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**Recommendations for
Updating Selected Practices
in Contraceptive Use:**

Results of a Technical Meeting

Volume I:

*Combined Oral Contraceptives
Progestin-Only Injectables
NORPLANT® Implants
Copper-Bearing Intrauterine Devices*

November 1994

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Volume I: Combined Oral Contraceptives

Progestin-Only Injectables

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Copper-Bearing Intrauterine Devices

**Produced by the Technical Guidance Working Group
(formerly the Interagency Guidelines Working Group)**

Secretariat:

Marcia A. Angle, INTRAH (Program for International Training in Health),
University of North Carolina at Chapel Hill

Douglas H. Huber, Pathfinder International

James D. Shelton, United States Agency for International Development

Roberto Rivera, Family Health International

Editors:

Kathryn M. Curtis and Patricia L. Bright, INTRAH and
The Department of Epidemiology

University of North Carolina at Chapel Hill

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I. Introduction

A. Purpose of the Document

In November 1992, the Interagency Guidelines Working Group (now known as the Technical Guidance Working Group) convened a meeting of representatives of many of the Cooperating Agencies of the United States Agency for International Development (USAID). This document is the product of that meeting. Initial recommendations were drafted at this technical meeting and subsequently reviewed and augmented by numerous international experts in family planning. Synthesis and incorporation of the reviewers' comments were accomplished by a subgroup (see Appendix D for complete lists of participants of the review process and participants of the subgroup which incorporated the reviewers' comments). Background research, editing and production of the text was the responsibility of the INTRAH Program (see Appendix E).

This document on procedural steps for administration of selected hormonal methods and intrauterine devices (IUDs) is intended to provide **guidance** for persons and organizations who are developing, updating or revising family planning procedural and service guidelines. The document should not be viewed as constituting actual service delivery guidelines. It supplies updated information about specific procedural steps for the administration of combined oral contraceptives, progestin-only injectables, NORPLANT® Implants, and intrauterine devices. For each recommendation, the scientific rationale is given and the supporting research is cited.

These recommendations for procedures for contraceptive use have been developed to update selected procedural guidelines and to make them consistent with current clinical and epidemiological evidence. The intention underlying this document is that, by clarifying and providing the underlying scientific rationale for procedures, both access to and quality of women's reproductive health services can be improved through use of existing resources.

B. Background

The Technical Guidance Working Group (TGWG) was established with USAID in August 1992, to provide leadership and guidance on updating selected procedures and practices in family planning service guidelines. The Working Group is attempting to address two converging problems:

- 1) existing family planning procedural guidelines are frequently inconsistent and sometimes in direct conflict with one another, and can result in confusion or perpetuation of outdated and unnecessarily restrictive procedures, and

- 2) in many instances, existing guidelines which are not scientifically current actually limit access to services.

This document, "Volume I: Combined Oral Contraceptives, Progestin-Only Injectables, NORPLANT® Implants, and Copper-Bearing Intrauterine Devices," is the first product of the Technical Guidance Working Group. Future volumes are planned to cover other technical issues related to quality of care and to other contraceptive methods.

C. Three Key Assumptions

It is important to note **three major assumptions** behind the guidance given in this document:

- 1) Many of the questions deal with initiation and re-administration of each method; **it is assumed that appropriate medical eligibility criteria for use of each method have been applied.** The World Health Organization (WHO) is compiling a list of medical eligibility guidance for each contraceptive method, as a result of the March 7-10, 1994 WHO Meeting on Improving Access to Quality of Care in Family Planning: Medical Criteria for Selected Methods of Contraception. This document has used the most recently available draft of the WHO list of medical eligibility criteria*.
- 2) **All guidance in this document assumes that the family planning client has made an informed choice to use a particular method.** Choice is of paramount importance in all decision-making about contraceptive use. Guidelines for informed choice are given in Appendix C.
- 3) All references in this document to "appropriately trained" and "properly trained" service providers assume the provider is adequately trained to deliver the specific contraceptive method according to **relevant national or institutional standards regarding the level of training required to achieve competency for each cadre of service provider.**

* World Health Organization. *Improving Access to Quality Care in Family Planning; Eligibility Criteria for Initiating Use of Selected Methods of Contraception; Combined Oral Contraceptives, Progestogen Only Contraceptives, DMPA, Norplant and Copper IUDs.* Revised Draft August 8, 1994. Geneva, WHO, 1994.

D. Content

The document opens with a general recommendation concerning the importance of addressing sexually transmitted diseases (STDs) within family planning care. Information in the following sections summarizes expert opinion on selected procedural questions in the delivery of combined oral contraceptives, progestin-only injectables, NORPLANT® Implants and IUDs. For each question, the tables include:

1. recommendations, and
2. some of the scientific rationale justifying the recommendations, with citations of the relevant literature.

The last tables for each method address selected process issues. The information in the tables indicates which of the following procedures fall into the following classes for the contraceptive method, and provides a rationale and citations for the classification. (The list of procedures is illustrative of procedures commonly used 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. Specific counseling points

Four classes were established to differentiate procedures:

- Class A** = essential and mandatory in all circumstances, for safe use of the contraceptive method
- Class B** = medically/epidemiologically rational in some circumstances to optimize the safe 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 related to safe use of the contraceptive method
- Class D** = not only unnecessary, but irrelevant to the safe use of the contraceptive method

Appendix A contains information on "How to Be Reasonably Sure the Woman Is Not Pregnant," which is applicable to all of the contraceptive methods.

Appendix B contains a list of abbreviations.

Appendix C contains a report of the Cooperating Agencies Task Force on Informed Choice. This report lists recommendations regarding the most important actions needed to promote informed choice in developing countries.

Appendix D contains a list of organizations and participating agencies with which the invited reviewers are affiliated, as well as lists of the participants who attended the November 1992 meeting of the Guidelines Working Group and/or who reviewed subsequent drafts of this document.

Appendix E contains acknowledgments of special contributions to the production of this document, including the important role of the International Planned Parenthood Federation (IPPF) 1992 publication, *Medical and Service Delivery Guidelines for Family Planning*.

E. Limitations of the Scope of This Document

The goal of this document was NOT to produce a set of "generic" guidelines, but rather to produce a reference for those service providers involved in developing and updating family planning service delivery guidelines. Although inconsistencies are found in current guidelines' treatment of contraceptive methods and of such issues as eligibility criteria, contraindications, provider bias and quality of care, this document is limited to those **technical** aspects of administering three hormonal methods and IUDs, related to outdated, unnecessarily restrictive or overmedicalized practices. The participants of the November 1992 meeting did not attempt to reach consensus on policy, program, social, economic and other types of service barriers, nor on all quality issues, nor on technical aspects of methods other than hormonals and IUDs. Reviewers of the document have noted the importance to clients of the scope, affordability and quality of family planning services, as well as other determinants of clients' use of services, such as service and method convenience and provider competence and responsiveness. These concerns merit attention by policymakers, program directors and client groups, but this volume has not attempted to deal comprehensively with these concerns.

These recommendations are part of USAID's broader effort to improve quality and access in family planning programs and so represent only one element of USAID's efforts in quality of care. Other USAID supported activities address training, communication research, policy and service delivery initiatives necessary to improve the quality of, and access to, family planning and reproductive health. Other documents reflecting USAID's recommendations on various aspects of quality of care in family planning and reproductive health are planned.

II. Prevention of Sexually Transmitted Diseases (STDs), in the Context of Family Planning Services

Ideally, family planning should be seen as one component of a package of interventions aimed at maintaining reproductive health. The integration of client education on STD prevention (including HIV) into this package of services enhances reproductive health care. Family planning programs should address the prevention of STDs. When providing non-barrier methods, men and women should be informed that such methods will not provide protection against sexually transmitted diseases.

Counseling for STD Prevention

Providers should be trained in culturally appropriate counseling techniques and should routinely ask questions to determine the client's risk status¹. In areas of high STD prevalence, it is particularly important to ask clients about STD risk (using a few simple history questions) and then to provide appropriate information on STD prevention, and explain any relationship between STD risk and available contraceptive methods.

Condoms for STD Prevention

For clients at risk of STDs, condoms (when used correctly) are potentially the most effective and widely available method of preventing STD transmission. Counseling on STD prevention and condom use should be incorporated into family planning services, when possible and as appropriate, regardless of contraceptive method or client age. When resources are limited and condom distribution must be prioritized to those at highest risk, information on STD prevention should still be offered to all clients, as appropriate.

For More Information

Those responsible for supervising or providing family planning services may wish to consult the following documents for information on STD prevention in the family planning context:

- 1) Controlling Sexually Transmitted Diseases. *Population Reports*, Series L, #9, June 1993.
- 2) Condoms – Now More Than Ever. *Population Reports*, Series H, #8, September 1990.

Population Reports are free in any quantity to persons in developing countries and may be purchased for a minimal fee by persons in developed countries. To obtain *Population Reports* write to:

Population Information Program
The John Hopkins School of Hygiene and Public Health
111 Market Place
Baltimore, Maryland 21202, USA.

1 World Health Organization, Family Planning and Population, Division of Family Health. *Providing An Appropriate Contraceptive Method Choice: What Health Workers Need to Know*. Geneva, WHO, 1993, p 41.

III. Combined Oral Contraceptives

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III. Combined Oral Contraceptives*

This section outlines recommendations on the following selected procedural questions for combined oral contraceptives (COCs):

1. When is the best time to **start COCs**?
2. When can COCs be started **postpartum**?
3. May COCs be started **immediately post-abortion**?
4. **How many COC cycles** should be given at the first visit for a new user? At subsequent visits?
5. Is a "**rest period**" advisable for women on COCs after some period of use?
6. Is there a **minimum age** to receive COCs? A **maximum**?
7. Are **back-up methods** advisable in the following situations:
 - a) If the client is taking antibiotics?
 - b) If the client is taking anticonvulsants (except valproic acid)?
 - c) If it is the client's first cycle of COCs?
 - d) If the client has missed pills?
 - e) If the client has diarrhea and/or vomiting?
 - f) If the client is taking anti-malarial medication?
8. Does a client **need to visit a clinic or see a doctor** to receive COCs?

* These recommendations presume the COCs used will contain no more than 35 micrograms of ethinyl estradiol (or similar estrogen).

Q.1. When is the best time to start COCs?

Recommendations	Rationales
<p>a) COCs may be started any time you can be reasonably sure that the woman is not pregnant (see Appendix A), for example, during the 7 days which begin with the onset of menses (days 1 through 7 of the menstrual cycle).</p>	<p>a) Starting within the first 7 days lowers the possibility of beginning the pill while she is already pregnant (although there is the possibility that the client is pregnant and implantation bleeding has been mistaken for menses).</p>
<p>(See Q.2. for postpartum initiation and Q.3. for post-abortion initiation.)</p>	<ol style="list-style-type: none"> 1) Dixon GW, Schlesselman JJ, Ory HW, Blye RP. Ethinyl estradiol and conjugated estrogens as postcoital contraceptives. <i>Journal of the American Medical Association</i> 1980;244:1336-1339. 2) Gray RH, Pardthaisong T, McDaniel EB, Doyle P. The timing of the first injection of Depo Provera. <i>IPPF Medical Bulletin</i> 1975;9(3):3-4. 3) Schiphorst LE, Collins WP, Roystar JP. An estrogen test to determine the times of potential fertility in women. <i>Fertility and Sterility</i> 1985;44:328-334.
<p>b) For a woman having menstrual cycles, no back-up method is needed if she is in the first 7 days of her menstrual cycle and is still menstruating. If she is in the first 7 days of her cycle, but is not menstruating, some programs may recommend use of a back-up method for 1 week.</p>	<p>b) A back-up method is NOT needed if the first package of pills is started while the woman is menstruating because the risk of conception is virtually nil.</p> <ul style="list-style-type: none"> • After day 5 of the cycle, the risk of pregnancy begins to rise. <ol style="list-style-type: none"> 1) Smith SK, Kirkman RJE, 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):513-522.
<p>COCs may be started anytime you can be reasonably sure the woman is not pregnant (see Appendix A). However, if COCs are started after day 7 of a regular cycle, the woman should also be counseled that:</p> <ul style="list-style-type: none"> • her regular bleeding pattern may be altered, and • a back-up method (or abstinence) should be used for 7 days. 	<p>Some programs might recommend a back-up method for women who are not menstruating at the time of COC initiation because there is a very slight risk of conception from unprotected intercourse on day 7 of the cycle.</p> <p>When back-up (or abstinence) is needed, it must be used for 7 days because 7 days of exposure to COCs are required to suppress follicular development.</p>
<p>(For information concerning need for back-up method see Q.7.)</p>	<ol style="list-style-type: none"> 1) Molloy BG, Coulson KA, Lee JM, Watters JK. "Missed pill" conception: fact or fiction? <i>British Medical Journal</i> 1985;290:1474-1475.
<p>c) If the client is using the 28-day pill packet, she should start a new packet the day after she finishes the previous packet (without a break). If the client is using the 21-day pill packet, she should skip 7 days before starting a new packet. If the pills are taken correctly, the client will always begin a new packet on the same day of the week.</p>	<p>c) The longer the pill-free interval, the higher the risk of ovulation (e.g., a 10-day pill free interval confers a 10% risk of ovulation).</p> <ol style="list-style-type: none"> 1) Landgren BM, Emiczky CS. The effect on follicular growth and luteal function of "missing the pill." <i>Contraception</i> 1991;43(2):149-159. 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.

Q.2. When can COCs be started postpartum?

