal of Medicine</i> 1992;327:492-4.</li> </ol>

## Q.1. What should be the role of barrier methods in family planning/reproductive health programs?

Recommendations	Rationale
<p>Barrier methods should be part of the method mix in all family planning/reproductive health (FP/RH) clinics. The advantages of barrier methods, such as STD protection, should be emphasized to providers and clients, as well as the importance of correct and consistent use to achieve pregnancy protection. Barrier methods provide less protection against pregnancy and STDs with typical use.</p> <p>Barrier methods should be presented to clients equally with other methods, allowing the client to choose the method most suitable for him or her.</p>	<p>Many users of FP are at risk of contracting STDs including HIV, yet are unable to avoid their risky sexual encounters and so need preventive methods. Barrier methods are the only class of FP methods that protect users against STDs. A second reason that barrier methods are important is that some people in need of FP are not medically eligible to use, or unwilling to use, hormonal methods, IUDs, NFP or surgical contraception.</p> <p>Yet anecdotal evidence points to provider bias against barrier methods. Providers may perceive barriers to be ineffective; they may also worry about the time required for client education, motivation and fitting (in the case of the diaphragm and cervical cap).</p> <p>While the typical effectiveness of barrier methods is indeed less than that of hormonal methods and IUDs, for consistent and correct users, barrier method effectiveness is quite high. Although some barrier methods do require more time with new acceptors, the potential benefits of STD prevention, and communication with sexual partners are considerable.</p> <ol style="list-style-type: none"> <li>1) Cervical cap: effective, convenient, but overlooked. <i>Contraceptive Technology Update</i> 1990;11:49-54.</li> <li>2) Trussell J, Sturgen K, Strickler J, Dominik R. Comparative contraceptive efficacy of the female condom and other barrier methods. <i>Family Planning Perspectives</i> 1994;26:66-72.</li> <li>3) Norsigian J. Feminist perspective on barrier use. In: Mauck CK, Cordero M, Gabelnick HL, Spieler JM, Rivera R (editors). <i>Barrier contraceptives: current status and future prospects</i>. New York: Wiley-Liss, 1994.</li> <li>4) Feldblum P, Joanis C. Modern barrier methods: effective contraception and disease prevention. Research Triangle Park, NC: Family Health International, 1994.</li> </ol>

## Classification of Selected Procedures for Barrier Methods

Procedure	Class	Class	Class	Rationale
	DIAPHRAGM	CONDOM	SPERMICIDE	
Pelvic examination (bimanual and speculum)	A	C	C	<ul style="list-style-type: none"> <li>• A pelvic exam is required for diaphragm/cap fitting.</li> <li>• A pelvic exam is not required for safe use of other barrier methods.</li> </ul>
Blood pressure	C	C	C	Barrier method use does not affect blood pressure <sup>1</sup> .
Breast examination	C	C	C	Barrier method use does not affect breast cancer risk <sup>1</sup> .
STD screening by lab tests (for asymptomatic persons)	C	C	C	<ul style="list-style-type: none"> <li>• Presence of an STD will not affect the safe use of barrier methods.</li> <li>• If an infected person chooses to have intercourse, use of a barrier may reduce the risk of transmission to the partner<sup>2-4</sup>.</li> </ul>
Cervical cancer screening	C	C	C	<ul style="list-style-type: none"> <li>• Cervical screening is not needed for the safe use of barrier methods<sup>1</sup>.</li> <li>• Use of barrier methods may reduce the risk of developing cervical cancer<sup>5-6</sup>.</li> </ul>
Routine mandatory lab tests (e.g., cholesterol, glucose, liver function tests)	D	D	D	Routine lab tests are not applicable to the use of barrier methods for contraception.
Proper infection prevention procedures	A	C	C	Proper infection prevention procedures are not applicable to barrier method use, except for fitting of diaphragms.

(continued on next page)

**KEY:**

- Class A** = essential and mandatory or otherwise important in all circumstances, for safe and effective use of the contraceptive method
- Class B** = medically/epidemiologically rational in some circumstances to optimize the safe and effective use of the contraceptive method, but may not be appropriate for all clients in all settings
- Class C** = may be appropriate for good preventive health care, but not materially related to safe and effective use of the contraceptive method
- Class D** = not materially related to either good routine preventive health care or safe and effective use of the contraceptive method

## Classification of Selected Procedures for Barrier Methods

(continued)

Procedure	Class DIAPHRAGM	Class CONDOM	Class SPERMICIDE	Rationale
<p>Specific counseling points for barrier method use:</p> <ul style="list-style-type: none"> <li>• correct use of method</li> <li>• efficacy</li> <li>• what to do in the event of condom breakage, or discomfort following spermicide or barrier method use</li> <li>• STD protection (when/as appropriate)</li> </ul>	A	B	B	<ul style="list-style-type: none"> <li>• Accurate client education is essential for maximum quality of FP services.</li> <li>• Appropriate counseling about contraceptive side effects at the time of method selection can lead to improved client satisfaction and contraceptive continuation<sup>7</sup>.</li> <li>• Clients should know that only barrier methods can protect against STDs. Consistent condom use reduces the risk of becoming infected with any STD<sup>8-11</sup>. Spermicidal methods, including diaphragms and caps, probably reduce the risk of bacterial STDs and may have an effect against viral STDs<sup>8,12-16</sup>.</li> <li>• The woman should be encouraged to return if she has any problems or at any time she has questions or concerns.</li> <li>• For condoms and spermicides, counseling is desirable, but perhaps not feasible for over the counter use. However, it should be encouraged.</li> <li>• When methods are dispensed in clinical settings, counseling should be provided.</li> </ul>

(continued on next page)

**KEY:**

- Class A** = essential and mandatory or otherwise important in all circumstances, for safe and effective use of the contraceptive method
- Class B** = medically/epidemiologically rational in some circumstances to optimize the safe and effective use of the contraceptive method, but may not be appropriate for all clients in all settings
- Class C** = may be appropriate for good preventive health care, but not materially related to safe and effective use of the contraceptive method
- Class D** = not materially related to either good routine preventive health care or safe and effective use of the contraceptive method

## Classification of Selected Procedures for Barrier Methods (continued)

### Citations for Procedures Table:

- 1) World Health Organization. Improving access to quality care in family planning: medical eligibility criteria for contraceptive use. Geneva: WHO, 1996.
- 2) Cates W Jr, Stone KM. Family planning, sexually transmitted diseases and contraceptive choice: a literature update-part 1. *Family Planning Perspectives* 1992;24:75-84.
- 3) Hatcher RA, Trussell J, Stewart F, Stewart GK, Kowal D, Guest F, et al. *Contraceptive Technology*. New York: Irvington Publishers, 1994.
- 4) Feldblum PJ, Morrison CS, Roddy RE, Cates W Jr. The effectiveness of barrier methods of contraception in preventing the spread of HIV. *AIDS* 1995;9(Suppl A):S85-S93.
- 5) Hildesheim A, Brinton LA, Mallin K, Lehman HF, Stolley P, Savitz DA, et al. Barrier and spermicidal contraceptive methods and risk of invasive cervical cancer. *Epidemiology* 1990;1(4):266-72.
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- 7) Cotten N, Stanback J, Maidouka H, Taylor-Thomas JT, Turk T. Early discontinuation of contraceptive use in Niger and Gambia. *International Family Planning Perspectives* 1992;18(4):145-9.
- 8) Update: barrier protection against HIV infection and other sexually transmitted diseases. *Morbidity and Mortality Weekly Report* 1993;42:589-91, 597.
- 9) Saracco A, Musicco M, Nicolosi A, Angarano G, Arici C, Gavazzeni G, et al. Man-to-woman sexual transmission of HIV: longitudinal study of 343 steady partners of infected men. *Journal of Acquired Immune Deficiency Syndrome* 1993;6:497-502.
- 10) de Vincenzi I, for the European Study Group on Heterosexual Transmission of HIV. A longitudinal study of human immunodeficiency virus transmission by heterosexual partners. *New England Journal of Medicine* 1994;331(6):341-6.
- 11) Soper DE, Shoupe D, Shangold GA, Shangold MM, Gutmann J, Mercer L. Prevention of vaginal trichomoniasis by compliant use of the female condom. *Sexually Transmitted Diseases* 1993;20:137-9.
- 12) Niruthisard S, Roddy RE, Chutivongse S. Use of nonoxynol-9 and reduction in rate of gonococcal and chlamydial cervical infections. *Lancet* 1992;339:1371-5.
- 13) Weir SS, Feldblum PJ, Zekeng L, Roddy RE. The use of nonoxynol-9 for protection against cervical gonorrhea. *American Journal of Public Health* 1994;84:910-4.
- 14) Kreiss J, Ngugi E, Holmes K, Ndinya-Achola J, Waiyaki P, Roberts PL, et al. Efficacy of nonoxynol 9 contraceptive sponge use in preventing heterosexual acquisition of HIV in Nairobi prostitutes. *Journal of the American Medical Association* 1992;268:477-82.
- 15) Zekeng L, Feldblum PJ, Godwin SE, Oliver RM, Kaptue L. HIV infection and barrier contraceptive use among high-risk women in Cameroon. *AIDS* 1993;7:725-31.
- 16) Feldblum PJ, Weir SS. The protective effect of nonoxynol-9 against HIV infection (letter). *American Journal of Public Health* 1994;84:1032-4.

## 1.10 Oral Contraceptives as Emergency Contraceptive Pills

This section outlines recommendations on the following selected procedural questions for Combined Oral Contraceptives (COCs) and oral levonorgestrel (0.75 mg) as Emergency Contraceptive Pills (ECPs). However, unless otherwise indicated, ECPs refers to using COCs with the Yuzpe method (See Question 1):

1. What COC pill formulation is recommended for ECPs?
2. Who may use ECPs?
3. May ECPs be used **four, five, or six days after unprotected intercourse?**
4. May ECPs be used if a woman has had **more than one act of unprotected intercourse during the current cycle?**
5. a) Since ECPs may cause nausea and vomiting, should **anti-emetics** be routinely prescribed?  
b) What is the recommendation if a woman **vomits** shortly after taking ECPs?  
c) Will **severe diarrhea** decrease ECP effectiveness?
6. Are there important **drug interactions** with ECPs?
7. **How frequently** can ECPs be used?
8. May ECPs be **provided in advance** of possible unprotected intercourse?
9. What contraceptive methods are appropriate for immediate initiation **after use of ECPs?** When are they appropriate to start?
10. What instructions should be given to the client if she suspects she is **pregnant after using ECPs?**
11. If **low-dose COCs** are initiated immediately after use of ECPs, should a full or partial cycle be provided?
12. Should ECP use be **restricted to the time around expected ovulation?**
13. May **oral levonorgestrel** be recommended for use as ECPs?

# Q.1. What COC pill formulation is recommended for ECPs?

Recommendations	Rationale						
<p>a) If COCs containing 50 mcg ethinyl estradiol (EE) and 250 mcg levonorgestrel (or 500 mcg norgestrel) are used, two pills should be taken in each dose. Two doses are taken 12 hours apart.</p> <p>The two doses should total at least 200 mcg of EE and 1.0 mg of levonorgestrel (or 2.0 mg norgestrel). This is the Yuzpe method, which is the recommended ECP regimen.</p>	<p>a) The Yuzpe method is recommended because it has been shown to be approximately 75% effective in preventing pregnancy and because COCs are accessible and safe. The safety and efficacy of alternative methods is now under investigation.</p> <ol style="list-style-type: none"> <li>1) Trussell J, Ellertson C, Stewart F. The effectiveness of the Yuzpe regimen of emergency contraception. <i>Family Planning Perspectives</i> 1996;28:58-64,87.</li> <li>2) Webb A. How safe is the Yuzpe method of emergency contraception? <i>Fertility Control Reviews</i> 1995;4(2):16-8.</li> </ol>						
<p>50 mcg EE pills (e.g., Ovral, Feminal) each with 250 mcg (0.25 mg) levonorgestrel or 500 mcg (0.5 mg) norgestrel:</p>	<p>The effectiveness calculation of 75% is based on the expected number of pregnancies compared to the observed number of pregnancies. Expected pregnancies are calculated by matching the cycle day of intercourse with expected cycle day-specific conception rates. Thus, if 100 women have unprotected intercourse once during the second or third week of their menstrual cycle, about eight would become pregnant. If those same 100 women used ECPs, only two would become pregnant (75% reduction).</p>						
<table border="1"> <tr> <td># pills in first dose</td> <td> </td> <td># pills in second dose (12 hours later)</td> </tr> <tr> <td>2</td> <td> </td> <td>2</td> </tr> </table>	# pills in first dose		# pills in second dose (12 hours later)	2		2	<ol style="list-style-type: none"> <li>1) Trussell J, Ellertson C, Stewart F. The effectiveness of the Yuzpe regimen of emergency contraception. <i>Family Planning Perspectives</i> 1996;28:58-64,87.</li> </ol>
# pills in first dose		# pills in second dose (12 hours later)					
2		2					
<p>b) If pills containing 30 mcg EE and 150 mcg levonorgestrel (or 300 mcg norgestrel) are used, four tablets should be taken followed by another four 12 hours later.</p> <p>30 mcg or 35 mcg EE pills (e.g., Lo-ovral, Lo-feminal) each with 150 mcg (0.15 mg) levonorgestrel or 300 mcg (0.3 mg) norgestrel:</p>	<p>b) Two doses each consisting of four 30/150 mcg pills are recommended because each dose at least meets the minimum of the Yuzpe regimen of 100 mcg of EE and 0.5 mg of levonorgestrel (or 1.0 mg of norgestrel) per dose.</p> <p>Norgestrel contains two isomers, only one of which is bioactive (levonorgestrel), thus 0.5 mg levonorgestrel is bioequivalent to 1.0 mg of norgestrel.</p>						
<table border="1"> <tr> <td># pills in first dose</td> <td> </td> <td># pills in second dose (12 hours later)</td> </tr> <tr> <td>4</td> <td> </td> <td>4</td> </tr> </table>	# pills in first dose		# pills in second dose (12 hours later)	4		4	<ol style="list-style-type: none"> <li>1) International Medical Advisory Panel, IPPF. Statement on emergency contraception. <i>Planned Parenthood in Europe</i> 1995;24(2):5-6.</li> <li>2) Program for Appropriate Technology in Health. Emergency contraception: a resource manual for providers. Seattle: PATH, 1997.</li> <li>3) Consortium for Emergency Contraception. Using emergency contraceptive pills (ECPs): a prototype ECP training curriculum. Welcome, Maryland: The Consortium, 1996.</li> </ol>
# pills in first dose		# pills in second dose (12 hours later)					
4		4					

## Q.2. Who may use ECPs?

Recommendations	Rationale
<p>Any woman who is concerned because she has had unprotected intercourse and who does not desire pregnancy may use ECPs. Use by women who are known to have an established pregnancy is not recommended, as evidence indicates that it will have no effect.</p>	<p>According to World Health Organization (WHO), International Planned Parenthood Federation (IPPF), the International Consortium for Emergency Contraception, Program for Appropriate Technology in Health (PATH) and most clinical guidelines, "established pregnancy" is the only medical contraindication for ECP use. "Established pregnancy" is technically defined by most specialists as an implanted embryo. Because ECPs will not disrupt an implanted embryo, ECPs will not have an effect on an established pregnancy. Further, the best evidence indicates that there are not any teratogenic effects from ECP exposure in utero.</p> <p>Beyond pregnancy, there are no other contraindications to ECP use, because the amount of steroids in the Yuzpe regimen and the duration of use are not considered substantial enough to have a clinically significant effect. A study of the effects of the Yuzpe method found no significant changes in clotting factors following treatment. Thus, the usual COC contraindications are not applicable.</p> <ol style="list-style-type: none"><li>1) World Health Organization. Improving access to quality care in family planning: medical eligibility criteria for contraceptive use. Geneva: WHO, 1996.</li><li>2) International Medical Advisory Panel, IPPF. Statement on emergency contraception. <i>Planned Parenthood in Europe</i> 1995;24(2):5-6.</li><li>3) Consortium for Emergency Contraception. Emergency contraceptive pills. <i>Wellcome, Maryland: The Consortium</i>, 1996.</li><li>4) Program for Appropriate Technology in Health. Emergency contraception: a resource manual for providers. <i>Seattle: PATH</i>, 1997.</li><li>5) Webb A. How safe is the Yuzpe method of emergency contraception? <i>Fertility Control Reviews</i> 1995;4(2):16-8.</li><li>6) Bracken M. Oral contraception and congenital malformations in offspring: A review and meta-analysis of the prospective studies. <i>Obstetrics and Gynecology</i> 1990;76:552-7.</li><li>7) Simpson JL, Phillips OP. Spermicides, hormonal contraception and congenital malformations. <i>Advances in Contraception</i> 1990;6:141-67.</li></ol>

### Q.3. May ECPs be used four, five, or six days after unprotected intercourse?

Recommendations	Rationale
<p>While it is recommended that ECPs be taken within 72 hours of unprotected intercourse for maximum effectiveness, ECPs may have some residual effect beyond 72 hours, particularly if ovulation has not occurred.</p>	<p>It is theorized that the efficacy of ECPs taken after 72 hours is lower than the efficacy of ECPs taken within the recommended window of 72 hours. Almost all studies, thus far, have only measured the effectiveness of ECPs up to 72 hours after intercourse. If the regimen is initiated more than 72 hours after intercourse, the failure rate may be increased.</p> <ol style="list-style-type: none"><li>1) Webb A. When to use post-coital contraception. <i>Fertility Control Reviews</i> 1992;2(2):15-7.</li><li>2) Emergency oral contraception. <i>ACOG Practice Patterns</i> 1996;3.</li></ol> <p>However, if the primary mechanism of action of ECPs is the prevention or delaying of ovulation, variations in timing of ECP use in relation to ovulation could result in ECPs being effective for longer than 72 hours. The 72 hour limit is currently being investigated.</p> <ol style="list-style-type: none"><li>1) Swahn ML, Westlund P, Johannisson E, Bygdeman M. Effect of post-coital contraceptive methods on the endometrium and the menstrual cycle. <i>Acta Obstetrica et Gynecologica Scandinavica</i> 1996;75:738-44.</li><li>2) Trussell J, Ellertson C, Rodriguez G. The Yuzpe regimen of emergency contraception: How long after the morning after? <i>Obstetrics and Gynecology</i> 1996;88:150-4.</li><li>3) Grou F, Rodrigues, I. The morning-after pill-how long after? <i>American Journal of Obstetrics and Gynecology</i> 1994;171:1529-34.</li><li>4) Consortium for Emergency Contraception. Emergency contraceptive pills update. <i>Welcome, Maryland: The Consortium</i>, March 1997.</li></ol>

## Q.4. May ECPs be used if a woman has had more than one act of unprotected intercourse during the current cycle?

Recommendations	Rationale
Yes, unless the woman has a known established pregnancy.	<p>ECPs are not effective once implantation has occurred. While the mechanism of action of ECPs is not known for certain, several studies have shown that ECPs can inhibit or delay ovulation.</p> <ol style="list-style-type: none"><li>1) International Medical Advisory Panel, IPPF. Statement on emergency contraception. <i>Planned Parenthood in Europe</i> 1995;24(2):5-6.</li><li>2) Consortium for Emergency Contraception. Emergency contraceptive pills update. <i>Wellcome, Maryland: The Consortium</i>, March 1997.</li><li>3) Swahn ML, Westlund P, Johannisson E, Bygdeman M. Effect of post-coital contraceptive methods on the endometrium and the menstrual cycle. <i>Acta Obstetrica et Gynecologica Scandinavica</i> 1996;75:738-44.</li></ol> <p>ECPs do not interrupt an established pregnancy. Nevertheless, if an error is made in determining whether the woman is pregnant, the best evidence indicates that taking ECPs will not be harmful to an embryo.</p> <ol style="list-style-type: none"><li>1) Webb A. How safe is the Yuzpe method of emergency contraception? <i>Fertility Control Reviews</i> 1995;4(2):16-8.</li><li>2) Bracken M. Oral contraception and congenital malformations in offspring: A review and meta-analysis of the prospective studies. <i>Obstetrics &amp; Gynecology</i> 1990;76(3):552-7.</li><li>3) Simpson JL, Phillips OP. Spermicides, hormonal contraception and congenital malformations. <i>Advances in Contraception</i> 1990;6:141-67.</li><li>4) Consortium for Emergency Contraception. Emergency contraceptive pills update. <i>Wellcome, Maryland: The Consortium</i>, March 1997.</li></ol> <p>If, after evaluation (by history and, where indicated, by physical exam) the woman wants ECPs and an established pregnancy remains a possibility, it is permissible to give ECPs, if you explain that she could already be pregnant, in which case the regimen will not be effective.</p> <ol style="list-style-type: none"><li>1) Consortium for Emergency Contraception. Emergency contraceptive pills. <i>Wellcome, Maryland: The Consortium</i>, 1996.</li></ol>

- Q.5. a) Since ECPs may cause nausea, should anti-emetics be routinely prescribed?**
- b) What is the recommendation if a woman vomits shortly after taking ECPs?**
- c) Will severe diarrhea decrease ECP effectiveness?**

Recommendations	Rationale
<p>a) <b>Should routine <u>anti-emetics</u> be given?</b></p> <p>Not necessarily. Anti-emetics have not been generally recommended for routine use because the use of anti-emetics will not benefit the majority of women receiving ECPs and routine use may not be cost-effective in some areas. Some providers recommend that ECPs be taken with food to reduce the risk of nausea and vomiting.</p> <p>However, when available, anti-emetics may be prescribed with instructions to take them an hour before the first dose of ECPs, particularly for a woman with a history of nausea and vomiting after taking estrogens.</p> <p>For anti-emetics to be effective with ECPs, they need to be taken before the onset of symptoms.</p> <p>b) <b><u>Vomiting</u>?</b></p> <p>If a patient vomits within two hours of taking ECPs, some providers recommend repeating the dose.</p> <p>In the case of severe vomiting, some providers recommend that the pills be administered vaginally.</p> <p>c) <b>Will <u>severe diarrhea</u> decrease effectiveness?</b></p> <p>Possibly. Severe diarrhea can potentially reduce the effectiveness of COCs, and thus ECPs.</p>	<p>a) Approximately 30 to 65% of women who take ECPs experience nausea and up to 30% will vomit. Use of a prophylactic anti-emetic can prevent nausea and vomiting, but oral anti-emetics are not significantly helpful after nausea has developed.</p> <ol style="list-style-type: none"> <li>1) Emergency contraceptive pills: safe and effective but not widely used. <i>Outlook</i> 1996;14(2):1-6.</li> <li>2) Webb A. Emergency contraception. <i>Fertility Control Reviews</i> 1995;4:2:3-7.</li> <li>3) Emergency oral contraception. <i>ACOG Practice Patterns</i> 1996;3.</li> <li>4) Bagshaw SN, Edwards D, Tucker AK. Ethinyl oestradiol and d-norgestrel is an effective postcoital emergency contraceptive: a report of its use in 1,200 patients in a family planning clinic. <i>Australian and New Zealand Journal of Obstetrics and Gynaecology</i> 1988;28:137-40.</li> </ol> <p>b) An effective dose of the hormones may not have been absorbed into the bloodstream within two hours. If vaginal administration is used, blood levels of estrogen and progestin are probably equivalent to oral administration, based on the frequency of estrogen-induced side effects and preliminary studies of effectiveness.</p> <ol style="list-style-type: none"> <li>1) International Medical Advisory Board, IPPF. Statement on Emergency Contraception. <i>Planned Parenthood in Europe</i> 1995;24(2):5-6.</li> <li>2) Consortium for Emergency Contraception. <i>Emergency contraceptive pills</i>. Welcome, Maryland: The Consortium, 1996.</li> </ol> <p>c) Severe diarrhea for more than 24 hours may possibly interfere with absorption of ECPs and reduce the effectiveness of the regimen.</p> <ol style="list-style-type: none"> <li>1) Orme M, Back DJ. Oral contraceptive steroids - pharmacological issues of interest to the prescribing physician. <i>Advances in Contraception</i> 1991;7:325-31.</li> </ol>