Recommendations	Rationales
<p>For Breastfeeding Women: (These restrictions do not apply to women who are only doing token, i.e., minimal, breastfeeding.)</p>	
<p>a) COCs should not be used in the first 6 weeks postpartum. COCs are considered by many experts to be the method of LAST choice during any state of lactation, especially in the first 6 weeks to 6 months.</p>	<p>a-b) Even low dose (30 to 35 mcg) COCs decrease breastmilk production.</p>
<p>b) After 6 to 8 weeks postpartum, breastfeeding women desiring hormonal contraception should be encouraged to use progestin-only pills (POPs) or injectables or NORPLANT® Implants. (Before 6 to 8 weeks postpartum, there is no risk of conception for a fully or nearly fully breastfeeding woman - see Appendix A.)</p>	<p>1) WHO Task Force on Oral Contraceptives. Effects of hormonal contraceptives on milk volume and infant growth. <i>Contraception</i> 1984;30(6):505-521.</p>
<p>c) If COCs remain the method of choice, but the woman chooses to rely on the Lactational Amenorrhea Method (LAM) initially, start COCs when her menses return,** or when the woman is no longer fully or nearly fully breastfeeding or at 6 months postpartum, whichever comes first. COC packets may be given to the woman before this time to ensure that she is able to start the method when she needs to.</p>	<p>c) For fully breastfeeding women, there is no known advantage to initiating COCs during LAM or while the LAM criteria apply.</p>
<p>** In breastfeeding women, bleeding in the first 56 days (8 weeks) postpartum is NOT considered "menstrual" bleeding, because it is not preceded by ovulation.</p>	<p>1) Kennedy KI. Breastfeeding and the double protection dilemma. Family Health International, September 1991. 2) Labbok M, Cooney K, Coly S. Guidelines: Breastfeeding, Family Planning, and the Lactational Amenorrhea Method - LAM. Washington, DC: Institute for Reproductive Health, 1994.</p>
<p>d) If she does not want to rely on LAM but is breastfeeding, she should be advised to choose a non-estrogenic method. If she still makes an informed choice to use COCs, they can be started anytime after the first 8 to 12 weeks postpartum if she is still amenorrheic, or whenever the service provider can be reasonably sure that the woman is not pregnant (see Appendix A).</p>	<p>In fact, initiating COCs before they are necessary may be a disadvantage because COCs have a detrimental effect on breastmilk volume and composition, which may affect the infant's health and growth.</p>
	<p>1) WHO Task Force on Oral Contraceptives. Effects of hormonal contraceptives on milk volume and infant growth. <i>Contraception</i> 1984;30(6):505-521. 2) WHO Task Force on Oral Contraceptives. Special Programme of Research, Development, and Research Training in Human Reproduction. Effects of hormonal contraceptives on breast milk composition and infant growth. <i>Studies in Family Planning</i> 1988;19(6):361-369.</p>
	<p>d) Even low dose (30 to 35 mcg) COCs decrease breastmilk production. Waiting at least 8 to 12 weeks postpartum permits breastfeeding to be better established. Whether exposure of the neonate (in the first 8 weeks) to exogenous estrogens and progestins may, in theory, affect neonatal growth and development is a question under study.</p>

(Continued on next page)

Q.2. Postpartum (continued)

Recommendations	Rationales
<p>For Non-Breastfeeding Women:</p> <p>a) If not breastfeeding, a woman can begin COCs after the second to third postpartum week.</p>	<p>a) Blood coagulation and fibrinolysis are essentially normalized by 3 weeks postpartum (and are close to normal at 2 weeks postpartum).</p> <p>1) Dahlman T, Hellgren M, Blombäck M. Changes in blood coagulation and fibrinolysis in the normal puerperium. <i>Gynecologic and Obstetric Investigation</i> 1985;20(1):37-44.</p>

Q.3. May COCs be started immediately post-abortion?

Recommendations	Rationales
<p>a) Yes, COCs are appropriate for use immediately post-abortion (spontaneous or induced), in either the first or second trimester, and should be initiated within the first seven (7) days post-abortion (or anytime you can be reasonably sure the woman is not pregnant, see Appendix A).</p> <p>b) If a client has a history or current indication of excessive clotting (coagulopathy), COCs should not be recommended.</p>	<p>a) Ovulation returns almost immediately post-abortion (spontaneous or induced): within 2 weeks for first trimester abortion and within 4 weeks for second trimester abortion. Within 6 weeks of abortion, 75% of women have ovulated.</p> <p>1) Lähteenmaki P, Ylöstalo P, Sipinen S, Toivonen J, Ruusuvaara L, Pikkola P, Nilsson CG, Luukkainen T. Return of ovulation after abortion and after discontinuation of oral contraceptives. <i>Fertility and Sterility</i> 1980;34(3):246-249.</p> <p>Immediate use of COCs post-abortion (spontaneous or induced) does not affect return to fertility following discontinuation of COCs.</p> <p>1) Lähteenmaki P. Oral contraception and immediate postabortion pituitary-ovarian function. <i>Acta Obstetrica et Gynecologica</i> 1978;76(Suppl):9-43.</p> <p>b) COCs may be safely started within the first week post-abortion (spontaneous or induced). Hypercoagulability of pregnancy probably does not become clinically significant until the third trimester. However, some experts recommend starting COCs exactly one week post-abortion, as there is a suggestion of a slight increase in coagulation factors measurable in the first few days after first trimester abortion, in women initiating COCs immediately post-abortion. If started later than one week, COCs may not be immediately effective because the ovary resumes follicular development as soon as one week after first trimester (spontaneous or induced) abortion.</p> <p>1) Lähteenmaki P. Postabortal contraception. <i>Annals of Medicine</i> 1993;25:185-189.</p> <p>2) Lähteenmaki P, Toivonen J, Rasi V, Luukkainen T, Myllyä G. Coagulation factors in women using oral contraceptives or intrauterine contraceptive devices immediately after abortion. <i>American Journal of Obstetrics and Gynecology</i> 1981;141:175-179.</p> <p>Incomplete abortion may also result in a condition of excessive blood clotting (disseminated intravascular coagulation), in which estrogens should be avoided.</p>

Q.4. How many COC cycles should be given at the first visit for a new user? At subsequent visits?

Recommendations	Rationales
<p>a) At first visit and each follow-up visit, give as many as 13 cycles, although only 3 or 4 may be programmatically reasonable. The greatest need is to guarantee continuous, ready access.</p> <p>b) Encourage a 3-month follow-up visit for counseling with initial acceptors 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>c) The number of cycles dispensed may be limited for programmatic, logistic or financial reasons, including client's ability to pay in a cost recovery system.</p> <p>d) The re-supply system should be flexible, so that the client can obtain pills easily in the amount and at the time she requires.</p> <p>e) There is no compelling medical reason for a routine return visit before one year, but clients should be encouraged to return at any time with concerns, problems and questions.</p>	<p>a-e) While some providers suspect that clients who receive multiple pill cycles may "share" these with friends, this is likely to be as safe as over-the-counter distribution methods.</p> <p>Some women (and/or some programs) may be able to afford to buy (dispense) many pill cycles at one visit.</p>

Q.5. Is a "rest period" advisable for women on COCs after some period of use?

Recommendations	Rationales
a) No, a "rest period" is not necessary. A woman may use COCs for as long as she is at risk of pregnancy. b) Stopping COCs 2 weeks before major elective surgery or after serious accidents that necessitate immobilization of the legs and resuming COCs once the woman is mobile is <i>optimal</i> , if she has a reliable alternative method.	a) A rest period would disrupt the woman's preferred and successful method of contraception. b) Due to the fact that estrogen may slightly increase the risk of post-operative thrombosis, it may be reasonable to stop COCs for 2 weeks before major elective surgery and resume COCs once the woman is mobile, before she resumes sexual activity. However, this small risk must be weighed against the risk of pregnancy and whether the client has a reliable alternative method. 1) Quinn DA, Thompson BR, Terrin ML, Thrall JH, Athanasoulis CA, McKusick KA, Stein PF, Hates CA. A prospective investigation of pulmonary embolism in women and men. <i>Journal of the American Medical Association</i> 1992;268(13):1689-1696.

Q.6. Is there a minimum age to receive COCs? A maximum?

Recommendations	Rationales
<p>COCs may be used at any age at which the woman is at risk of pregnancy (e.g., past menarche and through menopause).</p>	<p>a) Cardiovascular risks from COC use are minimal in healthy, non-smoking, older women.</p>
<p>a) Women over age 40 can take COCs, provided other risk factors have been considered (e.g., smoking, high blood pressure, diabetes).</p>	<p>1) Speroff L, Glass RH, Kase NG. <i>Clinical Gynecologic Endocrinology and Infertility</i>, 4th edition. Baltimore, Williams & Wilkins, 1989, p 487. 2) Guillebaud J. Contraception for women over 35 years of age. <i>British Journal of Family Planning</i> 1992;17:115-118.</p>
<p>b) Use of COCs does not compromise future fertility.</p>	<p>b) On average, the return to fertility after discontinuing COCs is about 2 months longer than for non-hormonal methods. The risk of amenorrhea after discontinuing COCs is small and more common in women who had irregular menses prior to COC use. Rather than causing "post-pill amenorrhea," COCs mask the irregular pattern by inducing cyclic withdrawal bleeding. Women who have irregular menses are more likely to develop secondary amenorrhea whether they take COCs or not.</p>
	<p>1) Bracken MB, Hellenbrand KG, Holford TR. Conception delay after oral contraceptive use: The effect of estrogen dose. <i>Fertility and Sterility</i> 1990;58:21-7. 2) Speroff L, Glass RH, Kase NG. <i>Clinical Gynecologic Endocrinology and Infertility</i>, 4th edition. Baltimore, Williams & Wilkins, 1989, p 481. 3) American College of Obstetricians and Gynecologists. Safety of oral contraceptives for teenagers. <i>International Journal of Gynaecology and Obstetrics</i> 1992;37:309-312. 4) Jacobs HS, Knuth UA, Hull MGR, Franks S. Post-"pill" amenorrhea – Cause or coincidence? <i>British Medical Journal</i> 1977;2:940-942.</p>

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

Recommendations	Rationales
<p>a) If the client is taking antibiotics? No — except rifampin or griseofulvin (an antifungal medication).</p>	<p>a) Rifampin, rifampicin, and griseofulvin require use of a back-up method (or increased COC dose if back-up is not possible) to compensate for hepatic micro-enzyme induction. Hepatic micro-enzyme induction by rifampin lasts for 4 weeks for short-term use and for 8 weeks for long-term use. Although anecdotal reports of failure to prevent pregnancy exist for other antibiotics, epidemiologic evidence suggests that antibiotics (except rifampin and griseofulvin) do not require a back-up method.</p>
<p>b) If the client is taking anticonvulsants (except valproic acid)? Use of one of the following may be necessary:</p> <ul style="list-style-type: none"> • switch to Depo Provera® or an effective non-hormonal method; • a back-up method (for short-term anti-convulsant use); • higher dose COCs (i.e., 50 mcg ethinyl estradiol (EE), or two 30 to 35 mcg EE COCs per day for more efficient contraception and/or to produce regular menses without breakthrough bleeding). 	<p>b) Anticonvulsants include phenobarbital/phenobarbitone, primidone, carbamazepine, and ethosuximide. Anticonvulsants, except valproic acid, significantly increase liver metabolism of estrogen and progestins, which decreases the effectiveness of COCs.</p> <p>Taking two 30 to 35 mcg COCs per day will provide adequate estrogen to compensate for increased metabolism. Levonorgestrel levels are also reduced by phenytoin (and presumably other anti-epileptics). Therefore, doubling up on COCs which contain Levonorgestrel is particularly important.</p>
<p>c) If it is the client's first cycle of COCs? If she is in the first 7 days of her cycle, but is not menstruating, some programs may recommend use of a back-up method for 1 week. COCs may be started anytime you can be reasonably sure the woman is not pregnant (see Appendix A). However, if COCs are started after day 7 of a regular cycle, the woman should also be counseled that her regular bleeding pattern may be altered and that additional contraceptive protection (or abstinence) is needed for the first 7 days. Dispensing a back-up method, however, especially condoms, is a good idea in case of failures of correct use, as well as for STD protection when needed.</p>	<p>c) The COC effect on cervical mucus is not as strong as the effect of progestin-only methods. COCs require 7 days to suppress follicular development.</p>

(Continued on next page)

Q.7. Back-up methods (continued)

Recommendations	Rationales
<p>d) If the client has missed pills? Back-up is needed only if 2 or more pills are missed, and back-up must be used until the client has taken 7 active pills (one active pill per day for 7 days).</p>	<p>d) If two or more pills are missed, a back-up must be used until the client has taken 7 active pills. Missed pills may occur at the beginning of the cycle (extending the pill-free interval from 7 to 9 days and perhaps allowing escape ovulation to occur).</p> <ol style="list-style-type: none">1) 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;6:33-40.2) Family Health International. <i>New simplified OC instructions</i>. April 1992.
<p>e) If the client has diarrhea and/or vomiting? Back-up may be advisable whenever vomiting or severe diarrhea occurs within one hour after taking the tablet. If vomiting or severe diarrhea persists for more than 24 hours (then two pills will have been missed), a back-up method will be needed (until client has taken one active pill per day for 7 days).</p>	<p>Seven days of exposure to COCs are required to suppress follicular development.</p> <ol style="list-style-type: none">1) Molloy BG, Coulson KA, Lee JM, Watters JK. "Missed pill" conception: fact or fiction? <i>British Medical Journal</i> 1985;290:1474-1475.2) Guillebaud J. The forgotten pill – and the paramount importance of the pill free week. <i>British Journal of Family Planning</i> 1987;12:35-43.
<p>f) If the client is taking anti-malarial medication? No back-up is needed.</p>	<p>e) Acute vomiting and severe diarrhea may interfere with the effectiveness of the pill. In these cases, a back-up method is reasonable.</p> <ol style="list-style-type: none">1) Orme M, Back DJ. Oral contraceptive steroids – Pharmacological issues of interest to the prescribing physician. <i>Advances in Contraception</i> 1991;7:325-331.2) Orme M, Back D, Breckenridge A. Clinical pharmacokinetics of oral contraceptive steroids. <i>Clinical Pharmacokinetics</i> 1983;8:95-136. <p>f) Anti-malarials studied to date have not been found to decrease the efficacy of COCs. Chloroquine and primaquine have not demonstrated an effect on plasma COC hormonal levels or on ovulation inhibition. Tetracycline (which is used at low dosage in combination with quinine) has not been found to compromise the effect of COCs.</p> <ol style="list-style-type: none">1) Back DJ, Breckenridge AM, Grimer S, Orme M, Purba H. Pharmacokinetics of oral contraceptive steroids following the administration of the anti-malarial drugs primaquine and chloroquine. <i>Contraception</i> 1984;30(3):289-295.2) Gupta KC, Joshi JV, Desai NK, Sankolli GM, Chowdhary VN, Joshi UM, Chitalange S, Satoskar RS. Kinetics of chloroquine and contraceptive steroids in oral contraceptive users during concurrent chloroquine prophylaxis. <i>Indian Journal of Medical Research</i> 1984;80:658-662.3) Murphy A, Zacur H, Charache P, Burkman R. The effect of tetracycline on levels of oral contraceptives. <i>American Journal of Obstetrics and Gynecology</i> 1991;164:28-32.4) D'Arcy PF. Drug interaction and reaction: Update: Drug interactions with oral contraceptives. <i>Drug Intelligence and Clinical Pharmacy</i> 1986;20:353-362.

Q.8. Does a client need to visit a clinic or see a doctor to receive COCs?

Recommendations	Rationales
<p>a) No.</p> <p>Trained providers other than doctors, including community-based distribution (CBD) workers, can initiate and resupply COCs both in clinical and non-clinical situations. Additionally, COCs may be provided "over-the-counter" if adequate information is given to clients (see "Specific counseling points for COC use," on last page of the Classification of Selected Procedures for Low Estrogen Combined Oral Contraceptives section).</p> <p>Community-based distributors (CBD) and other non-clinical FP providers should use screening checklists to identify conditions for which the woman can receive a limited supply of COCs and also be referred to a clinic. These screening checklists should, ideally, contain only 5 to 10 items.</p> <p>b) If complaints or symptoms arise which are of concern to the provider or to the woman (and which may or may not be due to COCs), the woman should be referred to an appropriate facility. If the woman wants to continue COCs, they should be continued unless a serious problem with estrogen (such as excess blood clotting) is suspected.</p>	<p>a) Studies show that COCs may be safely and effectively administered through non-clinical distribution.</p> <ol style="list-style-type: none">1) Contraceptive social marketing: Lessons from experience. <i>Population Reports Series J</i>, no. 30, July-August 1985.2) Pharmacists and family planning. <i>Population Reports Series J</i>, no. 37, November 1989.3) Rosenfield A, Maine D, Gorosh ME. Nonclinical distribution of the pill in the developing world. <i>International Family Planning Perspectives</i> 1980;6(4):130-135.4) Zavala AS, Perez-Gonzales M, Miller P, Welsh M, Wilkens LR, Potts M. Reproductive risks in a community-based distribution program of oral contraceptives, Matamoros, Mexico. <i>Studies in Family Planning</i> 1987;18(5):284-90. <p>b) Much harm can be done by stopping COCs unnecessarily (e.g., risks of pregnancy and risks of abortion).</p>

Classification of Selected Procedures for Low Estrogen Combined Oral Contraceptives (COCs)

Procedure	Class	Rationale
Pelvic examination (speculum and bimanual)	C	<ul style="list-style-type: none"> • Conditions which would restrict use of COCs should be identified by history before method initiation. • A pelvic exam may reveal reproductive tract infections or reproductive tract malignancies which should be treated for optimal preventive care. Routine pelvic exam screening for asymptomatic women, in the absence of tests for cervical cancer, however, is a low yield procedure¹. • A pelvic exam may help evaluate the question of pregnancy: in this case it is Class A. • A pelvic exam is not necessary to ensure safe use of COCs as a contraceptive method.
Blood pressure	B	<ul style="list-style-type: none"> • Due to their estrogen component, COCs have subtle (and usually insignificant) effects on blood pressure². Where possible, for clients at risk of high blood pressure, blood pressure screening would ideally accompany initiation of COCs. • Women with a long history of severe hypertension are at high risk of vascular disease, and thus arterial thrombosis (clotting), which estrogens may worsen.
Breast examination	B	Lumps that are suspicious for cancer should be evaluated. While any hormonal treatment may in theory cause such lumps to grow ³ , pregnancy causes much higher hormonal levels; therefore, a potential malignancy 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	For optimal health care, clients at risk for STDs (by personal history or socio-demographic risk factors) should be offered STD screening where possible. However, presence of an STD will not affect the safe use of COCs.

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KEY:

- Class A** = essential and mandatory in all circumstances, for safe use of the contraceptive method
- Class B** = medically/epidemiologically rational in some circumstances to optimize the safe 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 related to safe use of the contraceptive method
- Class D** = not only unnecessary, but irrelevant to the safe use of the contraceptive method

Classification of Selected Procedures for Low Estrogen Combined Oral Contraceptives (COCs) (continued)

Procedure	Class	Rationale
Cervical cancer screening	C	<p>Cervical cancer screening is indicated for women at risk of cervical carcinoma, and is recommended (where possible) for optimal preventive health care for women of reproductive age or beyond (particularly women at risk of STDs).</p> <p>NOTE: Though causality has not been established, long-term (more than 5 years) COC use may be associated with a slight increased risk of cervical cancer^{4,5}. Cervical cancer screening is advised for optimal preventive care for all women at risk of cervical cancer (e.g., smokers, women with partners having multiple partners, women with young age at first intercourse, etc.^{4,5}). All women at risk should ideally have access to a practical method of cervical cancer screening, treatment and follow-up.</p>
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 ⁶ .
Specific counseling points for COC use: <ul style="list-style-type: none"> • efficacy • common side effects • correct use of method (including instructions for missed pills) • signs and symptoms for which to see a health provider • STD protection (when/as appropriate) 	A	<ul style="list-style-type: none"> • Accurate client education is essential for maximum quality of family planning services. • Appropriate counseling about common contraceptive side effects at the time of method selection can lead to improved client satisfaction and contraceptive continuation⁷.
Counseling concerning change in menses, including irregular or absent menstrual bleeding	A	Low dose COCs commonly cause "breakthrough bleeding" (spotting or bleeding during the three weeks of active pills), especially in the first three months of COC use. Low dose COCs also commonly cause very light menses, and amenorrhea (absence of withdrawal bleeding) may occur.

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KEY:

- Class A** = essential and mandatory in all circumstances, for safe use of the contraceptive method
- Class B** = medically/epidemiologically rational in some circumstances to optimize the safe 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 related to safe use of the contraceptive method
- Class D** = not only unnecessary, but irrelevant to the safe use of the contraceptive method

Classification of Selected Procedures for Low Estrogen Combined Oral Contraceptives (COCs) (continued)

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1. Huber DH, Huber SC. Screening oral contraceptive candidates and inconsequential pelvic examinations. *Studies in Family Planning* 1975;6(2):49-51.
2. Task Force on Oral Contraceptives, WHO Special Programme of Research, Development and Research Training in Human Reproduction. The WHO Multicentre trial of the vasopressor effects of combined oral contraceptives: Comparisons with IUD. *Contraception* 1989;40:129-145.
3. Droegemueller W. Breast Diseases, in Herbst AL, Mishell DR, Stenchever MA, Droegemueller W (eds). *Comprehensive Gynecology*, 2nd edition. St. Louis, Mosby Year Book, 1992, pp 377-408.
4. Brinton LA. Oral contraceptives and cervical neoplasia. *Contraception* 1991;43(6):581-595.
5. Schlesselman JJ. Oral contraceptives in relation to cancer of the breast and reproductive tract - an epidemiological review. *British Journal of Family Planning* 1989;15:23-33.
6. Speroff L, Glass RH and Kase NG. *Clinical Gynecologic Endocrinology and Infertility*, 5th edition. Baltimore, Williams and Wilkins, 1994, pp 726-727.
7. Cotten N, Standback J, Maidouka H, Taylor-Thomas JT, Turk T. Early discontinuation of contraceptive use in Niger and The Gambia. *International Family Planning Perspectives* 1992;18(4):145-149.

IV. Progestin-Only Injectables

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IV. Progestin-Only Injectables (DMPA and NET-EN)

This section outlines recommendations on the following selected procedural questions for progestin-only injectables:

1. When can the first **progestin-only injection** be given (**interval**)? How soon does it become effective? Is a **back-up method** needed?
2. When can the first **progestin-only injection** be given **postpartum**?
3. Are progestin-only injectables appropriate for use **immediately post-abortion**?
4. Are there any **age/parity restrictions** on progestin-only injectables?
5. What is the preferred **site for a progestin-only injection**?
6. Is there a need for a **rest period** after a certain period of use of the progestin-only injectable, and is there a maximum recommended duration of use?
7. Should the progestin-only injectable be discontinued because of extended **amenorrhea**?
8. How much **grace period** is there for subsequent progestin-only injections?
9. If a woman complains of **heavier menses and/or prolonged bleeding**, is there a medical basis for discontinuing progestin-only injections?
10. Can progestin-only injectables be safely **initiated and resupplied only by doctors**?
11. Should progestin-only injectables be provided if **infection prevention measures** cannot be followed?

Q.1. When can the first progestin-only injection be given (interval)? How soon does it become effective? Is a back-up method needed?

Recommendations	Rationales
<p>a) Progestin-only injections may be given any time you can be reasonably sure the woman is not pregnant (see Appendix A), for example, during the 7 days which begin with the onset of menses (days 1 through 7 of the menstrual cycle).</p>	<p>a) Although ovulation can occur as early as day 10 of the menstrual cycle, this is rare⁴. Fertile ovulation is very uncommon before day 12¹. Intercourse 5 days before ovulation may have as much as a 5% chance of resulting in pregnancy²; however, since experts believe there are few fertile ovulations before day 13, there is only a very small chance that intercourse on day 7 of the cycle could result in pregnancy¹.</p> <p>In general, use of DMPA within the first 7 days after the woman's normal menses would assure that the probability of the woman already being pregnant, or becoming pregnant, is extremely low³.</p> <ol style="list-style-type: none"> 1) The Technical Guidance Working Group has reached this conclusion after a thorough review of the available literature and consultation with the following experts: William Collins, PhD, DSc, Department of Obstetrics and Gynecology, Kings College, UK Jeffrey Spieler, MSc, Research Division, Office of Population, USAID. 2) Dixon GW, Schlesselman JJ, Ory HW, Blye RP. Ethinyl estradiol and conjugated estrogens as postcoital contraceptives. <i>Journal of the American Medical Association</i> 1980;244:1336-1339. 3) Gray RH, Pardthaisong T, McDaniel EB, Doyle P. The timing of the first injection of Depo Provera. <i>IPPF Medical Bulletin</i> 1975;9(3):3-4. 4) Schiphorst LE, Collins WP, Royston JP. An estrogen test to determine the times of potential fertility in women. <i>Fertility and Sterility</i> 1985;44:328-334. <p>Although injectable progestins have no known teratogenic effects, avoiding the risk of fetal exposure is preferable on general principles. In addition, one study has suggested that <i>in utero</i> exposure may increase the risk of low birth weight babies.</p> <ol style="list-style-type: none"> 1) Simpson JL, Phillips OP. Spermicides, hormonal contraception and congenital malformations. <i>Advances in Contraception</i> 1990;6:141-147. 2) Bracken MB. Oral contraceptives and congenital malformations in offspring: A review and meta-analysis of the prospective studies. <i>Obstetrics and Gynecology</i> 1990;76:552-557. 3) Pardthaisong T, Gray RH. In utero exposure to steroid contraceptives and outcome of pregnancy. <i>American Journal of Epidemiology</i> 1991;134(8):795-803.

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Q.1. Interval; back-up method (continued)

Recommendations	Rationales
<p>b) For a woman having menstrual cycles, no back-up method is needed if she is in the first 7 days of her menstrual cycle and is still menstruating. If she is in the first 7 days of her cycle, but is not menstruating, some programs may recommend use of a back-up method for 1 week. Injectables may be started anytime you can be reasonably sure the woman is not pregnant (see Appendix A). However, if injections are started after day 7 of a regular cycle, a back-up method (or abstinence) may be needed (see c., below).</p> <p>c) Although there is good reason to believe the effect on cervical mucus will promptly provide contraceptive protection within 24 hours, it may be prudent to consider a back-up method for up to 7 days.</p> <p>(See Q.2. for postpartum initiation and Q.3. for post-abortion initiation.)</p>	<p>b) It is probable that progestin-only injections effectively thicken cervical mucus within 24 hours. Consistent with this theory, progestin-only pills have been shown to produce a thickened mucus with low sperm penetration within 3 to 4 hours after pill ingestion. Natural progesterones also cause cervical mucus to become scant, thick and sticky, decreasing or inhibiting sperm penetration, usually within 24 hours, but sometimes within 48 hours. Clinical judgement is also consistent with this theory.</p> <ol style="list-style-type: none">1) The Technical Guidance Working Group has reached this conclusion after a thorough review of the available literature and consultation with the following experts: Gary Grubb, MD, MPH, The RW Johnson Pharmaceutical Research Institute, Raritan, NJ, USA Michael Orme, Professor of Clinical Pharmacology, The University of Liverpool, UK.2) Wright SW, Fotherby K, Fairweather F. Effect of daily small doses of Norgestrel on ovarian function. <i>Journal of Obstetrics and Gynaecology of the British Commonwealth</i> 1970;77:65-68.3) Tsibris JCM. Cervical mucus, in Gould JJ, Josimovich JB (eds). <i>Gynecologic Endocrinology</i>. New York, Plenum Medical Book Company, 1987, pp 175-183.4) Insler V, Melmed H, Eichenbrenner I, Serr D, Lunenfeld B. The cervical score: A simple semiquantitative method for monitoring of the menstrual cycle. <i>International Journal of Gynaecology and Obstetrics</i> 1972;10(6):223-228.5) Flynn AM, Lynch SS. Cervical mucus and identification of the fertile phase of the menstrual cycle. <i>British Journal of Obstetrics and Gynaecology</i> 1976(83):656-659.6) Moghissi KS, Syner FN, Evans TN. A composite picture of the menstrual cycle. <i>American Journal of Obstetrics and Gynecology</i> 1972;114(3):405-418. <p>DMPA and NET-EN consistently inhibit ovulation.</p> <ol style="list-style-type: none">1) <i>Injectable Contraceptives: Their Role in Family Planning Care</i>. Geneva, World Health Organization, 1990.2) Mishell DR. Long-acting contraceptive steroids: Postcoital contraceptives and antiprogestins, in Mishell DR, Davajan V, Lobo RA, (eds). <i>Infertility, Contraception, and Reproductive Endocrinology</i>, 3rd edition. Boston, Blackwell Scientific Publications, 1991, pp 872-894. <p>c) Some programs might recommend a back-up method for women who are not menstruating at the time of progestin-only injectable initiation because there is a very slight risk of conception from unprotected intercourse on day 7 of the cycle.</p>

Q.2. When can the first progestin-only injection be given postpartum?