## Q.6. Are there important drug interactions with ECPs?

Recommendations	Rationale
<p>a) Probably. While there is little direct information for drug interactions with ECPs, known drug interactions with COCs should be presumed to apply to ECPs.</p> <p>b) Women taking liver enzyme-inducing drugs, mainly anticonvulsant treatments (phenytoin, phenobarbital, and carbamazepine) and the antibiotic rifampicin, may have to take a higher dose than the recommended ECP regimen. However, an increased dose of ECPs may increase the severity or duration of side effects.</p>	<p>a) Anticonvulsants, especially hydantoins (e.g., phenytoin), barbiturates (e.g., primidone, phenobarbital), and carbamazepine (non-barbiturates) lead to increased metabolism, thus eliminating estrogen and progesterin in the bile and decreasing the effectiveness of COCs (newly marketed anti-epileptics, including vigabatrin, lamotrigine, and valproic acid are not included).</p> <p>1) Anderson GD, Graves NM. Drug interactions with antiepileptic agents. <i>CNS Drugs</i> 1994;2(4):268-79.</p> <p>2) Webb A. How safe is the Yuzpe method of emergency contraception? <i>Fertility Control Reviews</i> 1995;4:2:16-18</p> <p>3) Orme M, Back DJ. Oral contraceptive steroids - pharmacological issues of interest to the prescribing physician. <i>Advances in Contraception</i> 1991;7:325-31.</p> <p>Rifampin/rifampicin (anti-tuberculosis) and griseofulvin (anti-fungal) cause hepatic micro-enzyme induction, thus reducing blood levels of COCs; it is presumed the effectiveness of the ECP regimen is also reduced.</p> <p>1) Orme M, Back DJ. Oral contraceptive steroids - pharmacological issues of interest to the prescribing physician. <i>Advances in Contraception</i> 1991;7:325-31.</p> <p>2) Angle M, Huff P, Lea J. Interactions between oral contraceptives and therapeutic drugs. <i>Outlook</i> 1991;9(1):1-6.</p> <p>b) For women taking anticonvulsants and rifampicin who require emergency contraception (EC), some experts have recommended doubling the ECP dose.</p> <p>1) Guillebaud J. <i>Contraception: your questions answered</i>. New York: Churchill Livingstone, 1993:114-5.</p> <p>2) Program for Appropriate Technology in Health. <i>Emergency contraception: a resource manual for providers</i>. Seattle: PATH, 1997.</p>

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## Q.6. Drug interactions with ECPs? (continued)

Recommendations	Rationale
<p>c) Since most anticonvulsants are associated with a risk of birth defects, prevention of unplanned pregnancy is particularly important.</p> <p>d) It is unlikely that broad spectrum antibiotics significantly affect the action of COCs, including ECPs.</p>	<p>c) Almost all anticonvulsants are teratogenic.</p> <ol style="list-style-type: none"><li>1) Drug facts and comparisons. St. Louis: Facts and Comparisons, January 1997.</li><li>2) Mattson RH, Rebar RW. Contraceptive methods for women with neurologic disorders. American Journal of Obstetrics and Gynecology 1993;168:2027-32.</li></ol> <p>d) There is evidence that broad spectrum antibiotics do not decrease COC effectiveness, so in the absence of data for ECPs, the experts presume no clinically important effects on ECP use, either.</p> <ol style="list-style-type: none"><li>1) Back DJ, Orme M. Drug interactions. In: Goldzieher JW, Fotherby K, editors. Pharmacology of the contraceptive steroids. New York: Raven Press, 1994:407-26.</li><li>2) Friedman CI, Huneke AL, Kim MH, Powell J. The effect of ampicillin on oral contraceptive effectiveness. Obstetrics and Gynecology 1980;55:33-6.</li><li>3) Grimmer SFM, Allen WL, Back DJ, Breckenridge AM, Orme M, Tjia J. Cotrimoxazole on oral contraceptive steroids in women. Contraception 1983;28:53-9.</li><li>4) Joshi JV, Joshi UM, Sankolli GM, Krishna U, Mandlekar A, Chowdhury V, et al. A study of interaction of a low-dose combination oral contraceptive with ampicillin and metronidazole. Contraception 1980;22:643-52.</li></ol>

## Q.7. How frequently can ECPs be used?

Recommendations	Rationale
<p>a) While ECPs conceivably can be used as often as a woman has unprotected intercourse, this is not recommended. There are no data to suggest that there are serious medical consequences of repeated treatment within one cycle. However,</p> <ul style="list-style-type: none"><li>• ECPs are not as effective as the regular use of other steroidal contraceptive methods;</li><li>• repeated use of ECPs, especially during one cycle, can result in a level of exposure to contraceptive steroids equal to or above routine COC use, in which case, COC medical eligibility concerns may become important; and</li><li>• unpleasant side effects of nausea and vomiting and the disruption of a woman's menstrual bleeding pattern due to ECPs make repeated use undesirable for most women.</li></ul> <p>b) Counseling about other contraceptive options after the use of ECPs should be encouraged at the same time as ECPs are provided, when appropriate.</p>	<p>a) The consequences of repeated use will be lower efficacy than other steroidal methods, repeated nausea and vomiting and a disruption in the bleeding pattern. There is some concern if ECPs are used so frequently that the average level of exposure to contraceptive steroids over one cycle is equal to or above routine COC use.</p> <p>1) Webb A. How safe is the Yuzpe method of emergency contraception? <i>Fertility Control Reviews</i> 1995;4(2):16-8.</p>

## Q.8. May ECPs be provided in advance of possible unprotected intercourse?

Recommendations	Rationale
<p>Yes.</p> <p>Providing ECPs in advance will improve access to the method and the ability of the client to use the regimen within the recommended 72 hours.</p> <p>For example, when a woman visits a provider for gynecological care, contraception or sexually transmitted disease (STD) treatment, she can be provided with ECPs and counseled on their use.</p> <p>Providing ECP information and supplies (or a prescription) in advance may be especially relevant for women relying on barrier methods or periodic abstinence.</p>	<p>The Yuzpe regimen is quite safe. If the prescription guidelines are followed by the provider, it is highly unlikely that women would suffer adverse affects from the regimen. In addition, ECPs help protect a woman from pregnancy and abortion, which are more dangerous than ECP use.</p> <p>Difficulty in getting access to ECPs within 72 hours of unprotected intercourse is a barrier to use. Providing ECP information and supplies (or a prescription) in advance can be convenient for both providers and women, educates women about how ECPs may be of use, eliminates the need for another clinic visit, and ensures that ECPs are available promptly after unprotected intercourse.</p> <ol style="list-style-type: none"><li>1) Trussell J, Stewart F, Guest F, Hatcher R. Emergency contraceptive pills: a simple proposal to reduce unintended pregnancies. <i>Family Planning Perspectives</i> 1992;24(6):269-73.</li><li>2) Webb A. How safe is the Yuzpe method of emergency contraception? <i>Fertility Control Reviews</i> 1995;4(2):16-28.</li><li>3) Glasier A. Emergency contraception: time for deregulation? (commentary) <i>British Journal of Obstetrics and Gynaecology</i> 1993;100:611-2</li><li>4) Program for Appropriate Technology in Health. <i>Emergency contraception: a resource manual for providers</i>. Seattle: PATH, 1997.</li><li>5) Trussell J, Ellertson C, Stewart F. The effectiveness of the Yuzpe regimen of emergency contraception. <i>Family Planning Perspectives</i> 1996;28:58-64,87.</li></ol>

## Q.9. What contraceptive methods are appropriate for immediate initiation after use of ECPs? When are they appropriate to start?

Recommendations	Rationale
<p>Barrier methods and other non-hormonal methods may be initiated immediately after ECP use.</p> <p>Oral contraceptives may be initiated immediately after ECP use (with routine screening). With routine screening, some providers also provide depo-medroxyprogesterone acetate (DMPA) immediately, because of the low risk of pregnancy (2%) following ECP use, and the low risk of teratogenic effects; other providers await the start of menses before providing injectable contraceptives.</p> <p>Long-term methods, such as an IUD or NORPLANT® Implants, can be initiated when menses return.</p>	<p>There are no clinical data indicating that one method is more appropriate than another for use after ECPs. The choice should be made by the client and the provider. If the client was a pill user when she came in for ECPs, the reason for her missed pills should be discussed.</p> <p>It is always recommended that a pregnant woman avoid unnecessary medication. However, if the woman is already pregnant or becomes pregnant due to failure of ECPs, and chooses a hormonal method, the best evidence indicates no increased risk of birth defects for the fetus.</p> <ol style="list-style-type: none"><li>1) Bracken M. Oral contraception and congenital malformations in offspring: A review and meta-analysis of the prospective studies. <i>Obstetrics and Gynecology</i> 1990;76:552-7.</li><li>2) Simpson JL, Phillips OP. Spermicides, hormonal contraception and congenital malformations. <i>Advances in Contraception</i> 1990;6:141-67.</li><li>3) Webb A. How safe is the Yuzpe method of emergency contraception? <i>Fertility Control Reviews</i> 1995;4(2):16-28.</li><li>4) World Health Organization. Improving access to quality care in family planning: medical eligibility criteria for contraceptive use. Geneva: WHO, 1996.</li></ol>

**Q.10. What instructions should be given to the client if she suspects she is pregnant after using ECPs?**

Recommendations	Rationale
<p>Tell the client to return to the provider if she becomes suspicious she is pregnant. In particular, symptoms include the absence of a menstrual period for longer than three weeks (see Appendix A for other signs and symptoms of pregnancy).</p>	<p>ECPs are 75% effective, with a 2% risk of pregnancy for one-time use among all women who use ECPs. The client needs to be aware of the possible signs of failed ECPs in order to recognize pregnancy.</p> <ol style="list-style-type: none"> <li>1) Farrell B, Solter C, Huber D. Comprehensive reproductive health and family planning training curriculum. Module 5: emergency contraceptive pills. Watertown, MA: Pathfinder International, 1997.</li> <li>2) CSAC. Emergency (postcoital) contraception guidelines for doctors. <i>British Journal of Family Planning</i> 1992;18(3):centrefold.</li> <li>3) Trussell J, Ellertson C, Stewart F. The effectiveness of the Yuzpe regimen of emergency contraception. <i>Family Planning Perspectives</i> 1996;28(2):58-64, 87.</li> </ol>

**Q.11. If low-dose COCs are initiated immediately after use of ECPs, should a full or partial cycle be provided?**

Recommendations	Rationale
<ol style="list-style-type: none"> <li>a) Either a full cycle of 21 hormonal pills may be provided or a woman can complete the cycle from which she took the ECPs. However, if high dose COCs (50 mcg EE) were used, completing the pill pack from which the ECPs were taken is not recommended.</li> <li>b) Some providers recommend that a non-hormonal back-up method (e.g., abstinence, condoms) be used for seven days.</li> <li>c) Linking ECP use to long term use of COCs is helpful to women desiring COCs for contraception.</li> </ol>	<ol style="list-style-type: none"> <li>a) There is no medical evidence indicating that less than a full cycle of COCs should be provided after ECP use. The length of the COC cycle is arbitrary.</li> <li>b) Use of COCs for seven days suppresses ovulation.               <ol style="list-style-type: none"> <li>1) Smith SK, Kirkman RJ, Arce BB, McNeilly AS, Loudon NB, Baird DT. The effect of deliberate omission of Trinordiol or Microgynon on the hypothalamo-pituitary-ovarian axis. <i>Contraception</i> 1986;34(5):513-22.</li> <li>2) Molloy BG, Coulson KA, Lee JM, Watters JK. "Missed pill" conception: a fact or fiction? <i>British Medical Journal, Clinical Research Edition</i> 1985;290(6480):1474-5.</li> </ol> </li> <li>c) Because the woman has just used ECPs, the provider can be reasonably sure the woman is not pregnant. There is only a 2% risk of pregnancy with one-time use of ECPs.               <ol style="list-style-type: none"> <li>1) Trussell J, Stewart F. The effectiveness of postcoital hormonal contraception. <i>Family Planning Perspectives</i> 1992;24(6):262-4.</li> </ol> </li> </ol>

## Q.12. Should ECP use be restricted to the time around expected ovulation?

Recommendations	Rationale
<p>No. ECPs can be used at any time during the menstrual cycle. If the client is concerned about the risk of pregnancy, she should receive ECPs regardless of the timing. This is especially true if the client has been using OCs.</p>	<p>It is difficult to know when ovulation occurs in a given cycle, particularly for women with irregular cycles. The risk of conception is highest between six days before and one day after ovulation.</p> <ol style="list-style-type: none"><li>1) Webb A. Emergency contraception. <i>Fertility Control Reviews</i> 1995;4:2:3-7.</li><li>2) Wilcox AJ, Weinberg CR, Baird DD. Timing of sexual intercourse in relation to ovulation. <i>New England Journal of Medicine</i> 1995;333:1517-21.</li></ol> <p>COC users do not have a "menstrual cycle" but withdrawal bleeding; missed OCs can permit follicular development which can lead to ovulation.</p> <ol style="list-style-type: none"><li>1) Landgren BM, Emiczky CS. The effect on follicular growth and luteal function of "missing the pill." <i>Contraception</i> 1991;43(2):149-59.</li><li>2) Killick SR, Bancroft K, Oelbaums MJ, Elstein M. Extending the duration of the pill-free interval during combined oral contraception. <i>Advances in Contraception</i> 1990;6:33-40.</li></ol>

## Q.13. May oral levonorgestrel be recommended for use as ECPs?

Recommendations	Rationale
<p>Yes. Preliminary data suggest that 0.75 mg levonorgestrel (e.g., Postinor®, Postinor® II) is at least as effective as COCs for ECP use, with fewer side effects than COCs.</p> <p>When high-dose oral levonorgestrel pills are used as ECPs, two doses of 0.75 mg levonorgestrel pills are taken 12 hours apart. The first dose should be taken within 72 hours of unprotected intercourse.</p> <p>If 0.75 mg levonorgestrel pills are not available, low-dose progestin-only pills (POPs) containing levonorgestrel might be tried.</p> <p>The use of low-dose progestin-only pills (POPs) as ECPs would require a woman to take 20 of the 0.0375 mg levonorgestrel POPs or 20 of the 0.075 mg norgestrel POPs in order to get the indicated 0.75 mg dose of levonorgestrel. The total course of therapy would therefore, be 40 tablets.</p>	<p>Early studies of levonorgestrel studied a 48-hour period after unprotected intercourse compared to 72 hours for the COC method. Another study is underway wherein the time limit has been extended to 72 hours after unprotected intercourse. Preliminary studies suggest that levonorgestrel is as effective or more effective than COCs as EC. Oral levonorgestrel pills as EC could improve patient compliance because of the lower incidence of side effects than is associated with COCs as ECPs.</p> <ol style="list-style-type: none"><li>1) Ho PC, Kwan MSW. A prospective randomized comparison of levonorgestrel with the Yuzpe regimen in post-coital contraception. <i>Human Reproduction</i> 1993;8(3):389-92.</li><li>2) Trussell J, Ellertson C. Efficacy of emergency contraception. <i>Fertility Control Reviews</i>, 1995; 4(2):8-11.</li><li>3) Consortium for Emergency Contraception. <i>Emergency contraceptive pills</i>. Welcome, Maryland: The Consortium, 1996.</li></ol> <p>An alternative regimen is comprised of a single dose of 0.6 mg of norgestrel (a racemic mixture of which levonorgestrel is the active isomer) taken within 12 hours of intercourse.</p> <ol style="list-style-type: none"><li>1) Marechaud M. La pilule du lendemain: contraception post-coitale. <i>Soins Gynecologie Obstetrique Puericulture Pediatrie</i> Dec. 1990-Jan 1991;115-6:29-30.</li></ol>

## Classification of Selected Procedures for OCs as ECPs

Procedure	Class	Rationale
Pelvic examination (speculum and bimanual)	C	<ul style="list-style-type: none"> <li>• Established pregnancy, the only condition which would restrict use of COCs, should be identified by history before method initiation. A pelvic exam is not necessary to ensure safe use of short-term COCs<sup>1,2</sup>.</li> <li>• When a pelvic exam is necessary to help evaluate the possibility of pregnancy, then it becomes Class A.</li> </ul>
Blood pressure	C	Because of the short duration of the ECP regimen, it is highly unlikely that ECPs would have adverse effects <sup>3</sup> .
Breast examination	C	A breast exam is not necessary to ensure the safe use of OCs or ECPs. While any hormonal treatment may in theory cause a pre-existing lump to grow it is highly unlikely that ECPs will affect the preexisting condition, due to the short duration of the regimen <sup>1,3</sup> .
STD screening by lab tests (for asymptomatic persons)	C	STD screening by lab tests for asymptomatic clients is not necessary for the safe, short-term use of COCs <sup>1</sup> .
Cervical cancer screening	C	Cervical cancer screening is unrelated to ECP use.
Routine, mandatory lab tests (e.g., cholesterol, glucose, liver function tests)	D	The effects of COCs on cholesterol, blood glucose and normal liver function are slight, and of no demonstrated clinical significance <sup>4</sup> .
Proper infection prevention procedures	C	Proper infection prevention procedures are not applicable to ECP use.

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**KEY:**

- Class A** = essential and mandatory or otherwise important in all circumstances, for safe and effective use of the contraceptive method
- Class B** = medically/epidemiologically rational in some circumstances to optimize the safe and effective use of the contraceptive method, but may not be appropriate for all clients in all settings
- Class C** = may be appropriate for good preventive health care, but not materially related to safe and effective use of the contraceptive method
- Class D** = not materially related to either good routine preventive health care or safe and effective use of the contraceptive method

## Classification of Selected Procedures for OCs as ECPs (continued)

Procedure	Class	Rationale
<p>Specific counseling points for ECP use:</p> <ul style="list-style-type: none"> <li>• efficacy</li> <li>• correct use of the method (including instructions for vomited pills)</li> <li>• what to do in the event ECPs fail</li> <li>• follow-up schedule</li> <li>• information on other contraceptive methods and time of initiation</li> <li>• signs and symptoms for which to see a health provider</li> <li>• common side effects (including potential disruption of menstrual cycle)</li> <li>• STD protection (when/as appropriate)</li> </ul>	A	<ul style="list-style-type: none"> <li>• Counseling is essential for the client to make an informed choice.</li> <li>• Accurate client education regarding efficacy is necessary to prepare the client for the possible failure of the method and subsequent pregnancy<sup>5</sup>.</li> <li>• In the event of ECPs failure, counseling on the absence of known risk of ECPs on fetal development, and referral to follow-up care, are necessary.</li> <li>• Lower abdominal pain, abnormally light, heavy or short bleeding, and the absence of a menstrual period three weeks after using ECPs are signs that a woman could be pregnant or experiencing an ectopic pregnancy. Both of these situations require medical attention<sup>6</sup>.</li> <li>• Appropriate counseling about common side effects of ECPs will prepare the client for the potential uncomfortable side effects and help her effectively manage them.</li> <li>• ECPs commonly cause a disruption in the length of the next menstrual cycle<sup>7</sup>. The client needs to be aware of this temporary disturbance because the arrival of the menstrual period will signify that she is not pregnant.</li> <li>• When time permits and the situation is appropriate, the client should be counseled on STD protection because the "unprotected" act of intercourse was unprotected from infection as well as from pregnancy.</li> </ul>

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**KEY:**

- Class A** = essential and mandatory or otherwise important in all circumstances, for safe and effective use of the contraceptive method
- Class B** = medically/epidemiologically rational in some circumstances to optimize the safe and effective use of the contraceptive method, but may not be appropriate for all clients in all settings
- Class C** = may be appropriate for good preventive health care, but not materially related to safe and effective use of the contraceptive method
- Class D** = not materially related to either good routine preventive health care or safe and effective use of the contraceptive method

## Classification of Selected Procedures for OCs as ECPs (continued)

### Citations for Procedures Table:

- 1) World Health Organization. Improving access to quality care in family planning: medical eligibility criteria for contraceptive use. Geneva: WHO, 1996.
- 2) Program for Appropriate Technology in Health. Emergency contraception: a resource manual for providers. Seattle: PATH, 1997.
- 3) Glasier A. Emergency Contraception: time for deregulation? *British Journal of Obstetrics and Gynaecology* 1993;100:611-2.
- 4) Speroff L, Glass R, and Kase N. *Clinical gynecologic endocrinology and infertility*, 5th edition. Baltimore: Williams and Wilkins, 1994.
- 5) Potter L. Oral contraceptive compliance and its role in the effectiveness of the method. In: Cramer J, Spilker B. *Patient compliance in medical practice and clinical trials*. New York: Raven Press, Ltd., 1991.
- 6) CSAC. Emergency (postcoital) contraception guidelines for doctors. *British Journal of Family Planning* 1992;13(3):centrefold.
- 7) Haspels A. Emergency contraception: a review. *Contraception* 1994;50:101-9.

## 1.11 Selected Questions on NORPLANT® Implants (Not covered in Volume I)

### Questions:

#### NORPLANT® Implants\*

1. What may happen if the NORPLANT® Implants are removed later than five years?
2. Is hard tubing still being used in the manufacturing of NORPLANT® Implants? Should the removal technique be handled differently in women with hard tubing?
3. What is the risk of an ectopic pregnancy while using NORPLANT® Implants?
4. Are NORPLANT® Implants less effective in heavier women?
5. What other methods can be used with NORPLANT® Implants? What are the recommendations for dual method use after five years of NORPLANT® Implants use?
6. What kind of training in insertion and removal is needed for a provider to provide NORPLANT® Implants? Which category of professionals have been found to insert and remove NORPLANT® Implants with few complications?
7. Should a client with keloids or a history of keloids be eligible for insertion or removal of NORPLANT® Implants?

#### Levonorgestrel Rod Implants (formerly known as NORPLANT® II Implants)

1. **How long** may one use levonorgestrel rod implants?
2. Apart from any differences in the effective duration of use, what is the **principal advantage** of the levonorgestrel rod implants over NORPLANT® Implants?

\* Currently NORPLANT® Implants are approved for only five years, however, if approval is extended beyond five years, the recommendations included here would have to be modified accordingly.

## Q.1. What may happen if the NORPLANT® Implants are removed later than five years\*?

Recommendations	Rationale
<p>There is no risk from the NORPLANT® Implants themselves after five years. However, since the hormone levels released by NORPLANT® Implants decrease with time, after five years of use NORPLANT® Implants do not prevent pregnancy as well as during the first five years of use. Available evidence suggests that, as the rate of pregnancy increases, so will the rate of ectopic pregnancy. Because of the increased risk of pregnancy, current recommendations (which apply to all women regardless of weight or age) is that these implants be removed at the end of five years. Providers and women should be aware, however, that recent data suggest that for women who weigh less than 60 kg and/or are over 30 years of age at implant insertion, good protection still exists in years six and seven after placement, although the protection is somewhat less than that provided in the first five years. As stated above, there may be an increasing risk of intrauterine and ectopic pregnancy, but this risk tends to fall with age.</p> <p>A woman may refuse to have her NORPLANT® Implants removed after five years. In such cases, the woman should be counseled on the potential risks (including pregnancy) and contraceptive benefits. If the woman still refuses to have the removal, she should be encouraged to use an additional method of contraception.</p>	<p>NORPLANT® Implants are a very highly effective method of protection against pregnancies for up to five years after placement. Also, in the first five years of use, the risk of ectopic pregnancy is also reduced (compared to use of no method). The blood levels of the hormone released by the implants decrease with time. Thus, it is assumed that pregnancy and ectopic pregnancy rates will both rise after five years. For these reasons, it is recommended that NORPLANT® Implants be removed after five years of use.</p> <p>Recent data from a very large Chinese study clarify some of the issues. Women who weighed less than 60 kg and women over age 30 at implant insertion did not experience marked increases in pregnancy rates in years six and seven of use as compared with rates in year five, and the pregnancy rates were still quite low. A second, much smaller study in Chile found that the pregnancy rate during implant use increased to four per 100 woman years in years six through eight, but that no ectopic pregnancies occurred after the fifth year. These data perhaps suggest that although the blood levels of the drug are reduced after five years of use, this reduction is somewhat offset by the aging of the women, a factor that may principally affect women over the age of 30 who participated in the study.</p> <p>Although the general recommendation to remove NORPLANT® Implants after five years pertains to all women, the Chinese and Chilean data suggest some leeway to organize and implement removal services at five years for populations where a large proportion of women weigh less than 60 kg or are over 35 years of age at the end of five years of implant use.</p>

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\* Currently NORPLANT® Implants are approved for only five years, however, if approval is extended beyond five years, the recommendations included here would have to be modified accordingly.