Recommendations	Rationales
<p>For Breastfeeding Women:</p> <p>a) If the woman chooses to rely on the Lactational Amenorrhea Method (LAM), start injectable progestins when her menses* return, or when the woman is no longer fully or nearly fully breastfeeding or at 6 months postpartum, whichever comes first (see "Relying on Lactational Amenorrhea Method" in Appendix A).</p> <p>* NOTE: In breastfeeding women, bleeding in the first 56 days (8 weeks) postpartum is NOT considered "menstrual" bleeding, because it is not preceded by ovulation.</p> <p>b) If she does not want to rely on LAM, ideally wait at least 6 weeks postpartum to initiate injectable progestins.</p>	<p>a) Risk of pregnancy during lactational amenorrhea is very low: less than 2% in first 6 months postpartum if fully breastfeeding; less than or equal to 7% in first 12 months. If the fully or nearly-fully breastfeeding woman remains amenorrheic, her risk of pregnancy is about the same as her risk with other modern contraceptive methods.</p> <ol style="list-style-type: none"> 1) Bellagio Consensus Conference on Lactational Infertility. Bellagio consensus statement on the use of breastfeeding as a family planning method. <i>Contraception</i> 1989;39(5):477-496. 2) Kennedy KI, Visness CM. Contraceptive efficacy of lactational amenorrhea. <i>The Lancet</i> 1992;339:227-230. 3) Perez A, Labbok MH, Queenan JT. Clinical study of the lactational amenorrhea method for family planning. <i>The Lancet</i> 1992;339:968-970. <p>b) Based on animal studies and observed fluctuations of human sex hormones in the first 6 weeks of life, plus the immaturity of the neonatal liver for the metabolism of exogenous steroids, it is considered prudent to wait to initiate progestin-only contraceptives until a breastfeeding woman is at least 6 weeks postpartum.</p> <ol style="list-style-type: none"> 1) Harlap S. Exposure to contraceptive hormones through breast milk - are there long-term health consequences? <i>International Journal of Gynaecology and Obstetrics</i> 1987;25(Suppl):47-55. 2) Ward RM. Pharmacologic principles and practicalities, in Tausch HW, Ballard RA, Avery ME (eds). <i>Diseases of the Newborn</i>. Philadelphia, WB Saunders Company, 1991. <p>Studies have detected no clinically measurable effects on the health or growth of breastfed babies of women who begin using progestin-only injectables at 6 weeks postpartum.</p> <ol style="list-style-type: none"> 1) WHO Task Force on Oral Contraceptives. Effects of hormonal contraceptives on milk volume and infant growth. <i>Contraception</i> 1984;30(6):505-521. 2) WHO Task Force on Oral Contraceptives. Special Programme of Research, Development, and Research Training in Human Reproduction. Effects of hormonal contraceptives on breast milk composition and infant growth. <i>Studies in Family Planning</i> 1988;19(6):361-369. 3) Karim M, Ammar R, El Mahgoub S, EL Ganzoury B, Fikri F, Abdou I. Injected progestogen and lactation. <i>British Medical Journal</i> 1971;1:200-203. 4) Pardthaisong T, Yencht C, Gray R. The long-term growth and development of children exposed to Depo-Provera during pregnancy or lactation. <i>Contraception</i> 1992;45:313-324. 5) Zacharias S, Aguilera E, Assenzo JR, Zanartu J. Effects of hormonal and non-hormonal contraceptives on lactation and incidence of pregnancy. <i>Contraception</i> 1986;33(3):203-213.

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Q.2. Postpartum (continued)

Recommendations	Rationales
<p>For Non-Breastfeeding Women:</p> <p>a) The first progestin-only injection can be given immediately postpartum and whenever the service provider can be reasonably sure that the woman is not pregnant (see Appendix A).</p>	<p>a) While there may be a theoretical concern of increased thrombogenic effect with COC use in the first week postpartum, there is no known clinical thrombogenic effect of progestin-only contraceptives; therefore injectable progestins can be safely used immediately postpartum, for non-breastfeeding women.</p> <ol style="list-style-type: none">1) <i>Injectable Contraceptives: Their Role in Family Planning Care.</i> Geneva, World Health Organization, 1990.2) Fotherby K. The progestin-only pill and thrombosis. <i>The British Journal of Family Planning</i> 1989;15:83-85.3) Chi I. The safety and efficacy of progestin-only oral contraceptives – An epidemiological perspective. <i>Contraception</i> 1993;47:1-21.

Q.3. Are progestin-only injectables appropriate for use immediately post-abortion?

Recommendations

- a) Yes, injectable progestins are appropriate for use immediately post-abortion (spontaneous or induced), in any trimester, and should be initiated within the first 7 days post-abortion (or anytime you can be reasonably sure the woman is not pregnant — see Appendix A).

Rationales

- a) Fertility returns almost immediately post-abortion (spontaneous or induced): within 2 weeks for first trimester abortion and within 4 weeks for second trimester abortion. Within 6 weeks of abortion, 75% of women have ovulated.

- 1) Lähteenmaki P, Ylöstalo P, Sipinen S, Toivonen J, Ruusuvaara L, Pikkola P, Nilsson CG, Luukkainen T. Return of ovulation after abortion and after discontinuation of oral contraceptives. *Fertility and Sterility* 1980;34(3):246-249.
- 2) Ostimihin BD, Otolocin ED, Ladipo OA. Sequential hormone measurements after first trimester abortion for normal Nigerian women. *Advances in Contraception* 1985;1 (1):83-90.

While there may be a theoretical concern of increased thrombogenic effect with COC use in the first week post-abortion, there is no known clinical thrombogenic effect of progestin-only contraceptives; therefore injectable progestins can be safely used immediately post-abortion (spontaneous or induced).

- 1) *Injectable Contraceptives: Their Role in Family Planning Care*. Geneva, World Health Organization, 1990.
- 2) Fotherby K. The progestin-only pill and thrombosis. *The British Journal of Family Planning* 1989;15:83-85.
- 3) Chi I. The safety and efficacy of progestin-only oral contraceptives — An epidemiological perspective. *Contraception* 1993;47:1-21.

Q.4. Are there any age/parity restrictions on progestin-only injectables?

Recommendations	Rationales
<p>a) No. However, young and/or childless women in particular need to understand that, on average, it takes a woman four months longer to become pregnant after discontinuing DMPA than after discontinuing COCs, IUDs or barrier methods.</p>	<p>a) After discontinuing DMPA, about 50% of women conceive by 7 months (i.e., 10 months after the last injection). This time delay to conception is approximately 4 months longer than the time it takes for women who discontinue COCs, IUDs or barrier methods to conceive. Residual amounts of DMPA will remain in circulation for about 7 to 9 months after an injection, at which time serum levels of DMPA become undetectable. By about 2 to 3 years after discontinuation of DMPA, the proportion of women who have conceived is virtually the same as for those who have discontinued use of IUDs, diaphragms and COCs. The delay in return to fertility with NET-EN is presumed to be no more than with DMPA.</p>
<p>Older Women: b) Injectable progestins may be used by women through menopause. Risks for use of injectable progestins for older women appear minimal.</p>	<ol style="list-style-type: none"> 1) Mishell DR. Long-acting contraceptive steroids: Postcoital contraceptives and antiprogestins, in Mishell DR, Davajan V, Lobo RA (eds). <i>Infertility, Contraception, and Reproductive Endocrinology</i>, 3rd edition. Boston, Blackwell Scientific Publications, 1991, pp 872-894. 2) <i>Injectable Contraceptives: Their Role in Family Planning Care</i>. Geneva, World Health Organization, 1990. 3) Schwallie PC, Assenzo JR. The effect of Depo-medroxyprogesterone acetate on pituitary and ovarian function, and the return of fertility following its discontinuation: A review. <i>Contraception</i> 1974;10(4):181-202. 4) Pardthaisong T. Return of fertility after use of the injectable contraceptive Depo Provera: Up-dated data analysis. <i>Journal of Biosocial Science</i> 1984;16:23. 5) International Center for Medical Research Task Force on Hormonal Contraception. Return to fertility following discontinuation of an injectable contraceptive - NET-EN. <i>Contraception</i> 1986;34(6):573-582. 6) <i>Depo-Provera C-150 NDA 20-246</i>. Advisory Committee Brochure, 1992, p 37. <p>b) DMPA confers many non-contraceptive benefits including decreased menstrual blood loss, as well as protection against endometriosis, acute PID and ectopic pregnancy and, of particular importance to older women, protection against endometrial cancer. DMPA may also inhibit intravascular sickling - an additional benefit to women who have sickle cell disease. Other effects which may be attributed to DMPA use include a slight increase in weight and slight (non-clinically significant) alterations in plasma lipid profiles. A theoretical risk of osteoporosis is currently under study.</p> <ol style="list-style-type: none"> 1) Depot-medroxyprogesterone acetate (DMPA) and cancer: Memorandum from a WHO Meeting. <i>Bulletin of the World Health Organization</i> 1986;64(3):375-382. 2) Liang AP, Levenson AG, Layde PM, Shelton JD, Hatcher RA, Potts M, Michelson MJ. Risk of breast, uterine corpus, and ovarian cancer in women receiving medroxyprogesterone injections. <i>Journal of the American Medical Association</i> 1983;249:2909-2912.

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Q.4. Age/parity restrictions (continued)

Recommendations

Rationales

Adolescents:

c) Use of progestin-only injectables generally leads to amenorrhea (in 50% of women by the end of the first year and 66% by the end of the second year for DMPA). Some evidence suggests that a hypoestrogenic state (as evidenced by amenorrhea), within the first two years after menarche, may increase the risk of osteoporosis later in life, particularly for women with other risk factors for osteoporosis (e.g., women who are small-boned, underweight, white or Asian, smokers, or malnourished). However, for those adolescents age 15 and under, for whom progestin-only injectables are the most appropriate method, the benefits of the method generally outweigh the risks.

- 3) Kaunitz AM. Injectable contraception. *Clinical Obstetrics and Gynecology* 1989;32(2):356-368.
- 4) Shoupe D. Injectable contraceptives and contraceptive vaginal rings, in Shoupe D, Haseltine FP (eds). *Contraception*. New York, Springer-Verlag, 1993, pp 144-157.
- 5) Deslypere JP, Thiery M, Vermeulen A. Effect of long-term hormonal contraception on plasma lipids. *Contraception* 1985;31(3):633-642.
- 6) Oyelola OO. Fasting plasma lipids, lipoproteins and apolipoproteins in Nigerian women using combined oral and progestin-only injectable contraceptives. *Contraception* 1993;47:445-454.
- 7) Solheim F. An assessment of quality of life in women treated with Depo-Provera in Sweden, in Zambrano D (ed). *Depo-Provera® (medroxyprogesterone acetate) for Contraception: A Current Perspective of Scientific, Clinical & Social Issues*. Kalamazoo, Michigan, The Upjohn Company, 1992, pp 61-72.
- 8) De Ceulaer K, Gruber C, Hayes R, Serjeant GR. Medroxyprogesterone acetate and homozygous sickle cell disease. *Lancet* 1982;ii:229-231.

Because women greater than 35 years of age are at increasing risk for endometrial (and ovarian) cancer, it is particularly important to:

- carefully evaluate irregular bleeding before administering the injectable and
- more carefully consider cancer as a possible cause if the woman returns with irregular bleeding after prolonged amenorrhea.

- 1) Herbst AL, Mishell DR, Stenchever MA, Droegmueller W. *Comprehensive Gynecology*, 2nd edition. St. Louis, Mosby Year Book, 1992, pp 1082-1083.
- 2) Parazzini F, La Vecchia C, Bocciolone L, Franceschi S. The epidemiology of endometrial cancer. *Gynecologic Oncology* 1991;41:1-16.

c) Amenorrhea while on progestin-only contraceptives is evidence of lower estrogen levels, and estrogen is necessary for the development and maintenance of strong bones (to prevent osteoporosis). The peak strength (density) of spinal bone is reached by girls around age 16; the greatest increase in bone density occurs in the first two years post-menarche.