**Q.1. NORPLANT® Implants removed later than five years?**  
(continued)

Recommendations	Rationale
	<p>High priority should be placed on linking women who desire removal with providers trained with the skills necessary to perform such removals. However, if a woman does not want her NORPLANT® Implants removed, she should be informed of the risks (and contraceptive benefits) associated with use of NORPLANT® Implants beyond five years, particularly decreasing effectiveness and the possibility of ectopic pregnancy.</p> <p>In additional method of contraception, and be advised about the signs and symptoms that occur with pregnancy or with ectopic pregnancy. She should further be advised to return to the clinic or facility at any time that she experiences signs or symptoms of a pregnancy or ectopic pregnancy.</p> <ol style="list-style-type: none"><li>1) NORPLANT® Levonorgestrel Implants: a summary of scientific data. New York: The Population Council, 1990.</li><li>2) Gu S, Sivin I, Du M, Zhang L, Ying L, Meng F, et al. Effectiveness of Norplant Implants through seven years: a large-scale study in China. <i>Contraception</i> 1995;52(2):99-103.</li><li>3) Diaz S, Pavez M, Miranda P, Johansson ED, Croxatto HB. Long-term follow-up of women treated with Norplant Implants. <i>Contraception</i> 1987;35(6):551-67.</li><li>4) Meeting Report: NORPLANT® Implants issues related to removal and quality of care. Washington, DC: USAID, June 6, 1995.</li></ol>

**Q.2. Is hard tubing still being used in the manufacturing of NORPLANT® Implants? Should the removal technique be handled differently in women with hard tubing?**

Recommendations	Rationale
<p>a) No. Hard tubing is no longer being used to manufacture NORPLANT® Implants.</p> <p>b) No. The removal procedure for women with hard tubing NORPLANT® Implants is identical to the removal of soft tubing NORPLANT® Implants.</p>	<p>a) NORPLANT® Implants manufactured with hard tubing are no longer manufactured or distributed. They were provided through 1992, however, and are still used by many women.</p> <p>b) The clinical parameters of NORPLANT® Implants differ between these two types of tubing. Heavy women using hard tubing NORPLANT® Implants experience a higher pregnancy risk than women using soft tubing because less hormone diffuses out through the hard tubing (see Question 4). However, the physical removal procedure is the same for both hard and soft tubing NORPLANT® Implants.</p>

### Q.3. What is the risk of an ectopic pregnancy while using NORPLANT® Implants?

Recommendations	Rationale
<p>The risk of ectopic pregnancy during the first five years of use is reduced compared to noncontraceptive users since NORPLANT® Implants are a highly effective method of contraceptive protection. Although NORPLANT® Implants reduce the total number of ectopics by decreasing the number of pregnancies, any pregnancies which do occur have an increased risk of being ectopic when compared to the risk of pregnancies being ectopic when using most alternative methods of contraception. Therefore, a woman who becomes pregnant while using NORPLANT® Implants should be monitored for signs and symptoms of ectopic pregnancy.</p>	<p>Because NORPLANT® contraceptive implants provide a high level of protection against all pregnancies during the first five years, the number of ectopic pregnancies is reduced when compared with no contraceptive use. Data suggest that the ectopic pregnancy rate of NORPLANT® implants is similar to the ectopic pregnancy rates for some very effective alternative methods such as female sterilization. However, the percent of any pregnancies which do occur that are ectopic when using NORPLANT® Implants is somewhat higher than the percent of pregnancies which are ectopic when using most other contraceptive methods.</p> <ol style="list-style-type: none"><li>1) NORPLANT® Levonorgestrel Implants: a summary of scientific data. New York: The Population Council, 1990.</li><li>2) International collaborative surveillance of Norplant. Post-marketing surveillance report of NORPLANT®: collaborating agencies progress report. Geneva: WHO, 1996.</li><li>3) Peterson HB, Xia Z, Hughes JM, Wilcox LS, Tylor LR, Trussell J. The risk of ectopic pregnancy after tubal sterilization. <i>New England Journal of Medicine</i> 1997;336:762-7.</li></ol>

### Q.4. Are NORPLANT® Implants less effective in heavier women?

Recommendations	Rationale
<p>Increased weight does not appear to substantially diminish the effectiveness of soft tubing NORPLANT® Implants. In contrast, NORPLANT® Implants made with older hard tubing (not manufactured since 1992) are less effective in women weighing more than 60 kg. However, these levels of effectiveness are acceptable to many women.</p>	<p>Heavy women using hard tubing NORPLANT® Implants experience a higher pregnancy risk than women using soft tubing because less hormone diffuses out through the hard tubing. NORPLANT® Implants made with hard tubing demonstrated a cumulative five year failure rate of 4.5% in women who weighed 60 to 69 kg. In contrast, NORPLANT® Implants made with soft tubing demonstrated a cumulative five year failure rate of 1.5% in women who weighed 60 to 69 kg. This difference between hard and soft tubing is more pronounced for heavier women. Women who weighed more than 70 kg had a five year cumulative failure rate of 9.3% for hard tubing NORPLANT® Implants and 2.4% for soft tubing use.</p> <p>Although recent data from China reported cumulative five year failure rates for hard tubing use which were lower than the failure rates reported above, an increased number of pregnancies was still associated with increasing weight – 1.46 pregnancies (over five years) per 100 women weighing 50 to 59 kg, 2.08 pregnancies (over five years) per 100 women weighing 60 to 69 kg, and 4.58 pregnancies (over five years) for women weighing 70 kg or more.</p>

#### Cumulative Five Year Failure Rate for NORPLANT® Implants

User's Weight	Pooled Data from Clinical Trials, 1988 <sup>1</sup>		Data from China, 1995 <sup>2</sup>
	Soft Tubing	Hard Tubing	Hard Tubing
60 to 69 kg	1.5%	4.5%	2.08%
70 kg or more	2.4%	9.3%	4.58%

- 1) Sivin I. International experience with NORPLANT and NORPLANT-2 contraceptives. *Studies in Family Planning* 1988;19(2):81-94.
- 2) Gu S, Sivin I, Du M, Zhang L, Ying L, Meng F, et al. Effectiveness of Norplant Implants through seven years: a large-scale study in China. *Contraception* 1995;52(2):99-103.

**Q.5. What other methods can be used with NORPLANT® Implants? What are the recommendations for dual method use after five years of NORPLANT® Implants use?**

Recommendations	Rationale
<p>a) <b>During the First Five Years:</b>                      During the first five years of use, NORPLANT® Implants are a highly effective contraceptive method. Therefore, no additional contraceptive method is required to provide pregnancy protection.</p> <p>b) <b>After the First Five Years of Using NORPLANT® Implants:</b>                      Under some circumstances (for example, if immediate removal is not practical in a woman weighing more than 60 kg or if the client refuses removal), it is reasonable for the client (and provider) to consider choosing any of the contraceptive methods in addition to the implants after the first five years when levonorgestrel has diminished to low levels. However, there is theoretical concern that the combination of a copper or inert IUD with NORPLANT® Implants may result in an unacceptable increase in menstrual blood loss enhancing the risk of anemia.</p>	<p>a) The cumulative pregnancy rate of users of NORPLANT® Implants at the end of five years of use is 1%.</p> <p>1) Sivini I. Contraception with Norplant Implants. <i>Human Reproduction</i> 1994;9(10):1818-26.</p> <p>b) If NORPLANT® Implants removal is delayed beyond five years or if a woman refuses removal, the client and provider may consider using an additional contraceptive method to avoid an unwanted (and possibly ectopic) pregnancy, particularly for women heavier than 60 kgs using NORPLANT® Implants with hard tubing. Since the blood levels of levonorgestrel are very low to begin with and are especially low after five years of hard tubing use, it is unlikely that safety problems will occur when NORPLANT® Implants are used in combination with another contraceptive method, including other hormonal methods. No contraindications exist against such dual method use. However, since both IUDs and progestin-only methods are associated with increased menstrual bleeding, there is concern that combined use of an intrauterine device (IUD) with NORPLANT® Implants could result in an even higher loss of menstrual blood increasing the risk of anemia in at risk populations.</p>

(continued)

**Q.5. Use of other methods with NORPLANT® Implants after five years of use?** (continued)

Recommendations	Rationale
<p>c) <b>For sexually transmitted disease (STD) protection:</b> At any time, for STD protection, condoms or other barrier methods may be used.</p>	<p>c) Like other hormonal methods, NORPLANT® Implants use does not protect against STDs. Therefore, using condoms in combination with NORPLANT® Implants will help protect against STDs, including human immunodeficiency virus (HIV).</p> <p>Supplemental use of contraceptive methods in women using NORPLANT® Implants may be important to provide protection from pregnancy (after five years of use) and from STDs/HIV. However, since current experience with dual method use is limited, supplemental use should be undertaken only after careful consideration. Furthermore, the short-term provision of supplemental contraception should not reduce programmatic efforts for removing NORPLANT® Implants at the end of year five in women desiring removal.</p>

**Q.6. What kind of training in insertion and removal is needed for a provider to provide NORPLANT® Implants? Which category of professionals have been found to insert and remove NORPLANT® Implants with few complications?**

Recommendations	Rationale
<p>a) The training should include:</p> <ul style="list-style-type: none"> <li>• counseling of potential acceptors (including the fact that some removals may be difficult and may require more than one removal procedure),</li> <li>• counseling that removal should be entirely voluntary and at the option of the client,</li> <li>• infection prevention measures, and</li> <li>• techniques for inserting and removing implants (with an emphasis on removal training).</li> </ul> <p>Those programs that focus on removal training and correct insertion training should experience less difficulty in performing removals. Training programs require practical, hands-on experience in insertion and removal techniques, and use of models for practice before working with clients is advisable.</p> <p>b) Doctors, nurses, midwives, paramedics, and other health workers can perform insertion and removal procedures provided they are appropriately trained.</p>	<p>a) Training in counseling is just as important as technical training for providers who supply NORPLANT® Implants. Counseling training should help providers to effectively communicate the advantages and disadvantages of the method, possible side effects, the length of protection provided, the procedures for insertion and removal, reasons to return to the clinic, and information on follow-up care.</p> <p>Insertion and removal of NORPLANT® Implants are minor surgical procedures. Therefore, all centers inserting and removing NORPLANT® Implants need to follow basic infection prevention measures. Insertion and removal are relatively easy to learn, but formal training is needed to minimize the potential for difficult removals that may result from poor insertion techniques. An emphasis on removal training allows providers to understand the relationship between good insertion placement and ease of implant removal. Providers who have mastered insertion and removal skills on models before working with clients achieve competency in a shorter time.</p> <p>b) Studies demonstrate that, with proper training, health workers other than physicians can safely insert and remove NORPLANT® Implants.</p> <ol style="list-style-type: none"> <li>1) Statement on NORPLANT® subdermal contraceptive implant system. IPPF Medical Bulletin 1995;29(5).</li> <li>2) McIntosh N, Blouse A, Schaefer L, editors. NORPLANT® Implants Guidelines for Family Planning Service Providers, second edition. Baltimore: JHPIEGO Corporation, 1995.</li> <li>3) NORPLANT® Levonorgestrel Implants: a summary of scientific data. New York: The Population Council, 1990.</li> </ol>

**Q.7. Should a client with keloids or a history of keloids be eligible for insertion or removal of NORPLANT®**

Recommendations	Rationale
<p>Yes. History of keloids is not a reason to restrict NORPLANT® Implants insertion or removal. However, a woman with previous keloid formation or a family history of keloids should be informed (during the counseling on risks and benefits of the method) that keloid formation at the insertion site is generally rare, but she may be at increased risk of keloid formation.</p>	<p>Keloid formation resulting from NORPLANT® Implants insertion is a rare event. However, some women are at greater risk of keloids following any surgical procedures. In general, the degree of risk of keloid formation can be evaluated according to the following factors: history of keloids, family history of keloids, and deeper skin pigmentation (of any race). The potential for keloid formation at the insertion site should be discussed with women at increased risk of keloids to allow them to make an informed decision about use of this method.</p> <p>1) Nuovo J, Sweha A. Keloid formation from levonorgestrel implant (Norplant system) insertion. <i>Journal of the American Board of Family Practice</i> 1994;7(2):152-4.</p>

### Q.1. How long may one use levonorgestrel rod implants?

Recommendations	Rationale
<p>As of this writing, levonorgestrel rod implants have been approved by the US FDA for a period of three years of continuous use (and may well be extended beyond three years).</p> <p>Over a period of three years of continuous use, two women per 1000 users of the levonorgestrel rod implants would become pregnant because of a method failure (three year pregnancy rate of 0.2 per 100 women).</p>	<p>Two recent studies on the levonorgestrel rod implants reported no pregnancies in 798 women who used the implants for three years.</p> <p>No data has been published on the current formulation of levonorgestrel rod implants beyond three years of use, thus the current recommendation is for three years of use.</p> <p>However, there are some data based on blood levels of levonorgestrel, that suggest the duration of effectiveness for levonorgestrel rods may be longer than three years.</p> <ol style="list-style-type: none"><li>1) Sivin I, Lalteenmaki P, Ranta S, Darney P, Klaisle C, Wan L, et al. Levonorgestrel concentrations during use of Levonorgestrel Rod (LNg Rod) implants. <i>Contraception</i> 1997;55(2):81-5.</li><li>2) Sivin I, Viegas O, Campodonico I, Diaz S, Pavez M, Wan L, et al. Clinical performance of a new two-rod levonorgestrel contraceptive implant: a three-year randomized study with Norplant implants as controls. <i>Contraception</i> 1997;55(2):73-80.</li></ol>

**Q.2. Apart from any differences in the effective duration of use, what is the principal advantage of the levonorgestrel rod implants over NORPLANT® Implants?**

Recommendations	Rationale
Because there are only two rods to be placed and removed with the levonorgestrel rod implants, the placement and removal procedures take less time than the same procedures for NORPLANT® Implants.	The levonorgestrel rod implants are a set of two 43mm rod implants as compared with the six capsules required for the NORPLANT® Implants. It has been shown that the mean time required for removal of the two rod contraceptive is significantly shorter than the mean time required to remove NORPLANT® Implants. Overall, the mean time required to remove the levonorgestrel rod implants is about half the time needed to remove NORPLANT® Implants.
	1) Sivin I, Viegas O, Campodonico I, Diaz S, Pavez M, Wan L, et al. Clinical performance of a new two-rod levonorgestrel contraceptive implant: a three-year randomized study with Norplant implants as controls. <i>Contraception</i> 1997;55(2):73-80.

## 1.12 Selected Questions on IUDs, COCs, and DMPA (Not Covered in Volume I)

This section outlines recommendations on the following procedural questions for intrauterine devices (IUDs), combined oral contraceptive (COCs), and depo-medroxyprogesterone acetate (DMPA) (not covered in Volume I):

### IUDs

1. Is it advisable to routinely give **prophylactic antibiotics** for IUD insertion?
2. How long should a client wait after a **Cesarean section** before having an IUD inserted?
3. Can IUDs be safely inserted by **appropriately trained nurses and midwives** after a client has had a **Cesarean section**?
4. Should **young nulliparous women** receive IUDs?

### COCs

1. **When during the cycle** can one switch from COCs to other methods?
2. How should **amenorrhea** in COC users be addressed?

### DMPA

1. Is an early second injection effective for **controlling heavy bleeding**?

## Q.1. Is it advisable to routinely give prophylactic antibiotics for IUD insertion?

### Recommendations

No, most authorities do not routinely recommend it, because there is no clear evidence that prophylactic antibiotics definitely prevent pelvic inflammatory disease (PID) in IUD users and the studies so far have found only a trivial impact on PID rates due to prophylactic antibiotics. However, opinions differ and there are arguments to support both sides.

There is a theoretical rationale for the practice of giving prophylactic antibiotics. PID rates in IUD users are highest in the first few weeks and antibiotics could reduce those PID rates. While there is no statistically significant evidence of a reduction in PID rates, one study found a lower rate of IUD-related unplanned returns to the clinic.

Arguments against the use of prophylactic antibiotics include the insignificant impact of antibiotics on reducing the PID rates in IUD users demonstrated in previous studies. Also, although the **rate** of PID in IUD users is highest in the first few weeks after insertion, due to the long duration of use of IUDs, the greatest **numbers** of PID cases will occur **after** the first few weeks after insertion. In addition, there is some concern about the programmatic feasibility and cost of prophylactic antibiotics.

Good infection control procedures, proper assessment of the client's risk for sexually transmitted diseases (STDs), and proper insertions are very important to keep the rate of PID low in IUD clients.

### Rationale

The scientific literature does not show any large advantage in reducing PID rates by giving prophylactic antibiotics for IUD insertion. However, in each of the studies, infection prevention procedures were followed and the rates of PID were very low. Also, the sample sizes in the studies were small.

Although not statistically significant, three studies all showed some reduction in the PID rate in women given prophylactic antibiotics.

Sinei et al. found that the PID rate for the first month after IUD insertion in women who were given doxycycline was 1.3% compared to 1.9% in the women who received a placebo. They also found that the women who received a placebo returned to the clinic for IUD-related problems that were suggestive of subclinical PID more often than the treated women.

Zorlu et al. found infection rates to be 2.1% and 2.9% in the doxycycline treated and the untreated women, respectively, within the first three months after IUD insertion.

Walsh et al. found that within the first three months after IUD insertion, 3.6% of the doxycycline group had the IUD removed for medical reasons compared to 4.5% of the placebo group.

- 1) Walsh T, Bernstein G, Grimes D, Freziers R, Bernstein L, Coulson A, et al. Effect of prophylactic antibiotics on morbidity associated with IUD insertion: results of a pilot randomized controlled trial. *Contraception* 1994;50:319-27.
- 2) Sinei S, Schulz K, Lamprey P, Grimes D, Mati J, Rosenthal S, et al. Preventing IUCD-related pelvic infection. *British Journal of Obstetrics and Gynaecology* 1990;97:412-9.
- 3) Zorlu C, Aral K, Cobanoglu O, Gurler S, Gokmen O. Pelvic inflammatory disease and intrauterine devices. *Advances in Contraception* 1993;9:299-302.
- 4) Ladipo OA, Farr G, Otolorin E, Konje JC, Sturgen K, Cox P, et al. Prevention of IUD-related pelvic infection: the efficacy of prophylactic doxycycline at IUD insertion. *Advances in Contraception* 1991;7:43-54.
- 5) Farley T, Rosenberg M, Rowe P, Chen J, Meirik O. Intrauterine devices and pelvic inflammatory disease: an international perspective. *Lancet* 1992;339:785-8.

## Q.2. How long should a client wait after a Cesarean section before having an IUD inserted?

Recommendations	Rationale
<p>a) A client may have an IUD placed at the fundus during a Cesarean section prior to closure of the uterus, unless there are signs of infection.</p> <p>b) If an IUD is not inserted at the time of the Cesarean section, it is recommended that the IUD be inserted no earlier than six weeks after the Cesarean section.</p>	<p>a) Immediate insertions during Cesarean sections by a properly trained provider have a lower expulsion rate than for vaginal insertions immediately (within 10 minutes) after delivery. Studies also found that women with IUDs inserted at the time of Cesarean section had longer continuation rates.</p> <ol style="list-style-type: none"> <li>1) Zhou S, Chi I. Immediate post-partum IUD insertions in a Chinese hospital – a two year follow-up. <i>International Journal of Gynecology and Obstetrics</i> 1991;35:157-64.</li> <li>2) Xu J, Connell C, Chi I. Immediate postplacental insertion of the intrauterine device: a review of Chinese and the world's experiences. <i>Advances in Contraception</i> 1992;10:71-82.</li> </ol> <p>b) Delayed postpartum insertions should take place no earlier than six weeks after Cesarean section because of the risk of uterine perforation. Clients need careful assessment for presence of infection before insertion even at this time.</p> <ol style="list-style-type: none"> <li>1) McIntosh N, Kinzie B, Blouse A, editors. <i>IUD guidelines for family planning service programs</i>. 2nd ed. Baltimore: JHPIEGO, 1993.</li> </ol>

## Q.3. Can IUDs be safely inserted by appropriately trained nurses and midwives after a client has had a Cesarean section?

Recommendations	Rationale
<p>Yes. IUDs can be safely inserted after Cesarean sections by nurses and midwives who are appropriately trained according to relevant national or institutional standards.</p>	<p>Nurses or midwives have been shown to have equal or superior competence in IUD insertion when compared to doctors.</p> <ol style="list-style-type: none"> <li>1) Eren V, Ramos R, Gray RH. Physicians vs. auxiliary nurse-midwives as providers of IUD services: a study in Turkey and the Philippines. <i>Studies in Family Planning</i> 1983;14:43-7.</li> </ol> <p>Training in proper insertion is the major factor for all providers in lowering the risk of uterine perforation. Proper insertion may also lower the risk of expulsion.</p>

## Q.4. Should young nulliparous women receive IUDs?

Recommendations	Rationale
<p>An IUD may be provided to young nulliparous women only after careful and thorough consideration. An IUD is only recommended for young nulliparous women if they are living in a stable, mutually faithful relationship.</p> <p>To receive IUDs, women should not be at increased risk of STDs. Counseling should focus on the risk of STDs, PID, and the possible risk of infertility.</p>	<p>Young women statistically have a higher risk of PID. IUDs, in comparison to all other modern contraceptive methods, increase the risk of PID when a woman is infected with an STD. PID is a major risk factor for tubal infertility and ectopic pregnancy. Because young women may have patterns of sexual activity that lead to STD risk, the relative risk of PID in young IUD users may be high. Additionally, nulliparous women receiving IUDs may be at higher risk for expulsion.</p> <p>The degree to which a client values future fertility is an important factor in the choice of a contraceptive method. Studies have shown that the risk of PID and subsequent tubal-factor infertility is directly proportional to the risk of exposure to STDs. IUDs do not protect women against PID or other STDs.</p> <p>Nevertheless, women should be allowed to make their own choice.</p> <ol style="list-style-type: none"> <li>1) World Health Organization Task Force of Intrauterine Devices, Special Programme of Research, Development and Research Training in Human Reproduction. PID associated with fertility regulating agents. <i>Contraception</i> 1984;30(1):1-21.</li> <li>2) Petersen KR, Brooks L, Jacobsen B, Skouky SO. Intrauterine devices in nulliparous women. <i>Advances in Contraception</i> 1991;7(4):333-8.</li> <li>3) Angle MA, Brown LA, Buekens P. IUD protocols for international training. <i>Studies in Family Planning</i> 1993;24(2):125-31.</li> <li>4) Luukkainen T, Nielson NC, Nygren KG, Pyorala T. Nulliparous women, IUD and pelvic infection. <i>Annals of Clinical Research</i> 1979;11:121-4.</li> </ol>

## Q.1. When during the cycle can one switch from COCs to other methods?

Recommendations	Rationale
<p>A client can switch methods at any time. If she has been taking the pills correctly and consistently, you can be reasonably sure she is not pregnant.</p> <p>A back-up method is not required. However, the provider may want to recommend that she continue to take her COC the day she gets her first injection or the implants.</p> <p>Some clinicians recommend that the woman finish her pack of pills to delay the onset of her next bleed.</p>	<p>Injectables and NORPLANT® Implants are usually effective within 24 hours, unless the woman already has fertile cervical mucus. The woman should take her pill as a back-up, if she is not menstruating, because there is a slight risk of conception from unprotected intercourse during those 24 hours until the injectable or implants become effective.</p> <ol style="list-style-type: none"> <li>1) Technical Guidance Working Group. Recommendations for updating selected practices in contraceptive use: results of a technical meeting. Volume I. Chapel Hill, NC: INTRAH, 1994.</li> <li>2) NORPLANT® Levonorgestrel Implants: a summary of scientific data. New York: The Population Council, 1990, p 2.</li> </ol>

## Q.2. How should amenorrhea in COC users be addressed?

Recommendations	Rationale
<p>Although amenorrhea is not unusual among COC users, the possibility of pregnancy should be considered. If the woman is correctly and consistently taking COCs and has no other symptoms of pregnancy, only reassurance is needed because the probability of pregnancy is extremely low. Even if the woman is pregnant and the embryo is exposed to COCs, the best evidence is that there is no harm to the embryo.</p> <p>If symptoms or other reasons to suspect pregnancy exist, such as missed pills, evaluate accordingly. If pregnancy evaluation cannot be performed immediately, the client can be advised to continue taking the pills until this evaluation is completed or referred to a health unit where she can be evaluated.</p>	<p>Amenorrhea may be a side effect of COCs. Amenorrhea is not uncommon in women using the low dose pills, 35 mcg or less of estrogen, due to a lack of buildup of the uterine lining.</p> <p>While pregnancy is a possibility, COCs are over 99% effective when used correctly.</p> <p>It is always recommended that a pregnant woman avoid unnecessary medication. However, if the woman is pregnant and is using COCs, there does not seem to be an increased risk of birth defects for the embryo.</p> <ol style="list-style-type: none"> <li>1) Hatcher R, Trussell J, Stewart F, Stewart G, Kowal D, Guest F, et al. The pill: combined oral contraceptives. In: Contraceptive Technology. New York: Irvington Publishers, 1994:223-84.</li> <li>2) Bracken M. Oral contraception and congenital malformations in offspring: a review and meta-analysis of the prospective studies. <i>Obstetrics and Gynecology</i> 1990;76:552-7.</li> <li>3) Simpson JL, Phillips OP. Spermicides, hormonal contraception and congenital malformations. <i>Advances in Contraception</i> 1990;6:141-67.</li> </ol>

## Q.1. Is an early second injection effective for controlling heavy bleeding?

### Recommendations

It is not known. There is no clear evidence that a second depo-medroxyprogesterone acetate (DMPA) injection (given 4 to 12 weeks after the first injection) offers measurable benefits for controlling heavy bleeding, but the existing studies are inadequate to address the question.

### Rationale

One study found a decrease in the number of days of bleeding and/or spotting in women immediately following each re-injection every 12 weeks.

Another study found no significant difference in the bleeding patterns of adolescents re-injected at 6 weeks compared to those re-injected at 12 weeks.

However, there were several limitations to the studies and more research is needed.

- 1) WHO Special Programme of Research, Development and Research Training in Human Reproduction. Multinational comparative clinical trial of long-acting injectable contraceptives: norethisterone enanthate given in two dosage regimens and depot-medroxyprogesterone acetate. Final Report. Contraception 1983;28(1):1-21.
- 2) Harel Z, Biro FM, Kollar LM. Depo Provera in adolescents: effects of early second injection or prior oral contraception. Journal of Adolescent Health 1995;16:379-84.

## SECTION 2

### **CBS (Community-Based Services) Checklists:**

- 2.1 Combined Oral Contraceptives (COCs) CBS Checklist,  
DMPA (or NET-EN) CBS Checklist, and  
Guides for Using COC and DMPA (or NET-EN) Checklists

## 2.1 Checklists For COCs And DMPA (or NET-EN) Use In Community-Based Services And Checklist Guide

COCs Checklist  
DMPA (or NET-EN) Checklist  
Guide for Applying or Adapting Checklists  
COCs Checklist Questions Explanation  
DMPA (or NET-EN) Checklist Questions Explanation

## Checklist for Clients Who Want to Initiate Combined Oral Contraceptives (COCs) in Community-Based Services (CBS)

Please ask the client all of these questions:	Check the correct box:	
1. Is your period late and do you think you could be pregnant now? .....	<input type="checkbox"/> Yes	<input type="checkbox"/> No
2. Are you currently breastfeeding a baby under 6 months of age? .....	<input type="checkbox"/> Yes	<input type="checkbox"/> No
3. Do you smoke cigarettes AND are you over 35 years of age? ...	<input type="checkbox"/> Yes	<input type="checkbox"/> No
4. Do you have frequent and very severe headaches that cause you problems; for example, blurred vision or temporary loss of vision, which you get during the headache? .....	<input type="checkbox"/> Yes	<input type="checkbox"/> No
5. Do you have high blood pressure? .....	<input type="checkbox"/> Yes	<input type="checkbox"/> No
6. Have you ever had a stroke, blood clot in your legs or lungs, or a heart attack? .....	<input type="checkbox"/> Yes	<input type="checkbox"/> No
7. Do you have diabetes (sugar in your blood)? .....	<input type="checkbox"/> Yes	<input type="checkbox"/> No
8. Do you have or have you had breast cancer? .....	<input type="checkbox"/> Yes	<input type="checkbox"/> No
9. Do you have a serious liver disease or jaundice (yellow skin or eyes)? .....	<input type="checkbox"/> Yes	<input type="checkbox"/> No
10. Do you regularly take any pills for tuberculosis (TB), fungal infections or seizures (fits)? .....	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<p><b>If the client answers YES to any of the above questions, refer her to the clinic/physician, and give her condoms and/or spermicide to use in the meantime. If the client answers NO to all the above questions, continue with the questions below.</b></p> <p>11. Do you have bleeding between menstrual periods which is unusual for you, or bleeding after intercourse (sex)? .....</p> <p style="text-align: right; margin-right: 50px;"><input type="checkbox"/> Yes      <input type="checkbox"/> No</p> <p><i>(If the client answers YES, she can use COCs, but refer her to the clinic/physician for further evaluation of bleeding. Continue with question 12.)</i></p> <p><b>If the client answers NO to all the questions, she can use COCs, but to find out when she can start, ask:</b></p> <p>12. How many days ago did you start your last menstrual period? _____</p> <p style="text-align: right; margin-right: 50px;"># days</p> <p><b>If the client began her last menstrual period within the past 7 days, she may begin COCs now.</b></p> <p><b>If the client began her last menstrual period more than 7 days ago, and if:</b></p> <ul style="list-style-type: none"> <li>• she has been using an effective method of contraception (including abstinence), give her COCs, instruct her to begin taking them now, and instruct her that she must use condoms and/or spermicides or abstinence for the next 7 days. Give her condoms and/or spermicides.</li> <li>• she has not been using an effective method of contraception (including abstinence), give her the COCs but instruct her to start using them on the first day or during the first 7 days of her next menstrual period. Give her condoms and/or spermicide to use in the meantime.</li> </ul>		

## Checklist for Clients Who Want to Initiate DMPA (or NET-EN) in Community-Based Services (CBS)

Please ask the client all these questions:	Check the correct box:	
1. Is your menstrual period late and do you think you could be pregnant now? .....	<input type="checkbox"/> Yes	<input type="checkbox"/> No
2. Have you ever had a stroke or heart attack? .....	<input type="checkbox"/> Yes	<input type="checkbox"/> No
3. Do you have diabetes (sugar in your blood)? .....	<input type="checkbox"/> Yes	<input type="checkbox"/> No
4. Do you have or have you had breast cancer? .....	<input type="checkbox"/> Yes	<input type="checkbox"/> No
5. Do you have a serious liver disease or jaundice (yellow skin or eyes)? .....	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<p><b>If the client answers YES to any of the above questions, refer her to the clinic/physician, and give her condoms and/or spermicide to use in the meantime. If the client answers NO to all the above questions, continue with the questions below.</b></p>		
6. Do you have bleeding between menstrual periods which is unusual for you, or bleeding after intercourse (sex)? .....	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<p><i>(If the client answers YES, she can be given DMPA now, but refer her to the clinic/physician for further evaluation of bleeding. Continue with question 7.)</i></p>		
<p><b>If the client answers NO to all the questions, she can use DMPA, but to find out when she can start, ask:</b></p>		
7. Are you currently breastfeeding? .....	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<p>If the client answers YES, go to question 7a. If client answers NO, go to question 8.</p>		
<p>7a. Is the baby less than 6 weeks old?</p> <p style="padding-left: 20px;">If client is breastfeeding a baby [<i>less than 6 weeks old</i>], instruct her to return for DMPA as soon as possible after the baby is 6 weeks old.</p> <p style="padding-left: 20px;">If client is breastfeeding a baby <i>6 weeks old or older and her menstrual periods have not returned</i>, she can be given DMPA now. If her menstrual periods <i>have returned</i>, go to question 8.</p>		
8. How many days ago did you start your last menstrual period? _____	# days	
<p>If the client began her last menstrual period within the past 7 days, she can be given DMPA now.</p> <p>If the client started her last menstrual period more than 7 days ago, and if:</p>		
<ul style="list-style-type: none"> <li>• she has been using an effective method of contraception (including abstinence), she can be given DMPA now, but instruct her that she must use condoms and/or spermicides or abstinence for the next 7 days. Give her condoms and/or spermicides.</li> <li>• she has not been using an effective method of contraception (including abstinence), she must wait until her next period to be given DMPA. Give her condoms and/or spermicide to use in the meantime.</li> </ul>		

# Guide For Applying Or Adapting COC And DMPA (or NET-EN) Checklists

## Goal:

These checklists provide an easy-to-use screening tool for community based services (CBS) workers. They are based on the guidance provided in the 1996 document from the World Health Organization (WHO) entitled: *Improving Access to Quality Care in Family Planning: Medical Eligibility Criteria for Contraceptive Use*. **Similar to the WHO recommendations, the checklists should be adapted to meet the needs of the local CBS program.**

## Purpose:

The checklists allow CBS workers to identify women who can safely initiate use of combined oral contraceptives (COCs) and DMPA (or NET-EN). This is done through a series of simple yes/no questions with further guidance/directions based on client responses. The checklists are not intended to identify or to newly diagnose conditions which may be "contraindications" for the method. Instead, the questions are intended to verify whether a client has or has had a known condition or disease. Women with either active conditions or a history of particular conditions will need further evaluation by a higher level health care provider before the method is initiated.

*The following section of this guide is meant to assist PROGRAM MANAGERS, POLICY-MAKERS, ADMINISTRATORS and TRAINERS.*

1. The DMPA (or NET-EN) checklist is intended to be used to determine eligibility only for *three- or two-month progestin-only injectables*. Similarly, the COC checklist is intended to be used to determine eligibility *only for low-dose combined estrogen-progestin oral contraceptives*.
2. Adapt both the language and style to meet the cultural and linguistic needs of your clients.
3. As you make the adaptations please be careful that you do not inadvertently change the intent of the question. Explanations of the intent of each question are provided with each checklist to help with these adaptations. The following is an example of a poorly adapted checklist question:

Original COC checklist question:

Do you smoke and are you over age 35?

Poorly adapted question:

Do you smoke? Are you over age 35?

This adaptation has separated the original question into two different parts. By doing so, the most important aspect of the original question could be misinterpreted: that only women who both smoke **and** who are over 35 years old have an increased risk of cardiovascular disease. This poor adaptation could prevent an eligible woman who desires COCs from receiving them. (See explanation of the COC checklist).

4. The purpose of the questions is to verify whether a client has a known condition or disease which needs to be further evaluated before she can receive COCs, DMPA or NET-EN. The purpose is **not** for CBS workers to make a diagnosis about conditions or diseases.
5. CBS workers and clients may not recognize the generic names of certain drugs. The following question requires that programs supply the locally available names for particular drugs:

**COC checklist question 10:**

“Do you regularly take any pills for tuberculosis (TB), fungal infections or seizures (fits)?” (Only these particular drugs interact with COCs.)

- rifampicin (for tuberculosis)
  - griseofulvin (an antifungal medication)
  - phenytoin (for epilepsy/seizures)
  - carbamazepine (for epilepsy/seizures)
  - barbiturates (for epilepsy/seizures)
6. The WHO Eligibility Criteria for Contraceptive Use classifies history of hypertension where blood pressure cannot be evaluated (such as CBS programs), and known mild-to-moderate hypertension as conditions where DMPA (or NET-EN) may generally be used (Category 2). However, DMPA (or NET-EN) is not usually recommended for women with known severe hypertension (at least 180+/110+), or with vascular disease, unless other more appropriate methods are unavailable or unacceptable (Category 3).
  7. Please keep in mind that the questions on the checklists are meant to identify women who should be seen by a higher level provider prior to initiating the method; the conditions listed are not necessarily contraindications for use of the method.

*The following section applies to both **PROGRAM MANAGERS** and **CBS TRAINERS**:*

1. The checklists are not meant to replace counseling. Providers should make sure the client makes an informed and voluntary choice to use either COCs or DMPA.
2. Once it has been determined that a client is eligible to initiate use of the method she has chosen, instruct her on how to use the method correctly and consistently and how to manage side effects and identify warning signs of more serious complications.

3. As mentioned above, the checklists identify clients eligible to **initiate** use of either COCs or DMPA (or NET-EN), under the supervision of the CBS worker. However, they may be used or adapted to identify clients eligible to continue the use of these methods. It is not thought to be necessary to repeat each of the questions at each visit.
4. Establish an appropriate training system for use of the checklists to assure that CBS workers use them in the correct way. Periodically evaluate the correct use of the checklists.
5. Be certain that a referral system to accessible clinical sites or private providers is established and that CBS workers are familiar with the referral site and procedures.

## Explanation of COC Checklist Questions for Trainers

Question 1. *Is your menstrual period late and do you think you could be pregnant now?* This question has two parts – both of which should be asked together, and the answer "yes" must apply to both parts of the question. One or more missed periods in combination with the women's own report that she is or might be pregnant is required before a woman should be referred to a higher level health care provider.

Question 2. *Are you currently breastfeeding a baby under 6 months of age?* This question is intended to identify women who are breastfeeding babies under 6 months of age. A breastfeeding woman can begin COCs 6 months after her baby is born. However, if a client does not plan to continue breastfeeding, she may be an eligible candidate for COCs even before the baby reaches 6 months of age.

Question 3. *Do you smoke cigarettes and are you over 35 years of age?* This is a two-part question – and both parts need to be asked together and the answer "yes" must apply to both parts of the question. A woman less than 35 years of age who smokes as well as a woman over the age of 35 who is a nonsmoker are not at risk for problems associated with the combination of smoking and older age. The answer "no" to one or both parts of this question means a client may be eligible for COC use.

Question 4. *Do you have frequent and very severe headaches that cause you problems, for example, blurred vision or temporary loss of vision, which you get during the headache?* This question is intended to identify women with a particular type of headache that may be problematic for COC users. The use of the words "frequent and severe" and the occurrence of other problems during the headache are essential parts of this question. These words help the client distinguish between those types of headaches that make her ineligible for COC use (such as migraines with focal neurologic symptoms) and the less severe (more common) mild headaches for which COCs may still be used.

Question 5. *Do you have high blood pressure?* The question is intended to identify women who have ever been told that they have high blood pressure, since women with this condition should be referred for further evaluation before receiving COCs.

Question 6. *Have you ever had a stroke, blood clot in your legs or lungs, or a heart attack?* This question is intended to identify women with already known serious vascular disease, not to determine whether women might have an undiagnosed condition. Women who have had any of these conditions will often have been told that they have had this condition, and will answer "yes," if appropriate.

Question 7. *Do you have diabetes (sugar in your blood)?* The intention of this question is to identify women who know that they have diabetes, not to assess whether they may have an undiagnosed condition.

Question 8. *Do you have or have you had breast cancer?* The intention of this question is to identify women who know they have had or currently have breast cancer.

Question 9. *Do you have a serious liver disease or jaundice (yellow skin or eyes)?* The intention of this question is to identify women who know that they currently have a serious liver disease and to distinguish between current severe liver disease (such as severe cirrhosis or liver tumors) and past liver problems (such as treated hepatitis).

Question 10. *Do you regularly take any pills for tuberculosis (TB), fungal infections or seizures (fits)?* The following medications make COCs less effective:

- rifampicin (for tuberculosis)
- griseofulvin (an antifungal medication)
- phenytoin (for epilepsy/seizures)
- carbamazepine (for epilepsy/seizures)
- barbiturates (for epilepsy/seizures)

Question 11. *Do you have bleeding between menstrual periods which is unusual for you, or bleeding after intercourse (sex)?* The intention of this question is to distinguish between normal bleeding changes (such as those associated with the use of another contraceptive method), and those that are different or unusual for the client, and to identify post-coital bleeding (since bleeding after intercourse may indicate an abnormality). The use of COCs does not make these conditions worse, but may change the bleeding pattern. Unusual bleeding changes can underlie a serious condition which should be evaluated by a higher level health care provider, but COC use need not be delayed.

Question 12. *How many days ago did you start your menstrual period?* The intention of this question is to determine when the client should start COCs. If she has just started her menstrual cycle and is within days 1 to 7 of the first day of bleeding, she can start the method immediately. If it is more than 7 days since her first day of bleeding, there are two options:

- if she has been using an effective method (correctly and consistently) of contraception which can help a provider rule out pregnancy, she can start taking the pill immediately but use a back-up method for 7 days.
- if she has not been using any effective method of contraception (including abstinence), in order to insure she is not pregnant, she needs to wait until her next menstrual period begins before starting COCs and be given condoms or spermicides to use in the meantime.

## Explanation of DMPA (or NET-EN) Checklist Questions for Trainers

Question 1. *Is your menstrual period late and do you think you could be pregnant now?* This question has two parts – both of which should be asked together, and the answer "yes" must apply to both parts of the question. One or more missed periods in combination with the women's own report that she is or might be pregnant is required before a woman should be referred to a higher level health care provider.

Question 2. *Have you ever had a stroke or heart attack?* This question is intended to identify women with already known serious vascular disease, not to determine whether women might have an undiagnosed condition. Women who have had any of these conditions will commonly have been told that they have had this condition. Those who have had this condition will answer "yes," if appropriate.

Question 3. *Do you have diabetes (sugar in your blood)?* The intention of this question is to identify women who know that they have diabetes, not to assess whether they may have an undiagnosed condition.

Question 4. *Do you have or have you had breast cancer?* The intention of this question is to identify women who know they have had or currently have breast cancer.

Question 5. *Do you have a serious liver disease or jaundice (yellow skin or eyes)?* The intention of this question is to identify women who know that they are currently suffering from a serious liver disease and to distinguish between current severe liver disease (such as severe cirrhosis or liver tumors) and past liver problems (such as treated hepatitis).

Question 6. *Do you have bleeding between menstrual periods which is unusual for you, or bleeding after intercourse (sex)?* The intention of this question is to distinguish between normal bleeding changes (such as those associated with the use of another contraceptive method), and those that are different or unusual for the client, and to identify post-coital bleeding (since bleeding after intercourse may indicate an abnormality). The use of DMPA or NET-EN does not make these conditions worse, but may change the bleeding pattern. Unusual bleeding changes can underlie a serious condition which should be evaluated by a higher level health care provider, but DMPA or NET-EN use need not be delayed.

Question 7. *Are you currently breastfeeding?* A breastfeeding woman can be given DMPA or NET-EN 6 weeks after her baby is born.

Question 7a. *Is the baby less than 6 weeks old?* If clients more easily think of time in terms of months instead of weeks change the question to: *"Is the baby less than a month and a half old?"*

Question 8. *How many days ago did you start your menstrual period?* The intention of this question is to determine when the client should start DMPA (or NET-EN). If she has just started her menstrual cycle and is within days 1 to 7 of the first day of bleeding, she can start the method immediately. If it is more than 7 days since her first day of bleeding, she will need to wait until her next menstrual period begins before she can be given DMPA and be given condoms or spermicides to use in the meantime.

## **SECTION 3**

### **Other Reproductive Health Issues: (Documents Reviewed Outside the May 1996 TG/CWG Meeting)**

- 3.1 Client-Provider Interaction in Family Planning Services**
- 3.2 Contraceptive Effectiveness**
- 3.3 STD Risk Assessment**
- 3.4 Dual Method Use**
- 3.5 Chart of Family Planning Methods and STD Protection**
- 3.6 Cervical Cancer Prevention**

## 3.1 Client-Provider Interactions (CPI) in Family Planning Services: Guidance from Research and Program Experience

The role of CPI in program effectiveness. A growing body of research, and insights from program experience, relate the quality of client-provider interactions (CPI) and contextual factors of clients' lives to the adoption, effective use, and continuation of modern contraception. Greater program effectiveness results from efforts to improve this aspect of quality of care<sup>1-4</sup>. The findings have implications for training of providers, program management, policy and further research. "Client" herein refers to women who receive Family Planning (FP) services from clinics or community-based distributors (CBD). Much of the guidance also applies to reproductive and other health care and to specific client groups--e.g., men, youth, and pregnant, postabortion and postpartum women--and settings such as workplaces or community groups. Although increasing numbers of programs offer information and services focused on these important groups and settings, discussion of their special needs is beyond the scope of this brief document. To emphasize the importance of both the **process** of interacting with clients and the **information** essential for informed choice, the two are dealt with separately below. In reality, they intertwine inseparably.

### Key Processes in Client-Provider Interactions (CPI)

**1. Treat the client well.** Clients are more likely to be satisfied with services if **all staff**, not only the counselor, treat them with respect and friendliness. In turn, client satisfaction is associated with improved use-effectiveness, continuation and positive "word-of-mouth" reports<sup>5-7</sup>. Conversely, poor CPI is associated with discontinuation and method failure. For example, research in Egypt found that client-centered (vs. physician-centered) consultations were associated with a three-fold higher level of both client satisfaction and continuation, even though the client-centered sessions lasted only one minute longer<sup>8</sup>. Clients feel more comfortable if assured that information will be kept confidential and if visual and auditory privacy is maintained during counseling and FP procedures. This contributes to an atmosphere of trust in which the client and provider can explore emotional, sexuality or gender-related aspects of method choice. Providers should encourage clients to ask follow-up questions about side effects or to clarify instructions. Both verbal and nonverbal communication skills are important; counselors must listen and observe actively, seeking to understand clients' feelings as well as their medical and personal history.

"Body language" that transmits warmth and interest (e.g., giving full attention, smiling and nodding when the client speaks) and a friendly tone of voice are behaviors that enhance CPI<sup>9</sup>.

**2. Provide the client's preferred method.** Informed choice remains the guiding principle: clients who already have a method preference should be given that method after screening and counseling unless it is inappropriate for medical or personal reasons. Research shows that clients who receive the method they came for--and a large number have a preference before they interact with the provider--are significantly more likely to continue using the method than those who do not receive their preferred method<sup>10,11</sup>. However, even clients with a prior preference should be told that other methods that work in various ways are available and asked if they would like to hear more about any or all of these methods. This is important in case the client asks for a method because it is the only one she is familiar with or she has been pressured to get that method. Programs that respond to a client's appropriate choice recognize that there is no single method good for all clients. There is great variation in what clients and their partners find essential, attractive, inconvenient or intolerable about contraceptive methods. Some clients place highest value on effectiveness in preventing pregnancy, while others weigh effectiveness against a method's potential impact on their sexual relations, personal feelings or health<sup>12,13</sup>. Not surprisingly, continuation is also significantly increased if there is prior couple agreement on the method; couple counseling has been shown to be more effective in general than dealing with the woman or man alone<sup>10,14</sup>. This may not be possible for women who have no steady partner, have multiple partners or whose partners may not be supportive of FP or willing to be counseled.

At an international meeting on counseling, participants stressed the point that policies established by governments, donors, country programs and service facilities can either facilitate or hinder sound CPI and informed choice. Clear policies can establish informed choice as the client's right and make counseling a programmatic priority. Biases for and against methods, such as targets at the provider level, method-specific incentives, provider's personal biases, and regulations such as those requiring a level of parity, or spousal approval, limit individual choice and thereby the achievement of programmatic goals<sup>15,16</sup>.

**3. Individualize.** Given that clients' lives and personalities (and their intentions, preferences, knowledge, beliefs, skills, needs and concerns about contraception) vary greatly, effective counseling is tailored to each individual<sup>17</sup>. Discovering individual characteristics, such as a client's difficulty with sticking to a routine, permits the provider to give special help when indicated. For example, one U.S. study which examined dropouts and method failures among oral contraceptive (OC) users found that one-fourth to one-third of the users would have benefited from more counseling on actual use behaviors, such as developing plans to operationalize their intentions and

strategies to remember to take the Pill each day<sup>18</sup>. An analysis of data from Demographic and Health Surveys (DHS) found that first-time FP users and those under age 24 have the highest dropout rates; these clients are likely to need extra support<sup>19</sup>. Some clients may also need more information and greater reassurance about the overall safety risks and the personal health impacts of FP methods; they may have deeply held beliefs and perceptions reinforced by family and community attitudes and rumors. Clarification must be respectful.

In addition to individual factors, a client may fall into a certain lifecycle stage or life situation that requires special attention from the provider. A provider should "locate" a woman and her fertility intentions on her reproductive life course. She may be a young, single woman who wants to avoid pregnancy, a breastfeeding mother who wants to space the next birth or an older woman who wants no more children. The counselor must also recognize that intentions may change over time and are often accompanied by ambivalence. In addition, the degree to which a woman has control over her sexual encounters bears upon the selection of a FP method. For example, if a woman has a controlling or even violent partner, and/or if her partner opposes FP, she may prefer a non-detectable method and may need to learn skills for discussing and negotiating reproductive matters with her partner. Furthermore, the nature of a woman's sexual activity is relevant--she may be in a mutually monogamous relationship or she may have multiple sexual partners. If her partner works elsewhere, she may have only intermittent, infrequent intercourse<sup>20-22</sup>. In sum, contraceptive counseling must be tailored to the needs of the specific lifestage and lifestyle of each individual client.