- 1) Bonjour JP, Theintz G, Buchs B, Slosman D, Rizzoli R. Critical years and stages of puberty for spinal and femoral bone mass accumulation during adolescence. *Journal of Clinical Endocrinology and Metabolism* 1991;73:555-563.
- 2) Theintz G, Buchs B, Rizzoli R, Slosman D, Clavien H, Sizonenko PC, Bonjour JP. Longitudinal monitoring of bone mass accumulation in healthy adolescents: Evidence for a marked reduction after 16 years of age at the levels of lumbar spine and femoral neck in female subjects. *Journal of Clinical Endocrinology and Metabolism* 1992;75:1060-1065.
- 3) Dhuper S, Warren M, Brooks-Gunn J, Fox R. Effects of hormonal status on bone density in adolescent girls. *Journal of Clinical Endocrinology and Metabolism* 1990;71:1083-1088.

Q.5. What is the preferred site for a progestin-only injection?

Recommendations	Rationales
a) Both the arm (deltoid) and the gluteal muscle are acceptable. The choice should be made by client preference. The progestin-only injection is deep intra-muscular and should not be massaged.	a) The deltoid is generally more acceptable to the client and has easier access for service providers. 1) <i>Injectable Contraceptives: Their Role in Family Planning Care.</i> Geneva, World Health Organization, 1990. Some providers prefer to offer NET-EN in the gluteal muscle because the oil-based NET-EN requires a larger bore needle and may be painful. Massaging at the site of progestin-only injection increases immediate absorption. The objective of the depot formulation in oil is to achieve slow release over time.

Q.6. Is there a need for a rest period after a certain period of use of the progestin-only injectable, and is there a maximum recommended duration of use?

Recommendations	Rationales
a) No, there is no need for a rest period. Injectable progestins may be used for as long as a woman wishes to avoid pregnancy.	a) There is no cumulative effect of injectable progestins; the time required to clear the drug from the body is the same after multiple injections as after a single injection. 1) Mishell DR. Long-acting contraceptive steroids: Postcoital contraceptives and antiprogestins, in Mishell DR, Davajan V, Lobo RA (eds). <i>Infertility, Contraception, and Reproductive Endocrinology</i> , 3rd edition. Boston, Blackwell Scientific Publications, 1991, pp 872-894.

Q.7. Should the progestin-only injectable be discontinued because of extended amenorrhea?

Recommendations	Rationales
a) No, there is no medical reason to discontinue. Emphasis should be on counseling, including reassurance that amenorrhea with injectable progestins is to be expected and is safe, as well as counseling on the benefits of amenorrhea.	a) It is reasonable to expect amenorrhea among injectable progestin users, and the likelihood of amenorrhea increases with increased duration of progestin-only injectable use (50% at end of first year, two-thirds of women by end of second year of use). Women who are counseled about this possible side-effect will be less concerned if they experience extended amenorrhea. 1) Mishell DR. Long-acting contraceptive steroids: Postcoital contraceptives and antiprogestins, in Mishell DR, Davajan V, Lobo RA (eds). <i>Infertility, Contraception, and Reproductive Endocrinology</i> , 3rd edition. Boston, Blackwell Scientific Publications, 1991, pp 872-894.
b) The question of whether progestin-only injectables may be related to osteoporosis is under study. In theory, this may be a particular concern for older women with prolonged amenorrhea. (See Q.4. concerning amenorrhea due to DMPA before age 16.)	b) Extended amenorrhea resulting from the use of injectable progestins is due to endometrial atrophy. There is no risk of endometrial hyperplasia. In fact, DMPA is protective against endometrial cancer. 1) Speroff L, Glass RH, Kase NG. <i>Clinical Gynecologic Endocrinology and Infertility</i> , 4th edition. Baltimore, Williams & Wilkins, 1989, p 201 and 227. 2) Herbst AL, Mishell DR, Stenchever MA, Droegemueller W. <i>Comprehensive Gynecology</i> . St. Louis, Mosby-Year Book, 1992, pp 1082-1083.

Q.8. How much grace period is there for subsequent progestin-only injections?

Recommendations	Rationales
<p>a) For DMPA (150 mg), on a 3-month schedule, it is acceptable to give the next injection:</p> <ul style="list-style-type: none"> • up to 2 weeks late and possibly up to 4 weeks late depending on the population, or • up to 4 weeks early though not ideal. <p>b) For NET-EN, on a 2-month schedule, it is acceptable to give the next injection:</p> <ul style="list-style-type: none"> • up to 1 week late and possibly up to 2 weeks late depending on the population, or • up to 2 weeks early though not ideal. <p>c) If a client comes in after the grace period, advise her that delays in obtaining progestin-only injections increase the risk of pregnancy and <i>in utero</i> exposure to the progestin-only injectable. It is acceptable to give the progestin-only injection if you can be reasonably sure she is not pregnant (see Appendix A). Although there is good reason to believe the effect on cervical mucus will promptly provide contraceptive protection within 24 hours, it may be prudent to consider a back-up method for up to 7 days. Reschedule the next injection (for 3 months with DMPA or 2 months with NET-EN).</p>	<p>a) DMPA blood levels consistently remain high enough to maintain contraceptive effect through 3 months post-injection and the pregnancy risk at 4 months post-injection is extremely low (and DMPA has no known teratogenic effects, although one study has suggested <i>in utero</i> DMPA exposure may possibly increase risk of low birth weight babies).</p> <ol style="list-style-type: none"> 1) Mishell DR. Long-acting contraceptive steroids: Postcoital contraceptives and antiprogestins, in Mishell DR, Davajan V, Lobo RA (eds). <i>Infertility, Contraception, and Reproductive Endocrinology</i>, 3rd edition. Boston, Blackwell Scientific Publications, 1991, pp 872-894. 2) Bracken MB. Oral contraceptives and congenital malformations in offspring: A review and meta-analysis of the prospective studies. <i>Obstetrics and Gynecology</i> 1990;76:552-557. 3) Pardthaisong T, Gray RH. In utero exposure to steroid contraceptives and outcome of pregnancy. <i>American Journal of Epidemiology</i> 1991;134(8):795-803. 4) Schwallie PC, Assenzo JR. The effect of Depo-medroxyprogesterone acetate on pituitary and ovarian function, and the return of fertility following its discontinuation: A review. <i>Contraception</i> 1974;10(4):181-202. <p>b) For NET-EN, blood levels remain high enough to maintain contraceptive effect through 74 days (2 months plus 2 weeks).</p> <ol style="list-style-type: none"> 1) Hall PE. Long-acting injectable formulations, in Diczfalusy E, Bygdeman M (eds). <i>Fertility, Regulation Today and Tomorrow</i>. New York, Raven Press, 1987, p 119. <p>c) It has been shown that the time it takes for progestin levels to be insufficient for contraception may vary somewhat from population to population. Studies show that Thai women seem to metabolize DMPA rapidly. Additionally, weight has also been shown to have an independent influence on progestin levels (in heavier women the contraceptive effects last longer).</p> <ol style="list-style-type: none"> 1) Garza-Flores J, Hall PE, Perez-Palacios G. Long-acting hormonal contraceptives for women. <i>Journal of Steroid Biochemistry and Molecular Biology</i> 1991;40(4-6):697-704. 2) Fotherby K, Koetsawang S, Mathrubutham M. Pharmacokinetic study of different doses of Depo Provera. <i>Contraception</i> 1980;22(5):528-536. 3) Bassol S, Garza-Flores J, Cravioto MC, Diaz-Sanchez V, Fotherby K, Lichtenberg R, Perez-Palacios G. Ovarian function following a single administration of Depo-medroxyprogesterone acetate (DMPA) at different doses. <i>Fertility and Sterility</i> 1984;42(2):216-222. 4) World Health Organization. A multicentered phase III comparative clinical trial of depot-medroxyprogesterone acetate given three-monthly at doses of 100 mg or 150 mg: I. Contraceptive efficacy and side effects. <i>Contraception</i> 1986;34(3):223-235.

Q.9. If a woman complains of heavier menses and/or prolonged bleeding, is there a medical basis for discontinuing progestin-only injections?

Recommendations	Rationales
<p>Not usually. Irregular and prolonged bleeding episodes are common and expected in the first 3 to 6 months of use.</p> <p>a) For prolonged spotting or moderate bleeding (equivalent to normal menstruation but longer in duration), the first approach should be counseling and reassurance. It should be explained that in the absence of evidence for other diseases, irregular bleeding commonly occurs in the first few months of use of injectable progestins.</p> <p>If counseling and reassurance are not sufficient for the woman and she wishes to continue the method, the following management approaches may be tried:</p> <ul style="list-style-type: none"> • short term (for 7 to 21 days) COCs or estrogen, or • ibuprofen (or similar non-steroidal anti-inflammatories other than aspirin), or • if the previous injection was given more than 4 weeks ago, giving another injection at this time may be an effective approach. <p>b) Heavy bleeding (greater than normal menstruation) is uncommon; it can usually be controlled by administration of increased doses of COCs (or estrogen). Some women will require stopping the use of injectable progestins due to medical reasons for excessive bleeding or due to the client's preference.</p> <p>c) If suspected, abnormal conditions which cause prolonged or heavy bleeding should be evaluated and treated as appropriate.</p> <p>d) Some prolonged or heavy bleeding may fail to be corrected and injections may need to be discontinued.</p> <p>e) Evaluate and address anemia if indicated. Give nutritional advice on the need to increase the intake of iron-containing foods.</p>	<p>a) The number of bleeding days decreases with months of injectable progestin use.</p> <p>1) Belsey EM, Task Force on Long-Acting Systemic Agents for Fertility and Regulation. Menstrual bleeding patterns in untreated women and with long-acting methods of contraception. <i>Advances in Contraception</i> 1991;(7):257-270.</p> <p>a-b) Management of prolonged or heavy bleeding may be achieved by:</p> <ul style="list-style-type: none"> • rebuilding endometrium with COCs/estrogen, or • ibuprofen* (which blocks prostaglandin synthesis and thus decreases uterine bleeding), or • accelerating the arrival of amenorrhea with another injection. There is evidence that bleeding decreases with a subsequent injection. <p>1) <i>Injectable Contraceptives: Their Role in Family Planning Care</i>. Geneva, World Health Organization, 1990.</p> <p>2) Diaz S, Croxatto HB, Davez M, Belhadj H, Stern J, Sivin I. Clinical assessment of treatments for prolonged bleeding in users of NORPLANT® Implants. <i>Contraception</i> 1990;42(1):97-109.</p> <p>3) Task Force on Long-Acting Agents for the Regulation of Fertility. Multinational comparative clinical trials of long-acting injectable contraceptives: Norethisterone enanthate given in two dosage regimens and Depot-medroxyprogesterone acetate: Final report. <i>Contraception</i> 1983;28(1):1-20.</p> <p>* NOTE: Nonsteroidal anti-inflammatory drugs (e.g., ibuprofen) should be used instead of aspirin because of aspirin's stronger and longer-lasting inhibitory effects on platelet aggregation (aspirin promotes bleeding).</p> <p>1) <i>American Hospital Formulary Service Drug Information</i>. Bethesda, MD, American Society of Hospital Pharmacists, 1994, p 1208.</p> <p>2) Field CS. Dysfunctional uterine bleeding. <i>Primary Care</i> 1988;15(3):561-574.</p>

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Q.9. *Heavier menses and/or prolonged bleeding* (continued)

Recommendations	Rationales
f) Do not perform uterine evacuation unless another medical condition is suspected (vacuum aspiration is generally the preferred method of uterine evacuation).	

Q.10. Can progestin-only injectables be safely initiated and resupplied only by doctors?

Recommendations	Rationales
a) No. Injectable progestins (including immediate postpartum injection in non-lactating women and post-abortion injection) can be safely administered by service providers (e.g., nurses, midwives, pharmacists, community-based distribution (CBD) workers, and others) who are appropriately trained according to relevant national or institutional standards.	a) Nurses, midwives, and other community health workers can be appropriately trained to initiate and resupply injectable progestins. 1) <i>Injectable Contraceptives: Their Role in Family Planning Care.</i> Geneva, World Health Organization, 1990.

Q.11. Should progestin-only injectables be provided if infection prevention measures cannot be followed?

Recommendations	Rationales
<p>a) No.</p> <p>All sites providing progestin-only injectable contraceptives should consistently follow basic infection prevention measures, including:</p> <ul style="list-style-type: none">• aseptic technique (including cleaning of the progestin-only injection site);• sterile needles and syringes (single use, disposable needles/syringes are preferred);• if sterilization of reusable needles/syringes is impossible, decontamination with bleach followed by high-level disinfection — if correctly executed — may be used; and• safe disposal of single-use needles/syringes.	<p>a) Because injecting a steroid contraceptive, such as Depo Provera®, penetrates the protective skin barrier, careful aseptic technique must be followed to prevent infection. One type of infection associated with this procedure is an injection abscess, commonly caused by normal skin flora (staph and strep). Thorough skin preparation done before the progestin-only injection will remove most microorganisms from the client's skin which helps prevent cellulitis (skin infection) and abscess formation at the injection site.</p> <p>Another concern is the increasing problem of transmission of hepatitis B and AIDS viruses 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 are used, they should be decontaminated immediately after use by soaking in 0.5% chlorine solution or other locally available and approved disinfectant. 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 AIDS following accidental needlesticks. Following decontamination, reusable needles and syringes should be thoroughly cleaned and finally sterilized or high-level disinfected.</p> <p>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, p 181.</p>

Classification of Selected Procedures for Progestin-Only Injectables (DMPA and NET-EN)

Procedure	Class	Rationale
Pelvic examination (speculum and bimanual)	C	<ul style="list-style-type: none"> • Conditions which would restrict use of injectables should be identified by history before method initiation. • A pelvic exam may reveal reproductive tract infections or reproductive tract malignancies which should be treated for optimal preventive care. Routine pelvic exam screening for asymptomatic women, in the absence of tests for cervical cancer, however, is a low yield procedure¹. • In some cases, a pelvic exam may help evaluate the question of pregnancy beyond 6 weeks duration: in this case it is Class A. • A pelvic exam is not necessary to ensure safe use of injectables as a contraceptive method.
Blood pressure	C	<ul style="list-style-type: none"> • Screening for high blood pressure is part of optimal preventive health care. • Current evidence does not demonstrate any notable effect of DMPA or NET-EN on blood pressure^{2,3}.
Breast examination	C	<ul style="list-style-type: none"> • For all women of reproductive age or beyond, a breast exam is recommended for optimal preventive health care. • Injectables do not cause breast cancer⁴. Lumps that are suspicious for 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.