**4. Engage the client in dynamic interaction.** Only interactive and dynamic (i.e., responsive) counseling can identify clients' needs, risks, concerns and preferences within their lifestage and life-situation. However, some providers make counseling almost a one-way process. Perhaps they are modeling behavior observed in their own schooling and training; perhaps the social distance between providers and clients makes instruction to a "patient" seem natural. In one study of counseling, for example, providers talked at length about available methods and then asked the client to choose one. There was rarely discussion of reasons for a client to choose a particular method and little checking to see if the clients understood the information given. The study concluded that providers' skills could be strengthened in the areas of eliciting the needs of clients, prioritizing information to make it more relevant to the individual client and empowering the client to make a FP decision<sup>23</sup>. This study and other research have given impetus to training which is focused on counseling as a dynamic interaction, with much less "telling" and much more asking, assessing, listening, encouraging, establishing rapport and clarifying--and letting the client know in advance that such interaction has the goal of helping the client make the best choice<sup>24,25</sup>.

Training in counseling yields positive results for provider and client; even radio-based distance education can improve providers' CPI performance<sup>26-29</sup>.

**5. Avoid information overload.** There are limits to the amount of information people can understand and retain--another reason why counseling should not be dominated by a recitation about every method offered in a program. Instead, providers should **focus factual information on the client's selected method** and be brief, non-technical and clear. This approach enhances understanding of the key information on that method (e.g., how to use, side effects) and also leaves time for questions, clarification and checking for comprehension. Earlier in the session, however, all clients should be informed that there are various methods available and that the counselor would be happy to describe any or all if the client so wishes. One major study found that clients who received the most information were more likely to drop the method they received than those who received less information<sup>10</sup>. This could be due to information overload that reduces retention of key points. A session dominated by information may also leave little time to help the client identify the most suitable method(s)--or perhaps the imparting of more information implies that clients' initial preferences were not honored. Affective factors may also be involved: a provider-centered session may lead to client dissatisfaction, a factor inversely associated with remembering and adhering to a regimen. U.S. studies have found that half or more of the information and instructions given during medical visits could not be recalled almost immediately afterwards. These studies also found involvement of the client and tailoring the educational component to the individual's learning style engendered greater client satisfaction, adherence to therapies and improved outcomes<sup>5,6</sup>. In addition, specific information that is organized logically is retained longer and more fully, especially if clients are encouraged to ask questions and repeat the instructions in their own words<sup>30</sup>.

**6. Use and provide memory aids.** During the counseling session, use of posters, flipcharts, illustrated booklets and sample contraceptives help the client remember key information and remind the provider to discuss important points. Use of take-home educational materials--pretested for comprehension and cultural acceptability with client groups--helps both providers and clients focus on key points during counseling and helps clients recall them later. Take-home materials on the method help to disseminate accurate information to others since clients often share the materials with their partners, relatives and friends<sup>31,32</sup>.

### **Key information for clients choosing a contraceptive method**

**1. Effectiveness.** Effectiveness should be explained in easily understood terms. Providers must emphasize that client-controlled methods (e.g., OCs, barrier methods, natural family planning

(NFP), lactational amenorrhea method (LAM) can effectively prevent pregnancy but only if correctly and consistently used--unlike long-term and permanent methods (sterilization, implants and IUDs) whose effectiveness is close to 100% once properly administered by the provider. Counseling can help each client weigh the trade-offs between effectiveness and other features of various methods and to consider the use of short-term methods in the context of their (and their partners') daily lives. Are clients able and willing, for example, to delay intercourse to insert a spermicide, take a pill every day, or return for the next injection at the time required? For clients choosing short-term methods, counseling should include plans for correct, consistent use. It is also useful for clients to receive information on how to use OCs as emergency contraception (EC) and/or where pre-packaged EC can be obtained.

**2. Side effects and complications.** Clients need information about common side effects and how to manage- or outlast- them. Clients should also be advised about the signs of rare complications and urged to seek immediate help should they occur. Providers should invite clients to return for advice if they have problems and reassure them that they can change methods if dissatisfied. DHS and other research identify side effects and perceived health problems as the major reasons clients give for dropping out of FP use; fear of these effects is also the major reason for not adopting modern methods in the first place<sup>19</sup>. One African study found that women who receive inadequate counseling about side effects are more likely to become FP dropouts when they experience side effects, while those who are fully counseled on side effects are likely to continue contracepting--with the same method or a different, more acceptable method<sup>33</sup>. In China, women who received pre-treatment counseling about DMPA side effects and ongoing support were almost four times more likely to continue with that method than women not so counseled<sup>34</sup>. Women who experience side effects for which they are not adequately prepared may worry that their health is endangered or that the side effect, even if not dangerous, may be permanent and debilitating<sup>35</sup>. They may even blame the method for unrelated ailments. Such worry, followed by discontinuation, is likely to discourage others from using the method, since concerns spread by "word-of-mouth" networks<sup>7</sup>. In addition, respectful clarification is called for if there are misperceptions about the health and/or libido effects of male and female sterilization, the health consequences of menstrual disruption, the IUD traveling outside the uterus or accumulation of pills in the body.

**3. Advantages and disadvantages.** In addition to side effects and health risks and benefits, providers and clients should discuss other important features of the method. These are often called "advantages and disadvantages," but it must be emphasized such perceptions vary widely among individuals and couples. For example, some women may want the highly effective, continual protection offered by the IUD or implant, while others might feel uncomfortable about a "foreign

object" in their body or want control over when to stop use. Some want methods with the fewest side effects and others want a method which does not require application at the time of having intercourse. Clients also assess the mode of application differently: some favor or shun injections; some reject implants because they may be seen and recognized by others; some cannot remember to take pills; some want condoms because they offer dual protection, while others find them unpleasant.

**4. How to use.** Clients need brief, practical information on how to use their selected method and an explanation of how the method works, if needed to correct misperceptions (e.g., that the OC need be taken only when intercourse occurs). Clear, specific instructions are associated with better client adherence and outcomes, and are essential for counseling on user-dependent methods such as OCs and barrier methods. Clients may need to develop strategies for using these methods consistently and correctly, and advice on what to do when a method fails or is used incorrectly (e.g., skipping pills). Programs which offer or refer women to reproductive health (RH) education may help them use their methods correctly by increasing their knowledge about the reproductive system, how pregnancy occurs and how contraception works.

**5. When to return.** Clients need advice on when to return for follow-up or resupply. The follow-up counseling session is a good time to reinforce correct and consistent use of client-controlled methods and to ask whether the client is experiencing any unpleasant side effects that need management. The need to change methods may be discovered during follow-up if over time a client has developed medical contraindications to the method or if a change in lifestage (e.g., a desire to get pregnant in six months) or lifestyle (client now has multiple partners) occurs. In addition to scheduling return visits, providers should tell clients that they are welcome to return to the clinic any time they have questions or concerns. Clients choosing implants should be helped to remember when it is time to have them removed--follow-up visits can help--and should be told that they can have them removed at any time before that date as well.

**6. STD/HIV prevention.** As the prevalence of STD/HIV infection spreads, risk-assessment and STD/HIV prevention messages are increasingly being integrated with FP counseling. Programs are also increasingly finding ways to approach treatment and referrals for sexually transmitted diseases (STDs). Clients should be informed whether their FP method protects them against STD/HIV and that abstinence or the consistent use of condoms is the most effective means of protection available<sup>36</sup>. Those who use long-term and permanent methods may be less likely to use condoms for protection, possibly because contraception is a higher priority or because they no longer associate having intercourse with the need for protection. Some--especially young adults or teens--may incorrectly believe that all contraceptives protect against STD/HIV. A study of

adolescents in Jamaica found that only about 25% of them knew that OCs did not provide such protection<sup>37</sup>. Providers should help clients assess their level of STD/HIV risk, and explain that the behavior of one's partner can also put a client at risk<sup>38</sup>. This can be done sensitively ("Many women may not be aware..."). Those at high risk need special encouragement, skills and support to use condoms in addition to any other method selected; counseling the couple may be the most effective approach. If this is not possible, helping clients build skills in condom negotiating and in communicating with partners about intercourse would be an effective addition to prevention messages.

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## 3.2 Contraceptive Effectiveness: an Approach for International Programs

Effectiveness and safety are often the two most central concerns of contraceptive users. Effectiveness can be improved through contraceptive choices made on the basis of accurate information on comparative pregnancy rates, particularly typical-use rates, short and long term rates, as well as by considering the context of use, such as the locus of control by the woman, man or provider. We emphasize typical-use pregnancy rates, which most accurately express the pregnancy risk for the average user.

Contraceptive effectiveness can vary greatly for methods requiring ongoing performance of both users and providers to achieve correct and consistent use. Oral contraceptives (OCs), barrier methods and traditional methods require consistent and correct use. For methods requiring regular re-supply, a reliable source of commodities and ready access are essential to effective use.

Many couples want no more children and, therefore, desire highly effective and long-term contraception. Many providers give contraceptive pregnancy rates for only the first year of use, even for long-term methods. However, annual pregnancy rates increase over time for some methods and decrease for others. Therefore, providers need to give a clear understanding of the long-term risk of pregnancy, particularly for women and men wanting to use a method for several years.

### Definitions of contraceptive effectiveness rates<sup>1</sup>

**Typical-Use Pregnancy Rate:** The pregnancy rate during **typical use** of a contraceptive method.

**Perfect-Use Pregnancy Rate:** The pregnancy rate during **perfect use**, (or correct and consistent use) of a contraceptive method.

Typical-use pregnancy rates are often the most relevant for clients and providers when considering the choice of a method. However, this rate may vary from one setting to another, since it is influenced by consistency and correctness of use, the capacity to conceive (fecundability), the timing and frequency of intercourse, and whether continued correct use is more dependent on the user or provider. Some clients who are very conscientious and motivated may find the perfect-use rates also to be helpful.

The short-term typical-use pregnancy rates in Figure 1 can be used for a relatively simple classification of methods:

### Practical Categories of Contraceptive Effectiveness by Typical-Use Pregnancy Rates

#### Very Good (0-1%)

- Female sterilization
- Male sterilization
- Intrauterine device (IUD) (CuT 380A)
- Injectables (DMPA) (less effective if access limited)
- Norplant® implants

**Good (2-12%) (very good with perfect use)**

Combined oral contraceptives (COC)  
Progestin-only-pills (POP) (more effective during breastfeeding or lactational amenorrhea method (LAM))

**Fair (15-21%) (good with perfect use)**

Condoms  
Diaphragm  
Periodic Abstinence  
Spermicides

**No Method (85%)**

**METHODS WITH GOOD OR FAIR EFFECTIVENESS**

**Barrier Methods and Periodic Abstinence**

Condoms, diaphragms, periodic abstinence, and spermicides have typical-use pregnancy rates from 15% to 21% in the first year (Figure 1). Consistent and correct use, or multiple method use, results in lower pregnancy rates. Conversely, erratic and incorrect use leads to rates higher than typical-use pregnancy rates.

**Combined Oral Contraceptives**

Combined oral contraceptives (COCs) have a typical-use pregnancy rate of 8%, primarily because of frequent incorrect and inconsistent use.

**Progestin-Only Pills**

Progestin-only-pills (POPs) are less effective than COCs for non-breastfeeding women. Typical-use pregnancy rates for POPs are not well documented; we have estimated the rate for POPs to be 12%, or 1.5 times the COC rate.

**Progestin-Only Pills during Breastfeeding**

POPs are generally provided to breastfeeding women (who naturally have a lowered fecundity) thereby, achieving a very high level of effectiveness. In one very large study, the pregnancy rate at 11 months in breastfeeding women using POPs was 1.2%<sup>2</sup>.

**Counseling, Supplies and Access for Methods with Good or Fair Effectiveness**

Perfect-use (or consistent and correct use) results in much lower pregnancy rates for each of these methods. However, pregnancy rates higher than for typical-use can occur, particularly if instruction and counseling are poor, and availability and access to supplies are limited (for pills, condoms, and spermicides).

Factors which greatly influence the contraceptive effectiveness of methods need to be clearly presented to clients as they choose a method (See Chapter 3.1, Client-Provider Interaction in Family Planning Services). These factors include:

- continued availability of supplies,
- ability of the client to return for supplies,
- capacity to manage side effects and complications,

- the client's understanding of how to respond to side effects (e.g., irregular menstrual bleeding), missed pills, etc., and
- correct instructions for use.

### **Dual or Multiple Method Use for Methods with Good or Fair Effectiveness**

The effectiveness of barrier methods and periodic abstinence may be increased when two or more methods are used together. However, this increase is not well quantified. Dual method use should be particularly attractive when there is a need to reduce the risk of sexually transmitted infection (STI) and human immunodeficiency virus (HIV) infection. Multiple methods to prevent sexually transmitted diseases (STDs) and improve contraceptive effectiveness, particularly where one or more methods is controlled by the woman, will increase consistent use of at least one.

Given the relatively high typical-use pregnancy rates in developing countries (and in developed countries for poorer, less-educated populations), providers should consider supplying clients with back-up methods when possible. Barrier methods can serve the double role of back-up contraceptive protection as well as protection from STDs, including HIV. Hormonal emergency contraceptive pills (ECPs) are another suitable back-up method to prevent pregnancy. Providers may give ECPs routinely to be available in the event she needs emergency contraception, or information about access to ECPs can be provided.

### **METHODS WITH VERY GOOD EFFECTIVENESS**

The intrauterine device (IUD) (TCu 380A), female and male sterilization, the injectable, DMPA (Depo Provera), and Norplant® implants have very low pregnancy rates at one year. Typical- and perfect-use rates are similar, as long as the method is used. Injectable contraceptives require regular reinjections and supplies, and the risk of pregnancy will increase if these conditions are not met, even though published typical-use rates do not reflect this consideration (see Counseling, Supplies and Access).

Long-term rates can be compared better by perfect-use pregnancy rates, since the methods usually used long-term are less reliant on regular and continued client and provider actions. Therefore, pregnancies are more often due to method failure, rather than user failure. Incorrect or inconsistent use are relatively uncommon causes of pregnancy among long-term methods.

Table 1 provides short and long-term perfect-use pregnancy rates for the most common long-term methods used in developing countries. DMPA is included here, since it is a long-acting method and is often chosen for long-term use.

### **Female Sterilization**

Female sterilization is one of the most widely used methods of contraception world-wide. Pregnancies are most likely to occur in the first year or two due to errors of the procedure or recanalization. Immediate postpartum contraceptive sterilization (within 48 hours after delivery) is equally or more effective than sterilization performed during the interval between pregnancies, using standard occlusion techniques during minilaparotomy. For couples wanting no more children, an advantage of sterilization is that, being permanent, it will be highly effective well beyond the 5 to 10 year period of other long-term methods.

### **IUDs**

Based on perfect-use pregnancy rates, the Copper T380A and the future LNG 20 IUDs (20 mcg levonorgestrel) are comparable with female sterilization. The first-year IUD pregnancy rates from

the Demographic and Health Survey (DHS) and Center for Disease Control (CDC) surveys represent higher typical use pregnancy rates since effective IUD use is somewhat dependent on continued actions of the client (checking for expulsion), but much less so than for pills, condoms, and barrier methods.

## **DMPA**

The perfect-use rates for the three month injectable contraceptive, depo-medroxyprogesterone acetate (DMPA), are similar to perfect-use rates for female sterilization, the TCu 380A and LNG 20 IUDs, and soft tubing Norplant® implants, through five years. However, due to dependency on returning for injections and on providers to maintain availability of the method, pregnancy rates may be higher.

## **Norplant® Implants**

There is no distinction for perfect- and typical-use for Norplant® implants, since there is no ongoing client or provider requirement for effective use, similar to contraceptive sterilization. The primary difference is between hard tubing Norplant® implants, provided in developing countries through mid-1992, compared with the soft-tubing Norplant® implants, now the only version available. Hard tubing pregnancy rates progressively increase over time and are more influenced by body weight than are soft tubing rates, especially in the fourth and fifth years of use. Pregnancy rates for soft tubing Norplant® implants are not so variable and show no increase in year five (See Chapter 1.11 Selected Questions on Norplant® Implants).

## **SOURCES AND QUALITY OF CONTRACEPTIVE EFFECTIVENESS DATA**

Most of the pregnancy rates presented here are from developed countries, in order to provide accuracy and consistency across methods. When possible, typical-use pregnancy rates reflect all pregnancies, including those ending in abortion.

Given the several factors that can influence contraceptive effectiveness, additional sources of information may be helpful at the country level. At present there is no precise mechanism for establishing country-specific pregnancy rates by method. A consensus from experts familiar with the various sources of information may be needed. For example, the 1994 Bangladesh DHS survey reported an oral contraceptive (OC) pregnancy rate of 1.7<sup>3</sup>. Conversely, Bairagi documented a one-year pill pregnancy rate of 15, almost 10 times higher, in Matlab, Bangladesh, where one would expect pills to be used more correctly and consistently than in the country as a whole<sup>4</sup>. In this same study he reports a pregnancy rate of 1.0 for injectables (DMPA). Presumably the field-worker documentation of actual use of injectables, may make this rate closer to a perfect-use pregnancy rate. Methodology of collecting information is likely to influence the pregnancy rates reported from various studies.

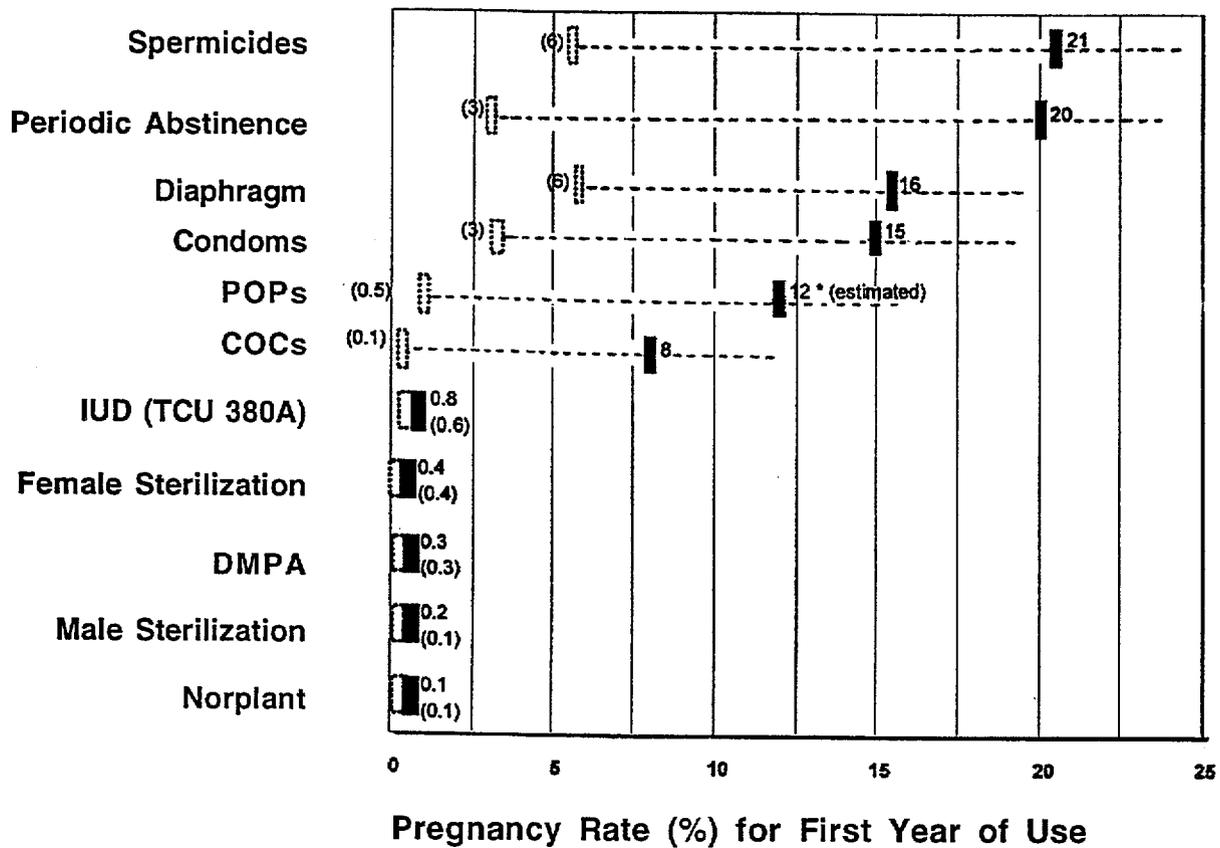
Local studies, such as those from Bangladesh, may be more useful than developed country data (especially data from clinical trials) for methods requiring ongoing client and provider actions.

## **CONCLUSION**

Typical-use pregnancy rates are often more appropriate than perfect-use rates for clients to use in understanding contraceptive effectiveness, especially for short-term use. Pregnancy rates can be lower or higher than average typical-use rates, depending on the level of consistent and correct use. The methods most often chosen for long-term contraception--sterilization, IUDs, DMPA, and Norplant® implants also have the lowest typical-use pregnancy rates (0-1%); COCs and POPs are higher (2-12%); and condoms, diaphragms, periodic abstinence, and spermicides are highest (15-21%). Long-term (5-year) perfect- or typical-use rates are similar among sterilization, IUDs,

DMPA, and Norplant® implants. However, lack of supplies or limited access to injectables, and low continued use may influence reported pregnancy rates in some settings. Use of multiple methods can improve contraceptive effectiveness and prevent STDs, as can other factors, such as whether control of the method is more with women, men, or providers.

**Figure 1**  
**Contraceptive Pregnancy Rates for Typical and Perfect Use, by Method**



 Typical Use  
 Perfect Use  
 (Consistent and Correct Use)

\* During breastfeeding POPs will have a much lower pregnancy rate.

Sources: Hatcher RA, Trussell J, Stewart F, Stewart G, Kowal D, Guest F, et al. *Contraceptive Technology*. New York: Irvington Publishers, 1994.  
 Jones EF, Forrest JD. Contraceptive failure rates based on the 1988 NSFG. *Family Planning Perspectives* 1992;24(1):12-9.  
 Graphic format adapted from FHI, *Contraceptive Technology Update series, Oral Contraceptives*, Sept. 1996.

**Table 1: Cumulative Long-Term Pregnancy Rates for Selected Family Planning Methods**

Method	Cumulative Pregnancy Rates through Completed Year of Use (pregnancies/100 women)										Ref
	1	2	3	4	5	6	7	8	9	10	
Female sterilization, postpartum*	0.06	0.4	0.5	0.5	0.6		0.6			0.8	5
Female sterilization, interval*	0.7	1.5	1.5	1.5	1.5		1.5			2.0	5
IUD, TCu 200	2.1	5.0									6
IUD, TCu 220C			3.3	3.9	3.9		4.9			5.7	7,8
IUD, TCu 380A	0.6		1.0	1.1	1.4		1.6			2.1	8,9
IUD, LNG 20	0.2				1.1		1.1				10, 11, 12
Injectable, DMPA	0.3	0.5	0.9	0.9	0.9						13
Norplant implant, Hard Tubing**	0.2	0.7	1.9	3.4	4.2						14
Norplant implant, Soft Tubing	0.1	0.1	0.5	1.0	1.0						14

\* Female sterilization using standard occlusion techniques during postpartum and interval minilaparotomy

\*\* Not supplied after mid-1992, although clients will require removals in 1997 and beyond

Source: Medical Services, Pathfinder International, July 1996.

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- 7) Rowe P. WHO randomized multicenter comparative trials of copper IUDS. Personal communication, Feb 1, 1988.
- 8) World Health Organization special programme of research, development and research training in human reproduction, task force on the safety and efficacy of fertility regulating methods. The TCu380A, TCu220C, Multiload 250 and Nova T IUDs at 3, 5, and 7 years of use- results from three randomized multicentre trials. *Contraception* 1990;42(2):141-58.
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- 11) Sivin I, el Mahgoub S, McCarthy T, Mishell DR Jr, Shoupe D, Alvarez F, et al. Long-term contraception with the levonorgestrel 20 mcg/day (LNg 20) and the copper T 380Ag intrauterine devices: A five-year randomized study. *Contraception* 1990;42(4):361-78.
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- 13) Schwallie P, Assenzo J. Contraceptive use efficacy study utilizing medroxyprogesterone acetate administered as an intramuscular injection once every 90 days. *Fertility and Sterility* 1973;24(5):331-9.
- 14) Sivin I. Contraception with NORPLANT® implants. *Human Reproduction* 1994;9(10):1818-26.

### 3.3 STD Risk Assessment (in Family Planning Clinic Settings)

Sexually Transmitted Disease (STD) risk assessment in the context of family planning (FP) is under study. STD risk assessment should have a variety of benefits in reproductive health (RH) and improve overall quality of care. A risk assessment will potentially help determine what type of RH services should be offered to a client, for example:

- a) what contraceptive options are best suited to the client's needs, including dual method use,
- b) what risk reduction counseling is needed,
- c) whether testing and/or treatment/referral for STDs is needed, and
- d) in the case of maternal and newborn care, what diagnostic and/or treatment options are needed to decrease maternal and neonatal morbidity and mortality.

Thus, appropriate STD risk assessment tools are under study for both effective STD management and appropriate FP counseling to form a unified pathway for integrated RH health services.

#### Uses of STD Risk Assessment in Reproductive Health

- **For all family planning clients:**  
STD risk assessment can be a tool to aid in counseling regarding appropriate contraceptive options. For example, clients determined to be at increased risk of current or future STDs would be poor candidates for intrauterine devices (IUDs), but may be good candidates for barrier methods.
- **For symptomatic clients:**  
For clients with symptoms and signs of an STD, syndromic management (i.e., management based on symptoms and signs as opposed to detection of specific organisms) is a programmatic option in settings where laboratory diagnosis is not feasible. Where STD treatment services are offered, clients should be treated with antibiotic regimens appropriate to cure the range of organisms typically causing the particular syndrome. Syndromic management of urethral discharge in men, and of genital ulcers in men and women, has been shown to have a high positive predictive value. In cases of vaginal discharge, where syndromic management is problematic, STD risk assessment may help predict more specific treatment, i.e., treatment for vaginitis alone or treatment for both vaginitis and cervicitis.
- **For asymptomatic clients:**  
STD risk assessment might help to identify those clients who are at greater risk of being infected and therefore good candidates for further clinical examination or laboratory evaluation, or alternatively for treatment of presumptive infections. Unfortunately, studies have shown that results of STD risk assessment in asymptomatic women do not correlate well with actual presence of infection, however, in some settings it may still be a useful approach to determine who should undergo further evaluation.

#### Risk Factors to be Assessed

Several recent investigations<sup>1-3</sup> have found that certain demographic, behavioral and non-laboratory clinical factors (e.g., self reported vaginal discharge or lower abdominal pain) were correlated with the presence of various STDs in the study populations. These factors were (or could be) used to assess the likelihood that persons coming for RH services are either currently infected or at high risk of future infection with STDs.

## Helping Clients Receive an Accurate STD Risk Assessment:

The studies mentioned above also have shown that the risk factors vary from one setting to another. Thus, a characteristic which indicates increased STD risk in one country/population may not be indicative of elevated risk in a different country/population. To increase the utility and predictive value of STD risk assessment, programs should try to establish what demographic characteristics, behavioral risk factors, and clinical symptoms and signs are associated with the various STDs seen in their local setting. When doing so is not possible, creating a risk assessment tool based on some of the characteristics which have been demonstrated to be risk factors for STD infection in other settings may be a useful alternative. The utility of using STD risk assessment without clinical validation must be judged in the context of the current services available and the scope of the STD problem.

Because of the sensitive nature of sexuality and STDs in many cultures, clients may be hesitant to respond truthfully during an STD risk assessment. Thus, the provider should ask questions in a non-judgmental manner and assure the client that the discussion is strictly confidential.

Self-assessment methods, where the client determines his or her own level of risk based on information given by the provider but does not indicate which specific risk factors apply, might be useful in such settings. Research into the utility of self-assessment for STD risk is ongoing.

### Citations:

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- 3) Behets FM, Williams Y, Brathwaite A, Hylton-Kong T, Hoffman I, Dallabetta G, et al. Management of vaginal discharge in women treated at a Jamaican sexually transmitted disease clinic: use of diagnostic algorithms versus laboratory testing. *Clinical Infectious Diseases* 1995;21(6):1450-5.

The following demonstrates a list of risk factors which have been associated with an increased risk of STDs. These risk factors are not meant to be universally applicable; the development of a local STD risk assessment, based on the local situation, would be useful and merits consideration.

### What Demographic, Behavioral and Clinical Characteristics have been associated with increased risk of STDs?

Risk Factors	Rationales
(Development of a local risk assessment protocol, based on local situation, is useful)	
<p><b>1. Demographic</b></p> <p>a) Age. (e.g., &lt;20 years old vs. ≥20 years old)</p>	<p>a) Recent surveys in several countries have shown that the prevalence of STDs is higher among women under 20. In general, adolescent males and females, are at greater risk for contracting STDs. Both biological (i.e., postulated immaturity of the female</p>
continued on next page)	

**What Demographic, Behavioral and Clinical Characteristics have been associated with increased risk of STDs? (continued)**

<p><b>Risk Factors</b> (Development of a local risk assessment protocol, based on local situation, is useful)</p>	<p><b>Rationales</b></p>
<p>b) Partnership Status Single vs. Married/Living with regular partner.</p>	<p>reproductive tract) and behavioral factors (i.e., greater number of partners, low awareness of acquired immunodeficiency syndrome (AIDS) and other STDs, and limited use of protection against STDs) are thought to contribute to this risk. <i>The actual "cut off" age may not be age 20 in all societies</i>, the true age for use in STD risk assessment should ideally be determined from local/regional information.</p> <ol style="list-style-type: none"> <li>1) Brabin L, Kemp J, Obunge OK, Ikimalo J, Dollimore N, Odu NN, et al. Reproductive tract infections and abortion among adolescent girls in rural Nigeria. <i>Lancet</i> 1995;345:300-4.</li> <li>2) Duncan ME, Tibaux G, Pelzer A, Reimann K, Peutherer JF, Simmonds P, et al. First coitus before menarche and the risk of sexually transmitted disease. <i>Lancet</i> 1990;335:338-40</li> <li>3) Duncan ME, Tibaux G, Pelzer A, Mehari L, Peutherer J, Young H, et al. Teenage obstetric and gynecological problems in an African city. <i>Central Africa Journal of Medicine</i> 1994;40:234-44.</li> <li>4) Lema VM, Hassan MA. Knowledge of sexually transmitted diseases, HIV infection and AIDS among sexually active adolescents in Nairobi, Kenya and its relationship to their sexual behaviour and contraception. <i>East African Medical Journal</i> 1994;71:122-8.</li> </ol> <p>b) In some cultures, marital status/living with a partner is a good indicator of a monogamous relationship. In the US, women using IUDs who are married or living with a partner have no elevation of pelvic inflammatory disease (PID) risk compared to similar women using no contraceptive method. PID is one of several possible health consequences of STDs.</p> <p>However, marital status or living with a partner does not necessarily offer protection from STDs, mainly due to women's inability to influence their husbands'/partners' behavior. <i>Local practices and customs must be taken into account when determining the likely importance of this factor in relation to STD risk.</i> Single women/women not living with a regular partner are at increased risk due to possible behavioral characteristics such as multiple partners or partners with multiple partners.</p> <ol style="list-style-type: none"> <li>1) Lee N, Rubin G, Borucki R. The intrauterine device and pelvic inflammatory disease revisited: new results from the Women's Health Study. <i>Obstetrics and Gynecology</i> 1988;72(1):1-6.</li> </ol>

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**What Demographic, Behavioral and Clinical Characteristics have been associated with increased risk of STDs? (continued)**

<p><b>Risk Factors</b> (Development of a local risk assessment protocol, based on local situation, is useful)</p>	<p><b>Rationales</b></p>
<p><b>2. Behavioral</b></p> <p>a) New or more than one sexual partner in the last three months.</p> <p>b) Partner has other/multiple sex partners.</p>	<p>2) Braddick MR, Ndinya-Achola J, Mirza N, Plummer FA, Irungu G, Sinei SK, et al. Towards developing a diagnostic algorithm for <i>Chlamydia trachomatis</i> and <i>Neisseria gonorrhoeae</i> cervicitis in pregnancy. <i>Genitourinary Medicine</i> 1990;66(2):62-5.</p> <p>3) Duncan ME, Tibaux G, Pelzer A, Mehari L, Peutherer J, Young H, et al. A socioeconomic, clinical and serological study in an African city of prostitutes and women still married to their first husbands. <i>Social Science &amp; Medicine</i> 1994;39(3):323-33.</p> <p>4) Moses S, Ngugi E, Bradley J, Njeru E, Eldridge G, Muia E, et al. Health care-seeking behavior related to the transmission of sexually transmitted diseases in Kenya. <i>American Journal of Public Health</i> 1994;84(12):1947-51.</p> <p>5) Rosenfield A, Fathialla M (editors). <i>The FIGO manual of human reproduction</i>. Park Ridge, NJ: Parthenon Publishing Group, 1990.</p> <p>a) Clients with a recent history of new or multiple partners are at increased risk of STDs, especially if they do not use condoms.</p> <p>1) Padian NS, Shiboski SC, Hitchcock PJ. Risk factors for acquisition of sexually transmitted diseases and development of complication. In: Wasserheit JN, Aral SO, Holmes KK (eds). <i>Research issues in human behavior and sexually transmitted diseases in the AIDS era</i>. Washington, DC: American Society for Microbiology, 1991:83-96.</p> <p>2) Catania JA, Binson D, Dolcini MM, Stall R, Choi KH, Pollack LM, et al. Risk factors for HIV and other sexually transmitted diseases and prevention practices among U.S. heterosexual adults: changes from 1990-1992. <i>American Journal of Public Health</i> 1995;85(11):1492-9.</p> <p>3) Levin LI, Peterman TA, Renzullo PO, Lasley-Bibbs V, Shu XO, Brundage JF, et al. HIV-1 seroconversion and risk behaviors among young men in the US army. <i>American Journal of Public Health</i> 1995;85(11):1500-6.</p> <p>4) Aral SO, Soskoline V, Joesoef RM, O'Reilly KR. Sex partner recruitment as a risk factor for STD: clustering of risky modes. <i>Sexually Transmitted Diseases</i> 1991;18(1):10-7.</p> <p>b) Clients whose partners have other or multiple partners are at increased risk of STDs. It may be extremely difficult for women to assess their partners' behavior.</p> <p>1) Faxelid E, Nilulo J, Ahlberg BM, Krantz I. Behaviour, knowledge, and reactions concerning sexually transmitted diseases: implications for partner notification in Lusaka. <i>East African Medical Journal</i> 1994;71(2):118-21.</p>

(continued on next page)



**What Demographic, Behavioral and Clinical Characteristics have been associated with increased risk of STDs? (continued)**

<p style="text-align: center;"><b>Risk Factors</b> (Development of a local risk assessment protocol, based on local situation, is useful)</p>	<p style="text-align: center;"><b>Rationales</b></p>
<p>c) Current symptoms or signs which may indicate an STD (some of these are very non-specific):</p> <ul style="list-style-type: none"> <li>• vaginal discharge</li> <li>• sores in genital area</li> <li>• pain during intercourse</li> <li>• bleeding after intercourse</li> <li>• pain when urinating</li> <li>• lower abdominal pain</li> </ul>	<p>c) Clients with symptoms/signs of an STD should be evaluated and their condition addressed according to local protocol. Several studies have assessed different algorithms for determining which symptomatic persons actually have STDs; unfortunately, in low risk populations, these algorithms have unacceptably low sensitivity and/or specificity (ability to detect if a client is truly positive or negative for an STD).</p> <ol style="list-style-type: none"> <li>1) Germain M, Alary M, Gredeme A, Mahony JB. Evaluation of a screening algorithm for the diagnosis of genital infections with <i>Neisseria gonorrhoea</i> and <i>Chlamydia trachomatis</i> among female sex workers in Benin. <i>Sexually Transmitted Diseases</i> 1997;24(2):109-15.</li> <li>2) Behets FM, Williams Y, Brathwaite A, Hylton-Kong T, Hoffman I, Dallabetta G, et al. Management of vaginal discharge in women treated at a Jamaican sexually transmitted disease clinic: use of diagnostic algorithms versus laboratory testing. <i>Clinical Infectious Diseases</i> 1995;21(6) 1450-5</li> <li>3) Daly C, Wangel A-M, Hoffman I, Canner J, Lule G, Lema V, et al. Validation of the World Health Organization diagnostic algorithm and development of an alternative scoring system for the management of women presenting with vaginal discharge in Malawi. [In press].</li> </ol>

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## Conclusion

Current research has indicated that an STD risk assessment approach can be a practical, feasible approach to determine high risk sexual behavior in clients for counseling purposes, including contraceptive choice. In conjunction with an STD algorithm, STD risk assessment has been applied as a method to determine if a symptomatic woman with a vaginal infection may also have a cervical STD infection. STD risk assessment approaches for asymptomatic women have been useful in identifying clients who are at greater risk of being infected with an STD, but problematic in determining which clients have current STD infections. With no currently available, simple, rapid diagnostic tests for many of the most common STDs, further research is warranted in order to investigate new approaches to improving existing STD risk assessment tools and syndromic algorithms.

## Additional Citations for more information:

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- 3) Dixon-Mueller R, Wasserheit J. The culture of silence: reproductive tract infections among women in the third world. New York: International Women's Health Coalition, 1991.
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- 6) WHO Global Programme on AIDS. *Management of sexually transmitted diseases*. Geneva: World Health Organization, 1994.
- 7) World Health Organization. *Improving access to quality care in family planning: medical eligibility criteria for contraceptive use*. Geneva: WHO, 1996.
- 8) Zurayk H, Khattab H, Younis N, Kamal O, el-Helw M. Comparing women's reports with medical diagnoses of reproductive morbidity conditions in rural Egypt. *Studies in Family Planning* 1995;26(1):14-21.
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## 3.4 Dual Method Use

This section outlines recommendations on the following selected questions for Dual Method Use:

1. When should users be advised to use **dual methods for increased contraceptive efficacy** of their contraceptive method?
2. When should women/couples be advised to use **dual methods for protection against pregnancy and sexually transmitted diseases (STDs)**?

## Q.1. When should users be advised to use dual methods for increased contraceptive efficacy of their contraceptive method?

---

For some contraceptives, users are typically advised to use dual methods:

- **Diaphragm:** Current instructions recommend the use of the diaphragm with spermicide. Research indicates the spermicide improves the contraceptive effectiveness.
- **Vasectomy:** Men are advised to use condoms, or have their partners use a contraceptive method, for approximately three months (or 20 ejaculations) after the vasectomy to make sure no sperm are in the ejaculate. Where possible, men should have a semen analysis before having intercourse without a back-up method.
- **Condoms:** In some programs condom users are also advised to use a spermicide to increase effectiveness. Where possible, this idea has been incorporated into spermicidally lubricated condoms.

Some providers urge **pill users** to have supplies of condoms as a back-up in the case of missed pills or when the pill user has run out of pills. This is a reasonable approach and provides a good opportunity for counseling on correct pill use.

Lactational amenorrhea method (LAM) users and breastfeeding women should be provided with barrier methods or progestin-only pills (POPs) to start when they want or need to. Preferably POPs should not be used prior to six weeks postpartum by breastfeeding women. Among LAM users, POPs may be used while she is still relying on LAM as dual protection or when the LAM criteria no longer apply.

Another approach to using dual methods is to provide **emergency contraceptive pills (ECPs)** to users of barrier methods (condom, diaphragm, sponge, spermicide), oral contraceptive (OC) pills, or natural family planning (NFP). Providing ECPs means giving the correct number of pills for emergency contraception (EC), along with instructions for their use. Having EC readily available is likely to decrease the risk of unintended pregnancy in cases of slippage/breakage/non-use of barriers, multiple missed OC pills, failure to abstain when necessary when using NFP, or other causes of unprotected intercourse.

## **Q.2. When should women/couples be advised to use dual methods for protection against pregnancy and sexually transmitted diseases (STDs)?**

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Decisions about contraceptives should reflect both the need to prevent unplanned pregnancies and the need to prevent STDs. To date, the methods most effective at preventing STDs – especially condoms, but also other barrier methods – may not necessarily be the most effective contraceptives. Combining a barrier method with a more effective contraceptive can maximize the dual protective effect. Yet, dual method use is relatively new, and is not appropriate for all clients. Choosing when to promote dual method use can be difficult, especially since it requires more counseling, more supplies, and places greater demands on each client. Providers have a responsibility to help clients decide which method or methods to use in light of this dilemma between pregnancy prevention and disease prevention. Providers will have to evaluate the dual needs of each client to assist him or her in making a safe, appropriate, and practical decision.

- A risk assessment and local sexually transmitted disease/human immunodeficiency virus (STD/HIV) prevalence rates can help providers understand how much STD risk their clients generally face. A risk assessment can identify individuals at higher risk and STD surveillance studies can measure STD/HIV prevalence rates for a geographical area.
- Clients who consider themselves or their partners at high risk of HIV and other STDs are good candidates for dual method use. These clients may choose to use one method for the primary purpose of pregnancy protection and condoms (or other barrier methods) for STD protection.
- Some clients may be able to achieve protection against both STDs and pregnancy using a barrier method alone. Motivated clients might use male condoms alone, since condoms are effective for both disease and pregnancy prevention when used correctly and consistently.
- For women who cannot persuade their male partners to use a male condom and who are at risk of contracting STDs, spermicides, a female condom, or a diaphragm with spermicide can be used for both STD protection and contraception. However, although spermicides, and probably diaphragms, appear to be modestly protective against bacterial STDs (gonorrhea and chlamydia), their effectiveness at protecting against viral STDs, including HIV, has not been determined.
- A woman should be informed if the contraceptive method she is using does NOT protect her against STDs. She should also be made aware that some methods may protect against some STDs but not others and that only male latex condoms have been proven to be highly effective for HIV prevention. If she is ever in a situation where she suspects she may be at risk (e.g., she thinks her husband or partner may have other sex partners), she should immediately start using additional protection.

## Considerations Concerning Dual Method Use

A difficult issue for reproductive health (RH) providers serving clients at risk of STDs/HIV is when and whether to encourage use of dual methods – one to prevent pregnancy and the other to prevent STDs/HIV. Clinicians promoting dual use must weigh factors such as cost and user compliance, as well as their relation to effective STD protection among particular client populations. Moreover, clients may attach differing priorities to preventing either pregnancies or infections, and these priorities may change over time and among various relationships.

Studies on dual method use are limited and have focused on the use of the male condom in combination with other methods of contraception. In general, based on preliminary evidence where participants were using primary methods of contraception in addition to condoms, the more effective the primary contraceptive method was at preventing pregnancy, the lower the level of consistent use of the male condom.

Several reasons can explain why concurrent condom use may decrease as perceived contraceptive effectiveness increases. First, many persons – even those with sexual behaviors putting them at risk of STD – see pregnancy as a greater immediate threat than STDs. Thus, having taken precautions against unintended pregnancy, they seem to be less motivated to undergo the extra effort and expense to use condoms. Second, this may represent differences in convenience of use between longer-term, coitally-independent methods and the coitally-dependent barrier methods. Without regular reminders of the need to protect against both pregnancy and STDs, individuals may be less likely to have condoms available when sexual intercourse occurs.

Clearly, more research is needed. Studies that examine the use of the female condom, diaphragm, and/or spermicides in conjunction with long-term methods will help clarify this issue. More research is also needed on the patterns of dual method use with different sex partners. For example, if an individual uses one method with a primary partner and adds condoms with other partners, this might reduce risk, even if dual method use is not consistent with the primary partner. Another important question is whether providers of temporary or less effective methods should routinely provide and counsel use of a second method, such as EC, as a back-up method.

### Citations:

1. Anderson JE, Brackbill R, Mosher WD. Condom use for disease prevention among unmarried U.S. women. *Family Planning Perspectives* 1996;28(1):25-8.
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3. Fox LJ, Williamson NE, Cates W Jr, Dallabetta G. Improving reproductive health: integrating STD and contraceptive services. *Journal of the American Women's Medical Association* 1995;50(3-4):129-36.
4. Institute of Medicine. *The best intentions: unintended pregnancy and the well-being of children and families*. Washington, DC: National Academy Press, 1995:118-21.
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## 3.5 Chart of Family Planning Methods and STD Protection

The Effects of Contraceptives on Bacterial and Viral Sexually Transmitted Diseases (STDs) compared to use of no contraceptive method:

Contraceptive Method	Bacterial STDs	Viral STDs (including HIV)
<b>Condoms</b> (male and female)	Protective	Protective
<b>Spermicides containing Nonoxynol-9</b>	Modestly protective against cervical gonorrhea and chlamydia	No evidence of protection <i>in vivo</i> ; <i>in vitro</i> evidence of virucidal effect
<b>Diaphragms (and probably Cervical Caps)</b>	Probably modestly protective against cervical infection	Protective against cervical cancer/human papilloma virus (HPV); otherwise undetermined
<b>Hormonal Contraceptive Methods</b>	Perhaps associated with increased cervical chlamydia  Protective against symptomatic pelvic inflammatory disease (PID); possible increased risk of unrecognized endometritis	Not protective
<b>Intrauterine Devices (IUD)</b>	Associated with increased risk of PID for women at elevated risk of STDs, especially in the first month after insertion (LNg IUDs might protect against PID, see LNg IUD Question 4)	Not protective
<b>Natural Family Planning (NFP)</b>	Not protective	Not protective
<b>Withdrawal</b>	Not protective	Not protective
<b>Lactational Amenorrhea Method (LAM)</b>	Not protective	Not protective
<b>Female Sterilization and Vasectomy</b>	Not protective	Not protective

- Citations:** 1) Cates W Jr. Contraceptive choice, sexually transmitted diseases, HIV infection, and future fecundity. *Journal of the British Fertility Society* 1996;11(1):18-22.  
 2) Feldblum P, Joanis C. Modern barrier methods: effective contraception and disease prevention. Research Triangle Park, NC: FHI, 1994.

## 3.6 Cervical Cancer Prevention

Cervical cancer is increasing throughout the world. In economically-restricted countries, where early detection methods are not as widespread and reliable, deaths from cervical cancer are climbing. In order to reduce the number of new cases of cervical cancer, many family planning (FP) programs have focused their efforts on both prevention (mutual monogamy, condoms) and methods of detection. As a result, some programs now require a Pap smear before providing FP. This requirement, in some places, reduces a woman's access to FP.

The following pages summarize, in a question/answer format, research up to mid-1996 on cervical cancer, with a focus on causes, prevention and recommendations regarding FP method choice. Hopefully, this will help clarify how cervical cancer can be prevented. For more detailed information, please refer to:

- Sherris J, Wells E, Tsu V, Bishop A. Cervical cancer in developing countries: a situation analysis. A working paper. Washington DC: World Bank, 1993.
- Bishop A, Wells E, Sherris J, Tsu V, Crook B. Cervical cancer: evolving prevention strategies for developing countries. *Reproductive Health Matters* 1995; 6(November): 60-71.

Both of these publications are available from PATH, 4 Nickerson Street, Seattle, Washington 98109-1699 USA, Telephone: (206) 285-3500, Fax: (206) 285-6619, e-mail: [info@path.org](mailto:info@path.org).

This information responds to requests for answers to questions about cervical cancer prevention. This chapter is also being published as an INTRAH Technical Information Memo Series (TIMS). For copies of INTRAH TIMS, please contact:

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INTRAH (Program for International Training in Health)  
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## Q.1. Why is cervical cancer an important women's reproductive health issue?

Answer	Rationale
a) Squamous cell cervical cancer is <b>the most common</b> cancer in women in the developing world.	a) Each year, half a million cases are diagnosed. 1) Manos M. Cervical cancer as a sexually transmitted disease. Report of Emerging Issues in Reproductive Health Meeting. Tiburon CA, The Population Council, June 15, 1995. 2) Parkin DM, Pisani P, Ferlay J. Estimates of the worldwide incidence of 18 major cancers in 1985. International Journal of Cancer 1993;54:594-606.
b) The number of cases of cervical cancer in developing countries is likely to increase significantly.	b) As populations age, as the number of human papilloma virus (HPV)-infected women increase and as the number of women with human immunodeficiency virus (HIV)-related immunosuppression increases during the coming decades, the number of women with cervical cancer is likely to increase. HIV increases susceptibility to cervical cancer and pre-cancer. 1) Bishop A, Wells E, Sherris J, Tsu V, Crook B. Cervical cancer: evolving prevention strategies for developing countries. Reproductive Health Matters 1995;6(November):60-71.
c) Cervical cancer is <b>deadly</b> .	c) An estimated 203,000 women die annually. 1) Kingman S. Human Papilloma virus vaccine tested in cervical cancer. The Journal of NIH Research, 1995.