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KEY:

- Class A** = essential and mandatory in all circumstances, for safe use of the contraceptive method
- Class B** = medically/epidemiologically rational in some circumstances to optimize the safe 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 related to safe use of the contraceptive method
- Class D** = not only unnecessary, but irrelevant to the safe use of the contraceptive method

Classification of Selected Procedures for Progestin-Only Injectables (DMPA and NET-EN) (continued)

Procedure	Class	Rationale
STD screening by lab tests (for asymptomatic persons)	C	For optimal health care, clients at risk for STDs (by personal history or socio-demographic risk factors) should be offered STD screening where possible. However, presence of an STD will not affect the safe use of injectables.
Cervical cancer screening	C	<ul style="list-style-type: none"> • Cervical cancer screening is indicated for women at risk of cervical carcinoma, and is recommended for optimal preventive health care for women of reproductive age or beyond (particularly women at risk of STDs). <p>NOTE: Cervical cancer screening is advised for optimal preventive care for all women at risk of cervical cancer (e.g., smokers, women with partners having multiple partners, women with young age at first intercourse, etc.). All women at risk should ideally have access to a practical method of cervical cancer screening, treatment and follow up.</p> <ul style="list-style-type: none"> • Cervical screening is not needed for the safe use of injectables⁵.
Routine, mandatory lab tests (e.g., cholesterol, glucose, liver function tests)	D	The effects of injectables on cholesterol, blood glucose and normal liver function are slight, and of no demonstrated clinical significance ⁶ .
General counseling points for progestin-only injectables use: <ul style="list-style-type: none"> • efficacy • common side effects (including alterations of bleeding patterns) • correct use of method • signs and symptoms for which to return to the clinic • STD protection (when/as appropriate) 	A	<ul style="list-style-type: none"> • Accurate client education is essential for maximum quality of family planning services. • Appropriate counseling about common contraceptive side effects at the time of method selection can lead to improved client satisfaction and contraceptive continuation⁷.

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KEY:

- Class A** = essential and mandatory in all circumstances, for safe use of the contraceptive method
- Class B** = medically/epidemiologically rational in some circumstances to optimize the safe 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 related to safe use of the contraceptive method
- Class D** = not only unnecessary, but irrelevant to the safe use of the contraceptive method

Classification of Selected Procedures for Progestin-Only Injectables (DMPA and NET-EN) (continued)

Procedure	Class	Rationale
Counseling concerning change in menses, including irregular or absent menstrual bleeding	A	Irregular or absent menstrual bleeding is the single most common side effect of progestin-only injectables, and the chief complaint leading to discontinuation ^{2,3} .

Citations:

1. Huber DH, Huber SC. Screening oral contraceptive candidates and inconsequential pelvic examinations. *Studies in Family Planning* 1975;6(2):49-51.
2. WHO Special Programme of Research, Development and Research Training in Human Reproduction. Multinational comparative trial of long-acting injectable contraceptives: Norethisterone enanthate given in two dosage regimens and depot-medroxyprogesterone acetate: Final report. *Contraception* 1983;28(1):1-20.
3. WHO Task Force on Long-Acting Systemic Agents for Fertility Regulation, Special Programme of Research, Development and Research Training in Human Reproduction. A multi-centered phase III comparative clinical trial of depot-medroxyprogesterone acetate given three-monthly at doses of 100 mg or 150 mg: I. Contraceptive efficacy and side effects. *Contraception* 1986,34(3):1223-1235.
4. *Injectable Contraceptives: Their Role in Family Planning Care*. Geneva, World Health Organization, 1990, p 69.
5. The WHO Collaborative Study of Neoplasia and Steroid Contraceptives. Depot-medroxyprogesterone acetate (DMPA) and risk of invasive squamous cell cervical cancer. *Contraception* 1992;45:199-312.
6. *Injectable Contraceptives: Their Role in Family Planning Care*. Geneva, World Health Organization, 1990, p 78.
7. Cotten N, Standback J, Maidouka H, Taylor-Thomas JT, Turk T. Early discontinuation of contraceptive use in Niger and The Gambia. *International Family Planning Perspectives* 1992;18(4):145-149.

KEY:

- Class A** = essential and mandatory in all circumstances, for safe use of the contraceptive method
Class B = medically/epidemiologically rational in some circumstances to optimize the safe 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 related to safe use of the contraceptive method
Class D = not only unnecessary, but irrelevant to the safe use of the contraceptive method

V. NORPLANT® Implants

V. NORPLANT® Implants

This section outlines recommendations on the following selected procedural questions for NORPLANT® Implants:

1. When can NORPLANT® Implants be **inserted (interval)**? How soon after the insertion are NORPLANT® Implants effective? Is there a need for a **back-up method**?
2. When can NORPLANT® Implants be **inserted postpartum**?
3. Are NORPLANT® Implants appropriate for use **immediately post-abortion**?
4. Are there any **age/parity restrictions** on NORPLANT® Implants?
5. Is there a need for a **routine pre-exam** (a separate visit) before insertion?
6. What should the routine **follow-up schedule** be?
7. If a woman complains of **heavier menses and/or prolonged bleeding**, is there a medical basis for removing NORPLANT® Implants?
8. Is there a **weight limit** for the use of NORPLANT® Implants?
9. Can NORPLANT® Implants be safely **inserted and removed only by doctors**?
10. Should NORPLANT® Implants be provided if **infection prevention measures** cannot be followed?

Q.1. When can NORPLANT® Implants be inserted (interval)? How soon after the insertion are NORPLANT® Implants effective? Is there a need for a back-up method?

Recommendations	Rationales
<p>a) NORPLANT® Implants may be inserted any time you can be reasonably sure the woman is not pregnant (see Appendix A), for example, during the 7 days which begin with the onset of menses (days 1 through 7 of the menstrual cycle).</p>	<p>a) Blood levels of levonorgestrel rise to a level sufficient to prevent conception within 24 hours of insertion.</p>
<p>b) For women having menstrual cycles, no back-up method is needed if she is in the first 7 days of her menstrual cycle and is still menstruating. If she is in the first 7 days of her cycle, but is not menstruating, some programs may recommend use of a back-up method for 1 week. NORPLANT® Implants may be inserted anytime you can be reasonable sure the woman is not pregnant (see Appendix A). However, if insertion is done after day 7 of a regular cycle, a back-up method (or abstinence) may be needed (see c., below).</p>	<p>1) <i>NORPLANT® Levonorgestrel Implants: A Summary of Scientific Data</i>. Monograph. New York, The Population Council, 1990, p 2.</p> <p>Although ovulation can occur as early as day 10 of the menstrual cycle, this is rare⁴. Fertile ovulation is very uncommon before day 12¹. Intercourse 5 days before ovulation may have as much as a 5% chance of resulting in pregnancy²; however, since experts believe there are few fertile ovulations before day 13, there is only a very small chance that intercourse on day 7 of the cycle could result in pregnancy¹.</p> <p>In general, use of NORPLANT® Implants within the first 7 days after the woman's normal menses would assure that the probability of the woman already being pregnant, or becoming pregnant, is extremely low³.</p> <p>1) The Technical Guidance Working Group has reached this conclusion after a thorough review of the available literature and consultation with the following experts: William Collins, PhD, DSc, Department of Obstetrics and Gynecology, Kings College, UK Jeffrey Spieler, MSc, Research Division, Office of Population, USAID.</p> <p>2) Dixon GW, Schlesselman JJ, Ory HW, Blye RP. Ethinyl estradiol and conjugated estrogens as postcoital contraceptives. <i>Journal of the American Medical Association</i> 1980;244:1336-1339.</p> <p>3) Gray RH, Pardthaisong T, McDaniel EB, Doyle P. The timing of the first insertion of Depo Provera. <i>IPPF Medical Bulletin</i> 1975;9(3):3-4.</p> <p>4) Schiphorst LE, Collins WP, Royston JP. An estrogen test to determine the times of potential fertility in women. <i>Fertility and Sterility</i> 1985;44:328-334.</p> <p>b) It is probable that NORPLANT® Implants effectively thicken cervical mucus within 24 hours. Consistent with this theory, progestin-only pills have been shown to produce a thickened mucus with low sperm penetration within 3 to 4 hours after pill ingestion. Natural progesterones also cause cervical mucus to become scant, thick and sticky decreasing or inhibiting sperm penetration, within 24 hours, but sometimes within 48 hours. Clinical judgement is also consistent with this theory.</p>

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Q.1. Interval; back-up method (continued)

Recommendations

Rationales

- c) Although there is good reason to believe the effect on cervical mucus will promptly provide contraceptive protection within 24 hours, it may be prudent to consider a back-up method for up to 7 days.

(See Q.2. for postpartum insertion and Q.3. for post-abortion insertion.)

- 1) The Technical Guidance Working Group (GWG) has reached this conclusion after a thorough review of the literature and consultation with the following experts:
Gary Grubb, MD, MPH, The RW Johnson Pharmaceutical Research Institute, Raritan, NJ, USA
Michael Orme, Professor of Clinical Pharmacology, The University of Liverpool, UK.
- 2) Wright SW, Fotherby K, Fairweather F. Effect of daily small doses of Norgestrel on ovarian function. *Journal of Obstetrics and Gynecology of the British Commonwealth* 1970;77:65-68.
- 3) Tsibris JCM. Cervical mucus, in Gould JJ, Josimovich JB (eds). *Gynecologic Endocrinology*. New York, Plenum Medical Book Company, 1987, pp 175-183.
- 4) Insler V, Melmed H, Eichenbrenner I, Serr D, Lunenfeld B. The cervical score: A simple semiquantitative method for monitoring of the menstrual cycle. *International Journal of Gynaecology and Obstetrics* 1972;10(6):223-228.
- 5) Flynn AM, Lynch SS. Cervical mucus and identification of the fertile phase of the menstrual cycle. *British Journal of Obstetrics and Gynaecology* 1976(83):656-659.
- 6) Moghissi KS, Syner FN, Evans TN. A composite picture of the menstrual cycle. *American Journal of Obstetrics and Gynecology* 1972;114(3):405-418.

- c) Some programs might recommend a back-up method for women who are not menstruating at the time of NORPLANT® Implants initiation because there is a very slight risk of conception from unprotected intercourse on day 7 of the cycle.

Q.2. When can NORPLANT® Implants be inserted postpartum?

Recommendations	Rationales
<p>For Breastfeeding Women:</p> <p>a) If the woman chooses to rely on the Lactational Amenorrhea Method (LAM), insert NORPLANT® Implants when her menses* return, or when the woman is no longer fully or nearly fully breastfeeding or at 6 months postpartum, whichever comes first (see "Relying on Lactational Amenorrhea Method" in Appendix A).</p> <p>* NOTE: In breastfeeding women, bleeding in the first 56 days (8 weeks) postpartum is NOT considered "menstrual" bleeding, because it is not preceded by ovulation.</p> <p>b) If the woman is fully breastfeeding, but does not want to rely on LAM, ideally wait until at least 6 weeks postpartum to initiate NORPLANT® Implants. If she is only partially breastfeeding and does not want to rely on LAM, it is still advisable to wait at least until 6 weeks postpartum before initiating NORPLANT® Implants.</p>	<p>a) Risk of pregnancy during lactational amenorrhea is very low: less than 2% in first 6 months postpartum if fully breastfeeding; less than or equal to 7% in first 12 months. If the fully or nearly-fully breastfeeding woman remains amenorrheic, her risk of pregnancy is about the same as her risk with other modern contraceptive methods.</p> <p>1) Bellagio Consensus Conference on Lactational Infertility. Bellagio consensus statement on the use of breastfeeding as a family planning method. <i>Contraception</i> 1989;39(5):477-496.</p> <p>2) Kennedy KI, Visness CM. Contraceptive efficacy of lactational amenorrhea. <i>The Lancet</i> 1992;339:227-230.</p> <p>3) Perez A, Labbok MH, Queenan JT. Clinical study of the lactational amenorrhea method for family planning. <i>The Lancet</i> 1992;339:968-970.</p> <p>b) Based on animal studies and observed fluctuations of human sex hormones in the first 6 weeks of life, plus the immaturity of the neonatal liver for the metabolism of exogenous steroids, it is considered prudent to wait to initiate progestin-only contraceptives until a breastfeeding woman is at least 6 weeks postpartum.</p> <p>1) Harlap S. Exposure to contraceptive hormones through breast milk - Are there long-term health consequences? <i>International Journal of Gynaecology and Obstetrics</i> 1987;25(Suppl):47-55.</p> <p>2) Ward RM. Pharmacologic principles and practicalities, in Tausch HW, Ballard RA, Avery ME (eds). <i>Diseases of the Newborn</i>. Philadelphia, WB Saunders Company, 1991.</p> <p>Most studies¹⁻⁵ have not detected clinically measurable effects on the health or growth of breastfed babies of women who begin using NORPLANT® Implants after 6 weeks postpartum, although not all studies report consistent findings^{6,7}. Based on current literature including studies with other progestin-only methods^{2,3,8,11}, it is unlikely that there is a significant effect on growth of breastfeeding infants whose mothers initiate NORPLANT® Implants after the sixth postpartum week.</p>

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Q.2. Inserted postpartum (continued)

Recommendations

Rationales

- c) Programs that wish to give clients the option of NORPLANT® Implant insertion immediately postpartum should also give clients the option of returning after 6 weeks to receive NORPLANT® Implants.