## Q.2. What causes most cases of cervical cancer?

Answer	Rationale
<p>a) Human Papilloma virus (HPV), a sexually-transmitted disease, is responsible for more than 90% of cervical cancer cases. However, not all women infected with HPV will develop cervical cancer.</p>	<p>a) Evidence suggests that, with refined laboratory techniques, <b>all</b> cervical cancer tumors will be found to contain HPV. However, of over 70 types of HPV, only 16 are moderately to strongly associated with cervical cancer risk. Four types account for 75% of cancers.</p>
<p>b) Consequently, behaviors which put a woman at risk for STDs also put her at risk for HPV and therefore, cervical cancer. Behaviors which increase the chance of becoming infected with HPV are:</p> <ul style="list-style-type: none"> <li>• having intercourse with many different partners or having intercourse with a person who has intercourse with many different partners;</li> <li>• beginning to have intercourse at an early age or having a first pregnancy at an early age (before 20 years old);</li> <li>• and <b>not</b> using barrier methods.</li> </ul>	<p>b) Research on each risk behavior is discussed below.</p> <ul style="list-style-type: none"> <li>• Studies have found a linear relationship between the number of sexual partners a woman has and her chance of having an HPV infection; as well as between male sexual behaviors and the rates of HPV infection in women in those populations.</li> <li>• Studies have found that young age of first intercourse or pregnancy increases the risk of cervical cancer. The cells on the cervix change rapidly during adolescence, which may make the cells more vulnerable.</li> <li>• Because condoms do not cover the vulva, introitus or scrotum, they cannot offer complete protection. However, use of barrier methods has been associated with a reduced risk of cervical cancer.</li> </ul> <ol style="list-style-type: none"> <li>1) Coker AL, Hulka BS, McCann MF, Walton LA. Barrier methods and cervical intraepithelial neoplasia. <i>Contraception</i> 1992;45(1):1-10.</li> <li>2) Manos M. Cervical cancer as a sexually transmitted disease. Report of Emerging Issues in Reproductive Health Meeting, June 15, 1995. Tiberon CA, The Population Council.</li> </ol>
<p>c) Another behavior which increases a woman's risk of cervical cancer is smoking.</p>	<p>c) Cigarette smoking doubles a smoker's risk of cervical cancer in comparison with a nonsmoker.</p> <ol style="list-style-type: none"> <li>1) Winklestein W. Smoking and cervical cancer — current status: a review. <i>American Journal of Epidemiology</i> 1990;131(6):945-57.</li> </ol>

(continued on next page)

## Q.2. Causes of most cases of cervical cancer? (continued)

Answer	Rationale
d) High number of pregnancies or live births may increase a woman's risk of cervical cancer.	d) Several studies have found a high number of pregnancies or live births to be a strong and important risk factor in cervical cancer (independent of HPV infection). However, this association is not well understood and is currently under investigation. <ol style="list-style-type: none"><li>1) Brinton LA, Hamman RF, Huggins GR, Lehman HF, Levine RS, Mallin K, et al. Sexual and reproductive risk factors for invasive squamous cell cervical cancer. <i>Journal of the National Cancer Institute</i> 1987;79:23-30.</li><li>2) Schiffman MH, Bauer HM, Hoover RN, Glass AG, Cadell DM, Rush BB, et al. Epidemiologic evidence showing that human papillomavirus infection causes most cervical intraepithelial neoplasia. <i>Journal of the National Cancer Institute</i> 1993;85:958-64.</li><li>3) Madeleine M, Schwartz S, Daling J. Risk factors for cervical cancer in young women by histologic type (abstract). <i>American Journal of Epidemiology</i> 1996;143(11 Suppl);S84.</li></ol>

### Q.3. How can deaths attributed to cervical cancer be prevented?

Answer	Rationale
<p>Cervical cancer is the most preventable form of major cancer worldwide. The two public health strategies are:</p>	<p>a) Preventing the transmission of HPV will require information, education and communication strategies that raise awareness among both men and women of the risk of HPV infection due to unprotected sexual intercourse, especially with multiple partners. Additionally, because only a few HPV types are strongly associated with cervical cancer, researchers are examining the benefits of developing a HPV vaccine.</p>
<p>a) <b>Primary prevention</b>, or keeping women from developing the disease. Cervical cancer is mostly caused by behaviors connected to life style. Therefore, priorities should focus on changing behavior, promoting barrier methods, discouraging smoking and helping women have the number of pregnancies they want.</p>	<ol style="list-style-type: none"> <li>1) Ponten J, Adami HO, Bergstrom R, Dillner J, Friberg LG, Gustafsson L, et al. Strategies for global control of cervical cancer. <i>International Journal of Cancer</i> 1995;60:1-26.</li> <li>2) Manos M. Cervical cancer as a sexually transmitted disease. Report of Emerging Issues in Reproductive Health Meeting, June 15, 1995. Tiberon CA, The Population Council.</li> </ol>
<p>b) <b>Secondary prevention</b>, or screening women who may have pre-cancerous lesions and treating them. Currently, screening with appropriate follow-up care is not widely available or economically feasible in many countries or settings.</p>	<p>b) On average, it takes about 10 years for pre-cancerous lesions to develop into cervical cancer. Most cervical cancer occurs in women over the age of 35. If detected early, there is a 95% success rate for treatment. However, screening is only useful in preventing cervical cancer deaths if appropriate medical follow-up services are available.</p>
	<p>The most common screening method used is the Pap smear. Providing Pap smears requires significant infrastructure. Without this, Pap smears are often poorly prepared and improperly interpreted. However, because it is still the best method for diagnosis if properly conducted, efforts are being made to improve Pap smear availability and interpretation.</p>
	<p>Other approaches to screening, including methods for enhanced visual inspection of the cervix and HPV detection, are being studied and refined now. These approaches may prove more useful and especially appropriate for economically restricted countries. Where resources are scarce, screening methods will be more effective in preventing cervical cancer deaths if they target women at high risk (e.g., over the age of 35).</p>
	<ol style="list-style-type: none"> <li>1) Bishop A, Wells E, Sherris J, Tsu V, Crook B. Cervical cancer: evolving prevention strategies for developing countries. <i>Reproductive Health Matters</i> 1995;6(November):60-71.</li> </ol>

## Q.4. Has the use of family planning methods been shown to increase the risk of cervical cancer?

Answer	Rationale
a) Barrier methods of contraception help to <b>decrease</b> the risk of cervical cancer.	a) In several studies, women reporting use of barrier methods (including condoms) appear to have a lower risk of cervical cancer. These findings have not been found in all studies, however. If cervical cancer is caused by a sexually transmitted disease (STD) such as HPV, it is plausible that barrier use will protect a woman from cervical cancer or pre-cancer, but she would need to use the barrier method whenever engaging in intercourse.
b) Intrauterine devices (IUDs) and tubal ligation do not increase the risk.	b) Research has <b>not</b> found IUDs or tubal ligation to increase cervical cancer risk in comparison to using no method.
c) There remains concern that hormonal contraceptives are associated with a low level increased squamous cervical cancer risk. (There is stronger evidence for a relationship between oral contraceptives (OCs) and adenocarcinoma, a more rare form of cervical cancer than the squamous cell cancer.)	c) Some researchers believe that long-term combined oral contraceptive (COC) use (beyond five years) may be associated with a slight increased risk of cervical cancer. Other researchers disagree, saying that this association may not be due to COCs, but may result if COC users receive better medical care and more frequent screening (screening biases), are not using barrier methods, are having more sexual partners, are initiating intercourse at an earlier age, or a number of other factors. Additionally, because COCs may increase cervical ectopy, it may be easier to get a positive Pap smear from a COC user.
	<ol style="list-style-type: none"> <li>1) Feldblum P, Joanis C. Modern barrier methods: effective contraception and disease prevention. Durham, NC: Family Health International, 1994, p 24.</li> <li>2) La Vecchia C. Depot-medroxyprogesterone acetate, other injectable contraceptives, and cervical neoplasia. <i>Contraception</i> 1994;49:223-30.</li> <li>3) Schlesselman JJ. Net effect of oral contraceptive use on the risk of cancer in women in the United States. <i>Obstetrics and Gynecology</i> 1995;85(5 pt 1):793-801.</li> <li>4) Swan S, Petitti D. A review of problems of bias and confounding in epidemiologic studies of cervical neoplasia and oral contraceptive use. <i>American Journal of Epidemiology</i> 1982;115(1):10-8.</li> <li>5) Thomas DB, Ray RM. Depot-medroxyprogesterone acetate (DMPA) and risk of invasive adenocarcinomas and adenosquamous carcinomas of the uterine cervix. <i>Contraception</i> 1995;52(5):307-12.</li> <li>6) World Health Organization. Improving access to quality care in family planning: eligibility criteria for contraceptive use. Geneva: WHO, 1996.</li> <li>7) WHO. Invasive squamous cell carcinoma and combined oral contraceptives: results from a multi-national study. <i>International Journal of Cancer</i> 1993;55:228-36.</li> </ol>

**Q.5. Is a Pap smear needed before beginning any Family Planning (FP) method? Should use be discontinued if a client develops cervical cancer while using any method?**

Answer	Rationale
<p>No. A Pap smear is not needed before beginning any method, nor should use of any FP method be discontinued if a client develops cervical cancer.</p>	<p>Although cervical cancer screening with appropriate follow-up is a good preventive health measure where economically feasible, this is not a requirement for FP use. Furthermore, some people use the Pap smear as a proxy screening test for clinically-inapparent cervical infection. Because of its low sensitivity and specificity for detecting infection, and high cost, STD risk should be assessed by history and clinical exam of the cervix instead of by Pap smear. Access to FP should not be restricted as a means to promote screening.</p> <p>Clients with cervical pre-cancer can continue using their contraceptive method. Patients with true cervical cancer will not require contraception if treated by radical surgery or radiation therapy. While there is a theoretical concern that COC use may affect the progression of the existing disease, women with cervical cancer may continue to use COCs or any other contraceptive method while awaiting treatment. Due to risk of infection or perforation, an IUD should not be inserted in a woman who has already been diagnosed with cervical cancer.</p> <p>1) World Health Organization. Improving access to quality care in family planning: eligibility criteria for contraceptive use. Geneva: WHO, 1996.</p>

# APPENDICES

**Appendix A: How to be Reasonably Sure the Woman is Not Pregnant**

**Appendix B: List of Abbreviations**

**Appendix C: 1) Meeting Participants' and Reviewers' Organizations**

**2) Participants in the May 23, 1996 Meeting**

**3) Reviewers**

**Appendix D: Acknowledgments**

**Appendix E: How to Access Volume I on the Internet**

**Appendix F: Summary Table of the 1996 WHO Medical Eligibility  
Criteria for Initiating Contraceptive Use**

## Appendix A

### How to Be Reasonably Sure the Woman Is Not Pregnant

You can be reasonably sure the woman is not pregnant if she has no symptoms (see "History," below) or signs (see "Physical exam," below) of pregnancy, and any of the conditions below:

- has not had intercourse since last normal menses, or
- has been correctly and consistently using another reliable method, or
- is within the first seven days after onset of normal menses, or
- is within four weeks postpartum (for NON-lactating women), or
- is within the first seven days postabortion, or
- is fully breastfeeding, amenorrheic, and less than six months postpartum (see "Relying on Lactational Amenorrhea," below).

#### History of symptoms of pregnancy

- absent (or altered) menses,
- nausea (with or without vomiting),
- fatigue (persistent),
- breast tenderness (and breast enlargement),
- increased frequency of urination,
- weight and mood changes,
- maternal perception of fetal movements (late symptom: at 16 to 20 weeks gestation).

**Physical exam** is seldom necessary, except to rule out pregnancy of greater than six weeks when uterine enlargement begins to be noticeable. Later (around 18 weeks), the fetal heart beat can be heard with a stethoscope and fetal movements can be perceived by the examiner.

#### Laboratory

In certain settings, pregnancy tests are not very helpful or practical because highly sensitive tests (positive +/- 10 days after conception) are not usually affordable. However, in cases where the possibility of pregnancy is difficult to rule out, a highly sensitive pregnancy test may be helpful, if readily available and not too expensive, and if part of routine clinic practice.

#### Relying on Lactational Amenorrhea Method

The Lactational Amenorrhea Method (LAM) is a highly effective contraceptive (98% protection during the first six months postpartum in women who are fully or nearly fully\* breastfeeding and amenorrheic)<sup>1-3</sup>. The effectiveness of LAM in the second six months postpartum has been studied, though more research is needed<sup>4</sup>. (See LAM chapter Question 3)

A service provider can be reasonably sure that a woman is not pregnant if she is still amenorrheic, within the first six months postpartum, fully or nearly fully\* breastfeeding and has  
(continued on next page)

\* "Fully" breastfeeding includes exclusive or almost exclusive breastfeeding (only occasional tastes of foods or water) day and night<sup>1-3</sup>. "Nearly fully" breastfeeding means that supplemental feedings are given but comprise a minimal part of the infant's diet<sup>1-3</sup>.

*Appendix A* (continued)

no clinical symptoms of pregnancy. When an accurate pregnancy test is not easily available or affordable, and a woman more than six months postpartum requests an IUD\*\* or NORPLANT® Implants or injectables, you can still be reasonably sure she is not pregnant if the woman has kept her breastfeeding frequency high\*\*\*, and she is still amenorrheic.

It should be noted that bleeding in the first eight weeks (56 days) postpartum is NOT considered "menstrual" bleeding in fully or nearly fully breastfeeding women.

- 1) Labbok M, Cooney K, Coly S. Guidelines: breastfeeding, family planning, and the Lactational Amenorrhea Method - LAM. Washington, DC: Institute for Reproductive Health, 1994.
- 2) Labbok MH, Perez A, Valdes V, Sevilla F, Wade K, Laukaran VH, et al. The Lactational Amenorrhea Method (LAM): a postpartum introductory family planning method with policy and program implications. *Advances in Contraception* 1994;10:93-109.
- 3) Labbok M, Krasovec K. Toward consistency in breastfeeding definitions. *Studies in Family Planning* 1990;21:226-30.
- 4) Cooney KA, Nyirabukeye T, Labbok M, Hoser P, Ballard E. Assessment of the nine-month Lactational Amenorrhea Method (MAMA-9) in Rwanda. *Studies in Family Planning* 1996;24:162-71.
- 5) Kennedy KI, Rivera R, McNeilly A. Consensus statement on the use of breastfeeding as a family planning method. *Contraception* 1989;39(5):477-96.

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\*\* It is more important to rule out pregnancy before inserting an IUD than before starting hormonal methods, because of the risk of septic miscarriage.

\*\*\* A woman who breastfeeds 10 times per day or more, or who gives more than 80% of her infant's meals as breastfeeds, is at less risk of being fertile<sup>2</sup>. Breastfeeding before giving each supplement is optimal.

## Appendix B

### List of Abbreviations

<b>AIDS</b>	acquired immunodeficiency syndrome
<b>BBT</b>	basal body temperature
<b>CBD</b>	community-based distributors
<b>CBS</b>	community-based services
<b>CIC</b>	combined injectable contraceptive
<b>CMM</b>	cervical mucus method
<b>COC</b>	combined oral contraceptive
<b>CPI</b>	client-provider interaction
<b>CuT 380A</b>	Copper T 380A intrauterine device
<b>DMPA</b>	depo-medroxyprogesterone acetate (Depo-Provera®)
<b>EC</b>	emergency contraception
<b>ECP</b>	emergency contraceptive pill
<b>EE</b>	ethinyl estradiol
<b>FP</b>	family planning
<b>HIV</b>	human immunodeficiency virus
<b>HLD</b>	high-level disinfection
<b>HPV</b>	human papilloma virus
<b>IUD</b>	intrauterine device
<b>LAM</b>	Lactational Amenorrhea Method
<b>LNg IUD</b>	levonorgestrel-releasing intrauterine device
<b>MAQ</b>	maximizing access and quality
<b>MBL</b>	menstrual blood loss
<b>N-9</b>	nonoxynol-9
<b>NET-EN</b>	norethisterone (norethindrone) enanthate
<b>NFP</b>	natural family planning
<b>OC</b>	oral contraceptive
<b>PID</b>	pelvic inflammatory disease
<b>POP</b>	progestin-only pill
<b>RH</b>	reproductive health

**Appendix B** (continued)

<b>RTI</b>	reproductive tract infection
<b>STD</b>	sexually transmitted disease
<b>STI</b>	sexually transmitted infection
<b>TB</b>	tuberculosis
<b>UTI</b>	urinary tract infection

## Appendix C\*

- 1) Meeting Participants' and Reviewers' Organizations
- 2) Participants in the May 23, 1996 Meeting
- 3) Reviewers\*\*

**NOTE:** This document was greatly enriched and informed by the diversity of view points expressed by the 33 participants who attended the May 1996 meeting, and by the 101 reviewers of subsequent drafts of the documents (most of the meeting participants also offered feedback by reviewing later drafts as well). The comments of the participants and reviewers were carefully catalogued, reconciled with current clinical and epidemiologic literature, and synthesized into the document. As with any endeavor involving such a large number of experts, unanimity on every point was impossible. Overall, the concepts of the original 1996 meeting participants, and the recommendations from all subsequent reviews, have been honored and are encompassed in this synthesis. A sincere effort was made to make the document reflect, as much as possible, the sense of all the meeting participants and the reviewers.

\* All lists are in alphabetical order by organization, then by last name

\*\* The Client-Provider Interaction, Contraceptive Effectiveness, and Cervical Cancer chapters and the CBS checklists and accompanying guide were also reviewed separately from Volume II. Thus, complete lists of reviewers for those sections are not included here.

## Meeting Participants' and Reviewers' Organizations

ACNM = American College of Nurse Midwives  
AED = Academy for Educational Development  
AIDSCAP/FHI  
AVSC International  
Boston Women's Health Book Collective  
CARE International  
CDC = Centers for Disease Control and Prevention  
CEMICAMP  
Columbia University School of Public Health  
CONRAD  
Emory University Family Planning Program  
FDA = US Federal Drug Administration  
FHI = Family Health International  
FPASL = Family Planning Association of Sri Lanka  
Futures Group/Options Project  
Futures Group SOMARC  
Institute of Tropical Medicine  
Istituto per la Regolazione Naturale Della Fertilita  
INTRAH = Program for International Training in Health  
IPPF = International Planned Parenthood Federation  
IRH = Institute for Reproductive Health, Georgetown University  
JHPIEGO Corporation  
JHU/CCP = Johns Hopkins University Center for Communication Programs  
Johns Hopkins University  
NHS Executive North West  
NICHD = National Institute of Child Health and Human Development  
PATH = Program for Appropriate Technology in Health  
Pathfinder International, USA  
The Population Council  
PPAG  
Princeton University

(continued on next page)

**Participants' and Reviewers' Affiliations** (continued)

Uganda Ministry of Health

UMATI, Tanzania

University of Denver

University of Malawi

UNC-CH = University of North Carolina at Chapel Hill

USAID/W = United States Agency for International Development/Washington

WHO = World Health Organization

ZNFPC

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**Note:** Alphabetized by organizational name, then by last name

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## Appendix D

### Acknowledgments

This volume is a collaborative project. Volunteer Resource Persons (see attached table) contributed initial chapter drafts and/or assisted with subsequent revisions. Some Volunteer Resource Persons will be further revising their chapters and publishing them outside of Volume II (e.g., Cervical Cancer Prevention, Community-Based Services Checklists).

All participants of the May 1996 meeting, reviewers of subsequent drafts, and individuals responsible for incorporating reviewers' feedback contributed their time, input and advice to the carefully considered recommendations contained in this document (see Appendix C).

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(continued on next page)

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1.9 Barrier Methods	Paul Feldblum, FHI; Monica Gaines, INTRAH; Jennifer Smith, and Patricia Bright, USAID
1.10 Oral Contraceptives as Emergency Contraceptive Pills	Tara Nutley, FHI; Linda Potter, Princeton University; Roberto Rivera, FHI; Douglas Huber, Pathfinder International; Jeffrey Spieler, USAID
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3.4 Dual Method Use	Willard Cates, Jr., Nancy Williamson, and Carol Joanis, FHI
3.5 Family Planning Methods and STD Protection (chart)	Willard Cates, Jr., FHI
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## Appendix E

### **How to Access Volume I, *Recommendations for Updating Selected Practices in Contraceptive Use* on the Internet**

Volume I, *Recommendations for Updating Selected Practices in Contraceptive Use* is currently accessible on the Internet (world wide web). Volume I is located in JHPIEGO's ReproLine® (Reproductive Health On-line) website. As of this printing, Volume I is located under International Reference Documents and is available in English, French, Portuguese and Spanish.

After accessing Volume I, you may download sections to your computer. The Adobe® Acrobat® Reader software is necessary to view and print the Volume I files, and other documents from ReproLine®. The Adobe® Acrobat® Reader is free software. See instructions below on how to download it from the Internet.

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Note: Because many web servers (the computers offering the web pages) are case-sensitive, it is best to type URLs exactly as shown.

The **Adobe® Acrobat® Reader** is free software that can be downloaded from the Internet. The software may be located through links in ReproLine or through the Adobe homepage at URL <http://www.adobe.com/>

From the Adobe homepage, the Adobe Acrobat Reader can be found under *Products*. By clicking on Adobe Acrobat Reader you will find information on the software, as well as other companion software that may be purchased, and instructions on how to download the correct version of the software (e.g., for PC or Macintosh, in English or another language) for your computer.

There are plans to make Volume II accessible on the Internet in the future.

## Appendix F

# Summary Table of the 1996 WHO Medical Eligibility Criteria for Initiating Contraceptive Use

**NOTE:** This table does not include the eligibility criteria for all methods covered in Volume II, but most of the methods covered in this volume plus each of the methods covered in Volume I.

### WHO Categories for Temporary Methods

- WHO 1** Can use the method. No restriction on use.
- WHO 2** Can use the method. Advantages generally outweigh theoretical or proven risks. If a doctor or nurse is available to make a clinical judgement, category 2 conditions could be considered in choosing a method. If the client chooses the method, more than usual follow-up may be needed.
- WHO 3** Should not use the method unless a doctor or nurse makes a clinical judgement that the client can safely use it. Theoretical or proven risks usually outweigh the advantages of the method. Method of last choice, for which regular monitoring may be needed.
- WHO 4** Should not use the method. Condition represents an unacceptable health risk if method is used.

### Simplified 2-Category System

Where a doctor or nurse is not available to make clinical judgements, the WHO 4-category classification system can be simplified into a 2-category system as shown in this table:

WHO Category	With Clinical Judgement	With Limited Clinical Judgement
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

**NOTE:** In the table that follows, Category 3 and 4 conditions are shaded to indicate the method should not be provided where clinical judgement is limited.

### WHO Categories for Female Sterilization and Vasectomy

- Accept** No medical reason prevents performing the procedure in a routine setting.
- Caution** The procedure can be performed in a routine setting but with extra preparation and precautions.
- Delay** Delay the procedure. Condition must be treated and resolved before the procedure can be performed. Provide temporary methods.
- Refer** Refer client to a center where an experienced surgeon and staff can perform the procedure. Setting should be equipped for general anesthesia and other medical support. Provide temporary methods. (WHO calls this category "Special")

**NOTE:** In the table that follows, "Delay" and "Refer" conditions are shaded.

- Sources:** 1) Hatcher RA, Rinehart W, Blackburn R, Geller JS. The essentials of contraceptive technology. Baltimore, MD: Johns Hopkins School of Public Health, Population Information Program, 1997.  
 2) World Health Organization. Improving access to quality care in family planning: medical eligibility criteria for contraceptive use. Geneva: WHO, 1996.

## WHO Medical Eligibility Criteria for Starting Contraceptive Methods

CONDITION	Combined OCS	Progestin-Only OCS	DMPA/NET EN	Norplant Implants	Female Sterilization	Vasectomy	Condoms	TCu-380A IUD	Spermicides	Diaphragm, Cervical Cap	Fertility Awareness-Based Methods	Lactational Amenorrhea Method (LAM)
<b>Pregnant</b>	4	4	4	4	Delay	—	1	4	1	1	—	—
<b>Age</b>												
Less than 16	1	2	2	2	Accept <sup>a</sup>	— <sup>a</sup>	1	2	1	1	1 <sup>b,c</sup>	1
16 to 19	1	1	1	1	Accept <sup>a</sup>	— <sup>a</sup>	1	2	1	1	1	1
20 to 39	1	1	1	1	Accept <sup>a</sup>	— <sup>a</sup>	1	1	1	1	1	1
40 and over	2	1	1	1	Accept <sup>a</sup>	— <sup>a</sup>	1	1	1	1	1 <sup>b,c</sup>	1
<b>Smoking</b>												
Less than age 35	2	1	1	1	Accept <sup>a</sup>	— <sup>a</sup>	1	1	1	1	1	1
Age 35 and over												
& Light smoker (20 or fewer cigarettes per day)	3	1	1	1	Accept <sup>a</sup>	— <sup>a</sup>	1	1	1	1	1	1
& Heavy smoker (over 20 cigarettes per day)	4	1	1	1	Accept <sup>a</sup>	— <sup>a</sup>	1	1	1	1	1	1
<b>High blood pressure (hypertension)</b>												
Mild (140/90 to 159/99)	2/3 <sup>d</sup>	1	2	1	Caution	—	1	1	1	1	1	1
Moderate (160/100 to 179/109)	3/4 <sup>e</sup>	1	2	1	Refer	—	1 <sup>f</sup>	1	1 <sup>f</sup>	1 <sup>f</sup>	1 <sup>f</sup>	1
Severe (greater than 180/110) <sup>g</sup>	4	2	3	2	Refer	—	1 <sup>f</sup>	1	1 <sup>f</sup>	1 <sup>f</sup>	1 <sup>f</sup>	1 <sup>h</sup>
Past hypertension where blood pressure cannot be evaluated	3	2	2	2	Caution	—	1	1	1	1	1	1
<b>Diabetes</b>												
Past elevated blood sugar levels during pregnancy	1	1	1	1	Accept	—	1	1	1	1	1	1

<sup>a</sup> Sterilization is appropriate for women and men of any age, but only if they are sure they will not want children in the future.