For Non-Breastfeeding Women:

- a) NORPLANT® Implants can be inserted immediately postpartum and whenever you can be reasonably sure the woman is not pregnant (see Appendix A).

- 1) Affandi B, Karmadibrata S, Prihartono J, Lubis F, Samil RS. Effect of NORPLANT® on mothers and infants in the postpartum period. *Advances in Contraception* 1986;2:371-380.
- 2) WHO Task Force on Oral Contraceptives. Effects of hormonal contraceptives on milk volume and infant growth. *Contraception* 1984;30(6):505-521.
- 3) WHO Task Force on Oral Contraceptives. Special Programme of Research, Development, and Research Training in Human Reproduction. Effects of hormonal contraceptives on breast milk composition and infant growth. *Studies in Family Planning* 1988;19(6):361-369.
- 4) Diaz S, Peralta O, Juez G, Herreros C, Casado M, Salvatierra A, Miranda P, Croxatto H. Fertility regulation in nursing women. VI. Contraceptive effectiveness of a subdermal progesterone implant. *Contraception* 1984;30(4):311-325.
- 5) Shaaban MM. Contraception with progestogens and progesterone during lactation. *Journal of Steroid Biochemistry and Molecular Biology* 1991;40:705-710.
- 6) Diaz S, Herreros C, Juez G, Casado ME, Salvatierra AM, Miranda P, Peralta O, Croxatto HB. Fertility regulation in nursing women: VII. Influence of NORPLANT® Levonorgestrel implants upon lactation and infant growth. *Contraception* 1985;32(1):53-74.
- 7) Shaaban M, Salem H, Abdullah K. Influence of Levonorgestrel contraceptive implants, Norplant, initiated early postpartum upon lactation and infant growth. *Contraception* 1985;32(6):623-635.
- 8) Karim M, Ammar R, El Mahgoub S, El Ganzoury B, Fikri F, Abdou I. Injected progestogen and lactation. *British Medical Journal* 1971;1:200-203.
- 9) Pardthaisong T, Yencht C, Gray R. The long-term growth and development of children exposed to Depo-Provera during pregnancy or lactation. *Contraception* 1992; 45:313-324.
- 10) Zacharias S, Aguilera E, Assenzo JR, Zanartu J. Effects of hormonal and non-hormonal contraceptives on lactation and incidence of pregnancy. *Contraception* 1986;33(3):203-213.
- 11) McCann MF, Moggia AV, Higgins JE, Potts M, Beeker C. The effects of a progestin-only oral contraceptive (Levonorgestrel 0.03 mg) on breastfeeding. *Contraception* 1989;40(6):635-648.

- c) In some service delivery settings, access to NORPLANT® Implants insertion may be difficult for clients to obtain outside of immediate postpartum services.

- a) While there may be a theoretical concern of increased thrombogenic effect with COC use in the first week postpartum, there is no known clinical thrombogenic effect of progestin-only contraceptives; therefore NORPLANT® Implants can be safely inserted immediately postpartum, for non-breastfeeding women.

- 1) *Injectable Contraceptives: Their Role in Family Planning Care*. Geneva, World Health Organization, 1990.
- 2) Fotherby K. The progestin-only pill and thrombosis. *The British Journal of Family Planning* 1989;15:83-85.
- 3) Chi I. The safety and efficacy of progestin-only oral contraceptives – An epidemiological perspective. *Contraception* 1993;47:1-21.

Q.3. Are NORPLANT® Implants appropriate for use immediately post-abortion?

Recommendations	Rationales
a) Yes, NORPLANT® Implants are appropriate for use immediately post-abortion (spontaneous or induced), in any trimester, and should be inserted within the first seven days post-abortion (or anytime you can be reasonably sure the woman is not pregnant — see Appendix A).	<p>a) Fertility returns almost immediately post-abortion (spontaneous or induced): within 2 weeks for first trimester abortion and within 4 weeks for second trimester abortion. Within 6 weeks of abortion, 75% of women have ovulated.</p> <ol style="list-style-type: none">1) Lähteenmaki P, Ylöstalo P, Sipinen S, Toivonen J, Runsvaara L, Pikkola P, Nilsson CG, Luukkainen T. Return of ovulation after abortion and after discontinuation of oral contraceptives. <i>Fertility and Sterility</i> 1980;34(3):246-249.2) Ostimihin BD, Otolorin ED, Ladipo OA. Sequential hormone measurements after first trimester abortion for normal Nigerian women. <i>Advances in Contraception</i> 1985;1(1):83-90. <p>While there may be a theoretical concern of increased thrombogenic effect with COC use in the first week post-abortion, there is no known clinical thrombogenic effect of progestin-only contraceptives; therefore NORPLANT® Implants can be safely used immediately post-abortion (spontaneous or induced).</p> <ol style="list-style-type: none">1) <i>Injectable Contraceptives: Their Role in Family Planning Care</i>. Geneva, World Health Organization, 1990.2) Fotherby K. The progestin-only pill and thrombosis. <i>The British Journal of Family Planning</i> 1989;15:83-85.3) Chi I. The safety and efficacy of progestin-only oral contraceptives — An epidemiological perspective. <i>Contraception</i> 1993;47:1-21.

Q.4. Are there any age/parity restrictions on NORPLANT® Implants?

Recommendations	Rationales
<p>a) No. NORPLANT® Implants may be used at any age at which the woman is at risk for pregnancy (e.g., past menarche and through menopause).</p>	<p>a) The contraceptive effect of NORPLANT® Implants ceases within 24 hours of removal and return to fertility is comparable to that of women who have not used contraception; 40 to 50% of women become pregnant after three months and 75 to 95% of women are pregnant by 12 months post-removal.</p> <ol style="list-style-type: none"> 1) Noerpramana N-P. The Norplant removal training and service at Dr. Kariadi Hospital, Semarang, Indonesia. <i>Advances in Contraception</i> December 1991; 7(4):389-401. 2) Sivin I, Diaz S, Holma P, Alvarez-Saneuez F, Robertson DN. A four-year clinical study of Norplants. <i>Studies in Family Planning</i> 1983;14(6-7):184-191. 3) Singh K, Viegas OAC, Ratnam SS. A three-year evaluation of Norplant in Singaporean acceptors. <i>Advances in Contraception</i> 1990;6:1-9.
<p>Older Women: b) NORPLANT® Implants may be used by women through menopause.</p>	<p>b) Many providers consider NORPLANT® Implants to be an especially appropriate method for older women, since they contain no estrogen.</p> <ol style="list-style-type: none"> 1) <i>Norplant Contraceptive Subdermal Implants: Managerial and Technical Guidelines</i>. Geneva, World Health Organization, 1990. <p>Because women greater than 35 years of age are at increasing risk for endometrial (and ovarian) cancer, it is particularly important to:</p> <ul style="list-style-type: none"> • carefully evaluate irregular bleeding before inserting NORPLANT® Implants and • more carefully consider cancer as a possible cause if the woman returns with irregular bleeding after prolonged amenorrhea. <ol style="list-style-type: none"> 1) Herbst AL, Mishell DR, Stenchever MA, Droegmueller W. <i>Comprehensive Gynecology</i>, 2nd edition. St. Louis, Mosby Year Book, 1992, pp 1082-1083. 2) Parazzini F, La Vecchia C, Bocciolone L, Franceschi S. The epidemiology of endometrial cancer. <i>Gynecologic Oncology</i> 1991;41:1-16.

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Q.4. Age/parity restrictions (continued)

Recommendations

Rationales

Adolescents:

c) Use of NORPLANT® Implants leads to amenorrhea in a small proportion of women, less than that for women using progestin-only injectables. Some evidence suggests that a hypoestrogenic state within the first two years after menarche may increase the risk of osteoporosis later in life, particularly for women with other risk factors for osteoporosis (i.e., women who are small-boned, underweight, white or Asian, smokers or malnourished). However, for those adolescents age 15 or under, for whom NORPLANT® Implants is the most appropriate method, the benefits of the method generally outweigh the risks.

c) Amenorrhea, while on progestin-only contraceptives, is generally evidence of lower estrogen levels (although not as low as menopausal levels). Estrogen is necessary for the development and maintenance of strong bones (to prevent osteoporosis). The peak strength (density) of spinal bone is reached by girls around age 16; the greatest increase in bone density occurs in the first two years post-menarche.

- 1) Faúndes A, Alvarez-Sanchez F, Brache V, Jimenez E, Tejada AS. Hormonal changes associated with bleeding during low dose progestogen contraception delivered by Norplant subdermal implants. *Advances in Contraception* 1991;7(1):85-94.
- 2) Shoupe D, Mishell DR, Bopp BL, Fielding M. The significance of bleeding patterns in Norplant implant users. *Obstetrics and Gynecology* 1991;77:256-260.
- 3) Bonjour JP, Theintz G, Buchs B, Slosman D, Rizzoli R. Critical years and stages of puberty for spinal and femoral bone mass accumulation during adolescence. *Journal of Clinical Endocrinology and Metabolism* 1991;73:555-563.
- 4) Theintz G, Buchs B, Rizzoli R, Slosman D, Clavien H, Sizonenko PC, Bonjour JP. Longitudinal monitoring of bone mass accumulation in healthy adolescents: Evidence for a marked reduction after 16 years of age at the levels of lumbar spine and femoral neck in female subjects. *Journal of Clinical Endocrinology and Metabolism* 1992;75:1060-1065.
- 5) Dhuper S, Warren M, Brooks-Gunn J, Fox R. Effects of hormonal status on bone density in adolescent girls. *Journal of Clinical Endocrinology and Metabolism* 1990;71:1083-1088.

Q.5. Is there need for a routine pre-exam (a separate visit) before insertion?

Recommendations	Rationales
a) No: <ul style="list-style-type: none">• If possible, handle all counseling and screening on the same day as the insertion.• A routine system of pre-exam visits is not necessary.	a) There is no medical need for a pre-exam (separate visit); it may be difficult for a woman to make two visits, and she may be at risk of unintended pregnancy during this interval.

Q.6. What should the routine follow-up schedule be?

Recommendations	Rationales
<p>a) Encourage the client to call or return to local provider if problems arise.</p> <p>b) A visit within the first 1 to 3 months may be advised if additional counseling is necessary or to check the insertion site.</p> <p>c) Inform the woman when removal will be necessary (in 5 years or sooner if she desires) and provide her with a means of remembering this date.</p> <p>d) Visits are encouraged for other preventive reproductive health care as available, including provision of condoms, when appropriate.</p>	<p>a-d) The client should be encouraged to return to the clinic if she has any problems or questions, after 5 years or when she desires removal, and for general reproductive health care. If women have no complaints, there is no need for routine contraceptive clinic visits before the end of the 5 years.</p> <p>1) <i>Norplant Contraceptive Subdermal Implants: Managerial and Technical Guidelines.</i> Geneva, World Health Organization, 1990.</p> <p>2) <i>NORPLANT® Levonorgestrel Implants: A Summary of Scientific Data.</i> Monograph. New York, The Population Council, 1990.</p> <p>3) Emerling JM, Palozzi P, Lelva J, Collins U. Subdermal contraceptive implants in nurse-midwifery practice. <i>Journal of Nurse-Midwifery</i> 1993; 38(2):809-875.</p>

Q.7. If a woman complains of heavier menses and/or prolonged bleeding, is there a medical basis for removing NORPLANT® Implants?

Recommendations	Rationales
<p>Not usually. Irregular and even prolonged bleeding episodes are common and expected especially in the first 3 to 6 months of NORPLANT® Implant use.</p>	
<p>a) For prolonged spotting or moderate bleeding (equivalent to normal menstruation but longer in duration), the first approach should be counseling and reassurance. It should be explained that in the absence of evidence for other diseases, irregular bleeding commonly occurs with NORPLANT® Implants.</p>	<p>a) NORPLANT® Implants may cause increased bleeding in some women and decreased bleeding in others, and changes in bleeding patterns tend to decrease over time.</p>
<p>If counseling and reassurance are not sufficient for the woman and the woman wishes to continue NORPLANT® Implants use, the following management approaches may be tried:</p>	<ol style="list-style-type: none"> 1) <i>NORPLANT® Levonorgestrel Implants: A Summary of Scientific Data.</i> Monograph. New York, The Population Council, 1990. 2) Croxatto HB. Norplant: Levonorgestrel-releasing contraceptive implant. <i>Annals of Medicine</i> 1993;25:155-160. 3) Wang SC, Wu SC, Xin XM, Chen JH, Gao J. Three years' experience with levonorgestrel-releasing intrauterine device and Norplant-2 implants: a randomized comparative study. <i>Advances in Contraception</i> 1992;8(2):105-111.
<ul style="list-style-type: none"> • short term (for 7 to 21 days) COCs or estrogen or • ibuprofen (or similar non-steroidal anti-inflammatories other than aspirin). 	<p>a-b) Bleeding is managed by rebuilding the endometrium with COCs, or by taking ibuprofen* which blocks prostaglandin synthesis and thus decreases uterine contractions. (COCs are preferred over estrogen because NORPLANT® Implants deliver such a low dose of progesterone that the contraceptive effect on the cervical mucus may be reduced by the addition of estrogen only.)</p>
<p>b) Heavy bleeding (greater than normal menstruation) is very uncommon with NORPLANT® Implants; it can usually be controlled by administration of increased doses of COCs or estrogen.</p>	<ol style="list-style-type: none"> 1) <i>Injectable Contraceptives: Their Role in Family Planning Care.</i> Geneva, World Health Organization, 1990. 2) Diaz S, Croxatto HB, Davez M, Belhadj H, Stern J, Sivin I. Clinical assessment of treatments for prolonged bleeding in users of NORPLANT® Implants. <i>Contraception</i> 1990;42(1):97-109.
	<p>* NOTE: Nonsteroidal anti-inflammatory drugs (e.g., ibuprofen) should be used instead of aspirin because of aspirin's stronger and longer-lasting inhibitory effects on platelet aggregation (aspirin promotes bleeding).</p>
	<ol style="list-style-type: none"> 1) <i>American Hospital Formulary Service Drug Information.</i> Bethesda, MD, American Society of Hospital Pharmacists, 1994, p 1208. 2) Field CS. Dysfunctional uterine bleeding. <i>Primary Care</i> 1988;15(3):561-574.