<sup>b</sup> This condition may affect ovarian function and/or change fertility signs and symptoms and/or make methods difficult to learn and use.

<sup>c</sup> Shortly after menarche (age at first menstrual bleeding) and as menopause approaches, menstrual cycles may be irregular.

<sup>d</sup> Category 2 where blood pressure can be monitored periodically. Otherwise, category 3.

<sup>e</sup> Category 3 where blood pressure can be monitored periodically. Otherwise, category 4.

<sup>f</sup> Higher typical failure rates of this method may expose the user to an unacceptable risk of dangerous unintended pregnancy.

<sup>g</sup> With or without vascular disease.

<sup>h</sup> Breastfeeding may not be recommended with drugs used to treat this condition.

— Condition not listed by WHO for this method; does not affect eligibility for method use.

Diabetes without vascular disease													
Not treated with insulin	2	2	2	2	Caution	Caution	1	1	1	1	1	1	1
Treated with insulin	2	2	2	2	Caution	Caution	1 <sup>f</sup>	1	1 <sup>f</sup>	1 <sup>f</sup>	1 <sup>f</sup>	1 <sup>f</sup>	1
Diabetes with vascular disease or diabetes for more than 20 years	3/4 <sup>i</sup>	2	3	2	Refer	Caution	1 <sup>f</sup>	1	1 <sup>f</sup>	1 <sup>f</sup>	1 <sup>f</sup>	1 <sup>f</sup>	1 <sup>h</sup>
<b>Thromboembolic disorder<sup>j</sup></b>													
Current thromboembolic disorder	4	1	1	1	Delay	—	1	1	1	1	1	1	1 <sup>h,k</sup>
Past thromboembolic disorder	4	1	1	1	Accept	—	1	1	1	1	1	1	1
<b>Ischemic heart disease<sup>l</sup></b>													
Current ischemic heart disease	4	2	3	2	Delay	—	1 <sup>f</sup>	1	1 <sup>f</sup>	1 <sup>f</sup>	1 <sup>f</sup>	1 <sup>f</sup>	1 <sup>h,k</sup>
Past ischemic heart disease	4	2	3	2	Caution	—	1 <sup>f</sup>	1	1 <sup>f</sup>	1 <sup>f</sup>	1 <sup>f</sup>	1 <sup>f</sup>	1
<b>Valvular heart disease</b>													
Without complications	2	1	1	1	Caution	—	1	1	1	1	1	1	1
With complications <sup>m</sup>	4	1	1	1	Refer	—	1 <sup>f</sup>	2	1 <sup>f</sup>	1 <sup>f</sup>	1 <sup>f</sup>	1 <sup>f</sup>	1 <sup>h,k</sup>
<b>Varicose veins</b>	1	1	1	1	Accept	—	1	1	1	1	1	1	1
<b>Superficial thrombophlebitis<sup>n</sup></b>	2	1	1	1	Accept	—	1	1	1	1	1	1	1
<b>Major surgery</b>													
With prolonged immobilization or surgery on the legs	4	1	1	1	Delay	—	1	1	1	1	1	1	1 <sup>h,k</sup>
Without prolonged immobilization	2	1	1	1	Accept	—	1	1	1	1	1	1	1
<b>Stroke (past cerebrovascular accident)</b>	4	2	3	2	Caution	—	1	1	1	1	1	1	1
<b>Headaches</b>													
Mild headaches	1	1	1	1	Accept	—	1	1	1	1	1	1	1
Severe headaches													
Recurrent, including migraine without focal neurological symptoms <sup>o</sup>	2	1	2	2	Accept	—	1	1	1	1	1	1	1 <sup>h</sup>
Recurrent, including migraine with focal neurological symptoms <sup>o</sup>	4	2	2	2	Accept	—	1	1	1	1	1	1	1 <sup>h</sup>
<b>Vaginal bleeding patterns</b>													
Irregular without heavy bleeding	1	2	2	2	Accept	—	1	1	1	1	1 <sup>p</sup>	—	—
Irregular with heavy or prolonged bleeding	1	2	2	2	Accept	—	1	2 <sup>q</sup>	1	1	1 <sup>p</sup>	—	—
<b>Unexplained abnormal vaginal bleeding</b>	3	3	4	4	Delay	—	1	4	1	1	1 <sup>p</sup>	—	—

<sup>i</sup> Category 3 or 4, depending on the severity of the condition.

<sup>j</sup> Circulatory disease due to blood clots.

<sup>k</sup> LAM has no impact on this condition, but the condition may rule out breastfeeding.

<sup>l</sup> Heart disease due to blocked arteries.

<sup>m</sup> Pulmonary hypertension, risk of arterial fibrillation, history of subacute bacterial endocarditis, or taking anticoagulant drugs.

<sup>n</sup> Inflammation of a vein just beneath the skin.

<sup>o</sup> Focal neurological symptoms= blurred vision, temporary loss of vision, sees flashing lights or zigzag lines, or has trouble speaking or moving.

<sup>p</sup> This condition may make the calendar method difficult or impossible to use effectively.

<sup>q</sup> Category 3 if client is anemic. Also, unusually heavy bleeding may indicate a serious underlying condition.

— Condition not listed by WHO for this method; does not affect eligibility for method use.

## WHO Medical Eligibility Criteria for Starting Contraceptive Methods (continued)

CONDITION	Combined OCs	Progestin-Only OCs	DMPA/NET EN	Norplant Implants	Female Sterilization	Vasectomy	Condoms	TCu-380A IUD	Spermicides	Diaphragm, Cervical Cap	Fertility Awareness-Based Methods	Lactational Amenorrhea Method (LAM)
<b>Breast cancer</b>												
Current	4	3	4	4	Caution	—	1 <sup>f</sup>	1	1 <sup>f</sup>	1 <sup>f</sup>	1 <sup>f</sup>	1 <sup>h,k</sup>
Past, with no evidence of disease in last 5 years	3	3	3	3	Accept	—	1	1	1	1	1	1
<b>Breast lump (undiagnosed)</b>	2	2	2	2	Accept	—	1	1	1	1	1	1
<b>Benign breast disease</b>	1	1	1	1	Accept	—	1	1	1	1	1	1
<b>Family history of breast cancer</b>	1	1	1	1	Accept	—	1	1	1	1	1	1
<b>Cervical cancer (awaiting treatment)</b>	2	2	2	2	Delay	—	1 <sup>f</sup>	4	2 <sup>f</sup>	1 <sup>f,r</sup>	1 <sup>b,f</sup>	1 <sup>h</sup>
<b>Noncancerous cervical lesions (cervical intraepithelial neoplasia)</b>	2	2	2	2	Accept	—	1	1	1	1 <sup>r</sup>	1 <sup>b</sup>	1
<b>Endometrial or ovarian cancer</b>	1	1	1	1	Delay	—	1 <sup>f</sup>	4	1 <sup>f</sup>	1 <sup>f</sup>	1 <sup>f</sup>	1 <sup>h</sup>
<b>Benign ovarian tumors (including cysts)</b>	1	1	1	1	Accept	—	1	1	1	1	1	1
<b>Pelvic inflammatory disease (PID)</b>												
Past PID (no known current risk of STDs)												
Became pregnant since PID	1	1	1	1	Accept	—	1	1	1	1	1	1
Has not become pregnant since PID	1	1	1	1	Caution	—	1	2	1	1	1	1
Current PID or in last 3 months <sup>s</sup>	1	1	1	1	Delay	—	1	4	1	1	1 <sup>b,t</sup>	1
<b>Sexually transmitted disease (STDs)<sup>u</sup></b>												
Current STD (including purulent cervicitis) <sup>v</sup>	1	1	1	1	Delay	Delay	1	4	1	1	1 <sup>b</sup>	1

<sup>b</sup> This condition may affect ovarian function and/or change fertility signs and symptoms and/or make methods difficult to learn and use.

<sup>f</sup> Higher typical failure rates of this method may expose the user to an unacceptable risk of dangerous unintended pregnancy.

<sup>h</sup> Breastfeeding may not be recommended with drugs used to treat this condition.

<sup>k</sup> LAM has no impact on this condition, but the condition may rule out breastfeeding.

<sup>r</sup> Cervical cap not recommended.

<sup>s</sup> Including endometritis (inflammation of the lining of the uterus) following childbirth or abortion.

<sup>t</sup> Condition does not affect vaginal bleeding patterns; calendar method can be used.

<sup>u</sup> Barrier methods, especially condoms, are always recommended for prevention of STDs, including HIV/AIDS.

<sup>v</sup> Purulent cervicitis—a pus-like discharge from the opening of the cervix.

— Condition not listed by WHO for this method; does not affect eligibility for method use.

STD in last 3 months (no symptoms persisting after treatment)	1	1	1	1	Accept	—	1	4	1	1	1 <sup>b,t</sup>	1
Vaginitis without purulent cervicitis <sup>v,w</sup>	1	1	1	1	Accept	—	1	2 <sup>w</sup>	1	1	1	1
Increased risk of STDs <sup>x</sup>	1	1	1	1	Accept	—	1	3	1	1	1	1
<b>Urinary tract infection</b>	—	—	—	—	—	—	—	—	1 <sup>y</sup>	1 <sup>y</sup>	1	—
<b>HIV infection/AIDS<sup>u</sup></b>												
HIV infected	1	1	1	1	Accept	Accept	1 <sup>f</sup>	3 <sup>z</sup>	1 <sup>f</sup>	1 <sup>f</sup>	1 <sup>f</sup>	1 <sup>aa</sup>
High risk of HIV infection <sup>x</sup>	1	1	1	1	Accept	Accept	1	3	2 <sup>ab</sup>	1	1	1 <sup>aa</sup>
AIDS	1	1	1	1	Refer	Refer	1 <sup>f</sup>	3 <sup>z</sup>	1 <sup>f</sup>	1 <sup>f</sup>	1 <sup>f</sup>	1 <sup>aa</sup>
<b>Gallbladder disease</b>												
Current disease	3	1	1	1	Delay	—	1	1	1	1	1	1
Treated with medication	3	1	1	1	Accept	—	1	1	1	1	1	1
Without symptoms or surgically treated	2	1	1	1	Accept	—	1	1	1	1	1	1
<b>Past cholestasis (jaundice)</b>												
Related to pregnancy	2	1	1	1	Accept	—	1	1	1	1	1	1
Related to past combined oral contraceptive use	3	2	2	2	Accept	—	1	1	1	1	1	1
<b>Viral hepatitis</b>												
Active disease	4	3	3	3	Delay	—	1	1	1	1	1	1 <sup>h</sup>
Carrier	1	1	1	1	Accept	—	1	1	1	1	1	1
<b>Cirrhosis of the liver</b>												
Mild (compensated)	3	2	2	2	Caution	—	1	1	1	1	1	1
Severe (decompensated)	4	3	3	3	Refer	—	1 <sup>f</sup>	1	1 <sup>f</sup>	1 <sup>f</sup>	1 <sup>b,f,t</sup>	1 <sup>h,k</sup>
<b>Liver tumors</b>												
Benign	4	3	3	3	Caution	—	1	1	1	1	1 <sup>b,t</sup>	1
Malignant	4	3	3	3	Caution	—	1 <sup>f</sup>	1	1 <sup>f</sup>	1 <sup>f</sup>	1 <sup>b,f,t</sup>	1 <sup>h,k</sup>
<b>Uterine fibroids</b>	1	1	1	1	Caution	—	1	2 <sup>ac</sup>	1	1	1	1
<b>Past ectopic pregnancy</b>	1	2	1	1	Accept	—	1	1	1	1	1	1
<b>Obesity</b>	1	1	1	1	Caution	—	1	1	1	1 <sup>ad</sup>	1	1

<sup>v</sup> In areas where STD incidence is high, vaginitis may indicate an STD.

<sup>x</sup> For example, currently has or will have more than one sex partner or a partner who has more than one partner.

<sup>y</sup> There is a potential increased risk of urinary tract infection with diaphragms and spermicides.

<sup>z</sup> For IUDs, HIV-infected or any other medical condition or medication that makes the body less able to fight infection.

<sup>aa</sup> In areas where infectious disease is the main cause of infant death, HIV-infected women should be advised to breastfeed. In other areas, if affordable alternatives to breastmilk are available, HIV-infected women should not breastfeed.

<sup>ab</sup> High dose of nonoxynol-9 spermicide may cause vaginal abrasions, which may increase risk of HIV infection.

<sup>ac</sup> Uterine fibroids distorting the uterine cavity; otherwise category 1.

<sup>ad</sup> Severe obesity may make diaphragm or cap placement difficult.

— Condition not listed by WHO for this method; does not affect eligibility for method use.

### WHO Medical Eligibility Criteria for Starting Contraceptive Methods (continued)

CONDITION	Combined OCs	Progestin-Only OCs	DMPA/NET-EN	Norplant Implants	Female Sterilization	Vasectomy	Condoms	TCu-380A IUD	Spermicides	Diaphragm, Cervical Cap	Fertility Awareness-Based Methods	Lactational Amenorrhea Method (LAM)
<b>Thyroid</b>												
Simple goiter	1	1	1	1	Accept	—	1	1	1	1	1	1
Hyperthyroid	1	1	1	1	Refer	—	1	1	1	1	<sup>b,t</sup>	1
Hypothyroid	1	1	1	1	Caution	—	1	1	1	1	<sup>b,t</sup>	<sup>h</sup>
<b>Thalassemia (inherited anemia)</b>	2	1	1	1	Caution	—	1	2	1	1	1	1
<b>Trophoblast disease</b>												
Benign	1	1	1	1	Accept	—	1	3	1	1	1	1
Malignant	1	1	1	1	Delay	—	<sup>1</sup>	4	<sup>1</sup>	<sup>1</sup>	<sup>1</sup>	<sup>h</sup>
<b>Sickle cell disease</b>	2	1	1	1	Caution	Accept	<sup>1</sup>	2	<sup>1</sup>	<sup>1</sup>	<sup>1</sup>	1
<b>Coagulation (blood clotting) disorders</b>	—	—	—	—	Refer	Refer	—	—	—	—	—	—
<b>Iron deficiency anemia</b>												
Hemoglobin 7 g/dl–10 g/dl	1	1	1	1	Caution	—	1	2	1	1	1	1
Hemoglobin less than 7 g/dl	1	1	1	1	Delay	—	1	2	1	1	1	1
<b>Epilepsy</b>	1	1	1	1	Caution	—	1	1	1	1	1	<sup>h</sup>
<b>Schistosomiasis</b>												
Without complications	1	1	1	1	Accept	—	1	1	1	1	1	1
With fibrosis of the liver	1	1	1	1	Caution	—	<sup>1</sup>	1	<sup>1</sup>	<sup>1</sup>	<sup>1</sup> <sup>b,t</sup>	<sup>h</sup>
With severe fibrosis of the liver	4	3	3	3	Refer	—	<sup>1</sup>	1	<sup>1</sup>	<sup>1</sup>	<sup>1</sup> <sup>b,t</sup>	<sup>h</sup>
<b>Malaria</b>	1	1	1	1	Accept	—	1	1	1	1	1	1

<sup>b</sup> This condition may affect ovarian function and/or change fertility signs and symptoms and/or make methods difficult to learn and use.

<sup>1</sup> Higher typical failure rates of this method may expose the user to an unacceptable risk of dangerous unintended pregnancy.

<sup>h</sup> Breastfeeding may not be recommended with drugs used to treat this condition.

<sup>t</sup> Condition does not affect vaginal bleeding patterns; calendar method can be used.

— Condition not listed by WHO for this method; does not affect eligibility for method use.

<b>Drug interactions</b>												
Taking the antibiotics rifampin (rifampicine) or griseofulvin	3	3	2	3	Caution	—	1	1	1	1	1	—
Taking other antibiotics <sup>a8</sup>	1	1	1	1	Accept	—	1	1	1	1	1	—
Taking anticonvulsants for epilepsy except valproic acid <sup>a1</sup>	3	3	2	3	Caution	—	1	1	1	1	1	—
<b>Allergy to latex</b>												
	—	—	—	—	—	—	3 <sup>a9</sup>	—	1	3	—	—
<b>Other drug use</b>												
Mood-altering drugs, lithium therapy, tricyclic antidepressants, or anti-anxiety therapies	—	—	—	—	—	—	—	—	—	—	1 <sup>b,1</sup>	ah
<b>Parity</b>												
Nulliparous (has no children)	1	1	1	1	Accept <sup>a1</sup>	Accept <sup>a1</sup>	1	2	1	1	1	—
Parous (has children)	1	1	1	1	Accept	Accept	1	1	1	2	1	1
<b>Severe dysmenorrhea (pain during menstruation)</b>												
	1	1	1	1	Accept	—	1	2	1	1	1	— <sup>a1</sup>
<b>Tuberculosis</b>												
Nonpelvic	1	1	1	1	Accept	—	1 <sup>f</sup>	1	1 <sup>f</sup>	1 <sup>f</sup>	1 <sup>f</sup>	1 <sup>ak</sup>
Pelvic	1	1	1	1	Refer	—	1 <sup>f</sup>	4	1 <sup>f</sup>	1 <sup>f</sup>	1 <sup>f</sup>	1 <sup>ak</sup>
<b>Endometriosis</b>												
	1	1	1	1	Refer	—	1	2	1	1	1	1
<b>Anatomical abnormalities</b>												
Distorted uterine cavity	—	—	—	—	—	—	—	4 <sup>a1</sup>	—	— <sup>am</sup>	—	—
Other abnormalities not distorting the uterine cavity and not interfering with IUD insertion <sup>a1</sup>	—	—	—	—	—	—	—	2	—	—	—	—
<b>Past toxic shock syndrome</b>												
	—	—	—	—	—	—	1	—	1	3	—	—
<b>Breastfeeding</b>												
Less than 6 weeks after childbirth	4	3	3	3	Accept	—	1	—	1	—	1 <sup>b</sup>	1
6 weeks to 6 months after childbirth (fully or almost fully breastfeeding)	3	1	1	1	Accept	—	1	—	1	1	1 <sup>b</sup>	1
6 months or more after childbirth	2	1	1	1	Accept	—	1	—	1	1	1 <sup>b</sup>	—

<sup>a8</sup> Antibiotics other than rifampin and griseofulvin.

<sup>a1</sup> Barbiturates, phenytoin, carbamazepine, primidone.

<sup>a9</sup> Allergy to latex is not a problem with plastic condoms, if available.

<sup>b</sup> In order to protect infant health, breastfeeding is not recommended.

<sup>a1</sup> Counseling requires special care to ensure an informed choice is made.

<sup>a1</sup> Menstruation indicates need for another contraceptive method.

<sup>ak</sup> Decision to breastfeed should take into consideration the risks and benefits to the infant.

<sup>a1</sup> Any abnormality distorting the uterine cavity so that proper IUD insertion is not possible.

<sup>am</sup> Diaphragm cannot be used in certain cases of prolapse; cap not acceptable for clients with severely distorted cervical anatomy.

<sup>a1</sup> Including uterine fibroids, cervical stenosis, or cervical lacerations.

— Condition not listed by WHO for this method; does not affect eligibility for method use.

## WHO Medical Eligibility Criteria for Starting Contraceptive Methods (continued)

CONDITION	Combined OCs	Progestin-Only OCs	DMPA/NET EN	Norplant Implants	Female Sterilization*	Vasectomy**	Condoms	TCu-380A IUD†	Spermicides	Diaphragm, Cervical Cap	Fertility Awareness-Based Methods	Lactational Amenorrhea Method (LAM)††
<b>Postpartum (nonbreastfeeding women)</b>												
Less than 21 days after childbirth	3	1	1	1	*	**	1	†	1	—	1 <sup>b</sup>	—
21 days or more after childbirth	1	1	1	1	*	**	1	†	1	— <sup>30</sup>	1 <sup>b</sup>	—
<b>Postabortion</b>												
First trimester	1	1	1	1	—	—	1	1	1	1	1 <sup>b</sup>	—
Second trimester	1	1	1	1	—	—	1	2	1	1 <sup>30</sup>	1 <sup>b</sup>	—
After septic abortion <sup>30</sup>	1	1	1	1	—	—	1	4	1	1	1 <sup>b</sup>	—

\*Additional conditions related to female sterilization:  
*Conditions that require delay:* abdominal skin infection; acute bronchitis or pneumonia; emergency surgery; surgery for an infectious condition; systemic infection or severe gastroenteritis.  
*Conditions that require referral to a special center:* chronic asthma, bronchitis, emphysema, or lung infection; fixed uterus due to previous surgery or infection; abdominal wall or umbilical hernia.  
*Conditions that require caution:* diaphragmatic hernia; kidney disease; elective surgery; severe nutritional deficiencies.  
*Conditions that pose no special requirements:* cesarian section.

*Postpartum sterilization conditions that require delay:* 7 days to 42 days after childbirth; severe preeclampsia/eclampsia; prolonged rupture of membranes (24 hours or more); severe hemorrhage; fever during or right after delivery; sepsis; severe trauma to the genital tract (cervical or vaginal tear at delivery); uterine rupture or perforation.  
*Postpartum sterilization conditions that pose no special requirements:* less than 7 days after childbirth; more than 42 days after childbirth; mild preeclampsia.  
*Postabortion sterilization conditions that require delay:* from 7 days after childbirth until uterine involution is complete (usually about 42 days after childbirth); severe sepsis or fever; severe hemorrhage; severe trauma to the genital tract; uterine perforation; acute hematometra (excess blood in the uterus).

\*\*Additional conditions related to vasectomy:  
*Conditions that require delay:* scrotal skin infection; active STD; balanitis; epididymitis or orchitis; systemic infection or severe gastroenteritis; filariasis or elephantiasis; intrascrotal mass.  
*Condition that requires referral to a special center:* inguinal hernia.  
*Conditions that require caution:* previous scrotal surgery or injury; large varicocele, large hydrocele; cryptorchidism. (In some circumstances, cryptorchidism may require referral.)

†Additional conditions related to TCu-380A IUD, postpartum insertion (breastfeeding or nonbreastfeeding):  
*Condition that represents an unacceptable health risk (WHO 4):* puerperal sepsis (genital tract infection during the first 42 days after childbirth).  
*Condition that requires a doctor or nurse to make a clinical judgement that the client can safely use an IUD (WHO 3):* 48 hours to 4 weeks postpartum.  
*Condition for which advantages of IUD use generally outweigh theoretical or proven risks (WHO 2):* less than 48 hours after childbirth.  
*Condition that requires no restriction:* More than 4 weeks after childbirth.

†† Additional conditions related to LAM:  
*Conditions that represent an unacceptable health risk to the infant:* use of reserpine, ergotamine, antimetabolites, cyclosporine, cortisone, bromocriptine, radioactive drugs, lithium, or anticoagulants.  
*Conditions for which LAM has no effect on the condition, but the condition may prevent breastfeeding:* sore nipples; mastitis (breast inflammation); congenital deformity of infant's mouth, jaw or palate; infant small for age, premature birth, or neonatal intensive care; past breast surgery; certain infant metabolic disorders.  
*Condition that requires no restrictions (WHO 1):* breast engorgement.

<sup>b</sup> This condition may affect ovarian function and/or change fertility signs and symptoms and/or make methods difficult to learn and use.

<sup>30</sup> Can start diaphragm use 6 weeks after childbirth.

<sup>30</sup> Can start diaphragm use 6 weeks after second-trimester abortion.

<sup>30</sup> That is, immediately after abortion involving genital tract infection.

— Condition not listed by WHO for this method; does not affect eligibility for method use.