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Q.7. *Heavier menses and/or prolonged bleeding* (continued)

Recommendations	Rationales
<p>c) If suspected, abnormal conditions which cause prolonged or heavy bleeding should be evaluated and treated as appropriate.</p> <p>d) Some prolonged or heavy bleeding may fail to be corrected. Some women will require removal of NORPLANT® Implants due to medical reasons for excessive bleeding or due to client's preference.</p> <p>e) Evaluate and address anemia, as appropriate. Give nutritional advice on the need to increase the intake of iron containing foods.</p> <p>f) Do not perform uterine evacuation unless another medical condition is suspected (vacuum aspiration is generally the preferred method of uterine evacuation).</p>	

Q.8. Is there a weight limit for the use of NORPLANT® Implants?

Recommendations	Rationales
a) There are no known weight limits for NORPLANT® Implants use.	a) Previous concerns about a 70 kg weight limit apply only to the older, harder tubing. Currently, only the new softer tubing is in use. Studies involving this new tubing have been conducted through year 3 and preliminary results have not shown a significant difference in pregnancy rates associated with the woman's weight. Final results, however, are pending. 1) <i>NORPLANT® Levonorgestrel Implants: A Summary of Scientific Data.</i> Monograph. New York, The Population Council, 1990. 2) Sivin I. International experience with Norplant and Norplant II contraceptives. <i>Studies in Family Planning</i> 1988;19(2):81-94.

Q.9. Can NORPLANT® Implants be safely inserted and removed only by doctors?

Recommendations

Rationales

a) No. NORPLANT® Implants (including immediate post-partum and post-abortion insertion) can be safely inserted by service providers (e.g., nurses, midwives, and others), who are appropriately trained according to national or institutional standards.

a) Any specially trained doctor, nurse, midwife, or other health worker can perform NORPLANT® Implants insertions and removals.

1) *NORPLANT® Levonorgestrel Implants: A Summary of Scientific Data.* Monograph. New York, The Population Council, 1990.

Q.10. Should NORPLANT® Implants be provided if infection prevention measures cannot be followed?

Recommendations	Rationales
<p>a) No.</p> <p>All centers inserting and/or removing NORPLANT® Implants should follow basic infection prevention measures, including:</p> <ul style="list-style-type: none">• careful aseptic technique (including appropriate handwashing by the provider and thorough cleaning of the insertion site),• proper decontamination of reusable sharps and other instruments,• sterilization (or, at a minimum, high-level disinfection) of all equipment, and• safe disposal of contaminated sharps, and other disposables.	<p>a) Although insertion and removal of NORPLANT® Implants are minor surgical procedures, careful aseptic technique, including good surgical technique, must be followed to prevent an increase in infections at the insertion site. Infection may result in early removal or spontaneous expulsion of the NORPLANT® Implants capsule.</p> <p>Another concern is the increasing problem of transmission of hepatitis B and AIDS viruses to clients, health care providers and clinic staff, especially cleaning personnel. To minimize this risk, blood contaminated waste must be properly disposed of, and soiled instruments, gloves and other items must be decontaminated, then thoroughly cleaned and then sterilized or high-level disinfected after every case.</p> <p>Sterilization (the destruction of all microorganisms, including endospores) is the preferred practice for processing instruments and other items that come in contact with the blood stream or touch tissue beneath the skin. When sterilization is not possible, high-level disinfection (which destroys all microorganisms except some endospores) is acceptable.</p> <p>Regardless of which method (sterilization or high level disinfection) is used for instruments and other items, thorough cleaning of the client's arm and hand to remove soil and organic material is also necessary to prevent infection. Appropriate dressing and instruction to clients on hygiene of the insertion site are also important.</p> <p>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, pp 152-154.</p>

Classification of Selected Procedures for NORPLANT® Implants

Procedure	Class	Rationale
Pelvic examination (speculum and bimanual)	C	<ul style="list-style-type: none"> • Conditions which would restrict use of NORPLANT® Implants should be identified by history before method initiation. • A pelvic exam may reveal reproductive tract infections or reproductive tract malignancies which should be treated for optimal preventive care. Routine pelvic exam screening for asymptomatic women, in the absence of tests for cervical cancer, however, is a low yield procedure.¹ • In some cases, pelvic exam may help evaluate the question of pregnancy beyond 6 weeks duration: in this case it is Class A. • A pelvic exam is not necessary to ensure safe use of NORPLANT® Implants as a contraceptive method.
Blood pressure	C	<ul style="list-style-type: none"> • Screening for high blood pressure is part of optimal preventive health care. • NORPLANT® Implants do not affect blood pressure².
Breast examination	C	<ul style="list-style-type: none"> • For all women of reproductive age or beyond, a breast exam is recommended for optimal preventive health care. • NORPLANT® Implants do not cause breast cancer². Lumps that are suspicious for 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	For optimal health care, clients at risk for STDs (by personal history or socio-demographic risk factors) should be offered STD screening where possible. However, presence of an STD will not affect the safe use of NORPLANT® Implants.

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KEY:

Class A = essential and mandatory in all circumstances, for safe use of the contraceptive method

Class B = medically/epidemiologically rational in some circumstances to optimize the safe 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 related to safe use of the contraceptive method

Class D = not only unnecessary, but irrelevant to the safe use of the contraceptive method

Classification of Selected Procedures for NORPLANT® Implants (continued)

Procedure	Class	Rationale
Cervical cancer screening	C	<ul style="list-style-type: none"> • Cervical cancer screening is indicated for women at risk of cervical carcinoma, and is recommended for optimal preventive health care for women of reproductive age or beyond (particularly women at risk of STDs). <p>NOTE: Cervical cancer screening is advised for optimal preventive care for all women at risk of cervical cancer (e.g., smokers, women with partners having multiple partners, women with young age at first intercourse, etc.). All women at risk should ideally have access to a practical method of cervical cancer screening, treatment and follow-up.</p> <ul style="list-style-type: none"> • NORPLANT® Implants use has no known relation to risk of cervical carcinoma².
Routine, mandatory lab tests (e.g., cholesterol, glucose, liver function tests)	D	The effects of NORPLANT® Implants on cholesterol, blood glucose and normal liver function are slight, and of no demonstrated clinical significance ³ .
Specific counseling points for NORPLANT® Implants use: <ul style="list-style-type: none"> • efficacy • common side effects • correct use of method • signs and symptoms for which to return to the clinic • STD protection (when/as appropriate) 	A	<ul style="list-style-type: none"> • Accurate client education is essential for maximum quality of family planning services. • Appropriate counseling about common contraceptive side effects at the time of method selection can lead to improved client satisfaction and contraceptive continuation⁴.
Counseling concerning change in menses, including irregular or absent menstrual bleeding	A	NORPLANT® Implants may cause increased frequency of bleeding in some women and decreased bleeding in others; changes in bleeding patterns tend to decrease over time ⁵ . Bleeding pattern changes are the most common side effect of NORPLANT® Implants and the most common cause of discontinuation ⁵ .

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KEY:

Class A = essential and mandatory in all circumstances, for safe use of the contraceptive method

Class B = medically/epidemiologically rational in some circumstances to optimize the safe 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 related to safe use of the contraceptive method

Class D = not only unnecessary, but irrelevant to the safe use of the contraceptive method

Classification of Selected Procedures for NORPLANT® Implants (continued)

Citations:

1. Huber DH, Huber SC. Screening oral contraceptive candidates and inconsequential pelvic examinations. *Studies in Family Planning* 1975;6(2):49-51.
2. NORPLANT® Levonorgestrel Implants: *A Summary of Scientific Data*. New York, The Population Council 1990, p 11.
3. Singh K, Viegas OAC, Loke DFM, Ratnam SS. Effect of NORPLANT® Implants on liver, lipid and carbohydrate metabolism. *Contraception* 1992;45(2):141-153.
4. Cotten N, Standback J, Maidouka H, Taylor-Thomas JT, Turk T. Early discontinuation of contraceptive use in Niger and The Gambia. *International Family Planning Perspectives* 1992;18(4):145-149.
5. NORPLANT® Levonorgestrel Implants: *A Summary of Scientific Data*. New York, The Population Council 1990, pp 9-11.

VI. Copper-Bearing Intrauterine Devices

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VI. Copper-Bearing Intrauterine Devices

This section outlines recommendations on the following selected procedural questions for copper-bearing intrauterine devices (IUDs):

1. When can an IUD be **inserted (interval)**?
2. When can an IUD be **inserted postpartum**?
3. Can an IUD be **inserted immediately post-abortion**?
4. What is an appropriate **follow-up schedule** after IUD insertion?
5. Is there a need for a **routine pre-exam** (a separate visit) before IUD insertion?
6. Is there a **minimum or maximum age** to receive IUDs?
7. Can **nulliparous** women receive IUDs?
8. a) Is there a need for a "**rest period**" with IUDs after a certain period of use?
b) Are there medical reasons for removal of an IUD?
9. Following removal of an IUD (for reasons of partial expulsion without infection, or expiration of the IUD), should one **wait to insert another**?
10. If a woman is at low risk of STDs based on history, may IUDs be **inserted without any lab tests** if there is no mucopurulent endocervical discharge or clinically apparent PID or cervicitis?
11. Should an IUD be removed if the **partner complains** about the string?
12. If the cervix is red due to eversion of the squamo-columnar junction (**ectopy/ectropion**), may the IUD be inserted without further investigation?
13. If a woman complains of **heavier menses or bleeding between menses**, is there a medical basis for the IUD to be removed?
14. Can IUDs be safely **inserted by trained nurses and midwives**?
15. How much time should elapse between **STD treatment and insertion**? What about **previous STD incidence**?
16. Should IUDs be provided if **infection prevention measures** cannot be followed?

Q.1. When can an IUD be inserted (interval)?

Recommendations	Rationales
<p>a) The IUD may be inserted at anytime during the menstrual cycle, at the user's convenience, when you can be reasonably sure the woman is not pregnant (see Appendix A).</p> <p>(See Q.2. for postpartum insertion and Q.3. for post-abortion insertion).</p> <p>The IUD is effective immediately.</p>	<p>a) The IUD prevents pregnancy if inserted before implantation.</p> <p>1) Tatum HJ, Connell EB. A decade of intrauterine contraception: 1976 to 1986. <i>Fertility and Sterility</i> 1986;46(2):173-192.</p>

Q.2. When can an IUD be inserted postpartum?

Recommendations	Rationales
<p>An IUD may be inserted:</p> <p>a) Immediately post-placental, or during or immediately after a Cesarean-section (special training required).</p> <p>b) Prior to hospital discharge (up to 48 hours after delivery) (special training required).</p> <p>c) As early as 4 to 6 weeks postpartum, to accommodate women who come to the clinic for routine postpartum care and who request an IUD. Copper T IUDs may be safely inserted at this time. For other types of IUDs, it may be prudent to wait until 6 weeks postpartum.</p> <p>d) In breastfeeding women.</p>	<p>a-b) With the appropriate technique, IUDs inserted immediately after placental delivery or Cesarean section can be safe and effective. Expulsion rates for postpartum insertion vary greatly depending on both the IUD type and provider's technique. Current information indicates that the expulsion rates may be higher from 10 minutes to 48 hours after delivery than in the first 10 minute period. To minimize risk of expulsion, only properly trained providers (according to relevant national or institutional standards) should insert IUDs postpartum. Use of an inserter for IUD placement tends to reduce expulsion risk. Clients should be counseled that expulsion rates are higher postpartum than for interval insertion and should be carefully trained to detect expulsions.</p> <p>c) A Copper T may be safely inserted at 4 or more weeks postpartum. The withdrawal technique for Copper T insertion presumably helps minimize perforations when inserting IUDs at the routine 4 or 6 week postpartum visit. Other IUDs that have a different profile or a push insertion technique might have different perforation rates. Given the relative lack of information on other IUDs at 4 to 6 weeks postpartum, it is prudent to wait until 6 weeks for the insertion of IUDs other than Copper Ts.</p> <p>1) Chi I, Farr G. Postpartum IUD contraception – a review of an international experience. <i>Advances in Contraception</i> 1989;5:127-146.</p> <p>2) O'Hanley K, Huber D. Postpartum IUDs: Keys for success. <i>Contraception</i> 1992;45:351-361.</p> <p>3) Mishell DR, Roy S. Copper intrauterine contraceptive device event rates following insertion 4 to 8 weeks postpartum. <i>American Journal of Obstetrics and Gynecology</i> 1982;143(1):29-33.</p> <p>d) It has been shown that IUDs can be safely used in breastfeeding women.</p> <p>1) Farr G, Rivera R. Interactions between intrauterine contraceptive devices use and breastfeeding status at time of intrauterine contraceptive device insertion: Analysis of TCu-380A acceptors in developing countries. <i>Advances in Contraception</i> 1992;167(1):144-151.</p>

Q.3. Can an IUD be inserted immediately post-abortion?

Recommendations	Rationales
a) Yes, the IUD may be inserted immediately post-abortion (spontaneous or induced) if the uterus is not infected , or during the first seven days post-abortion, (or anytime you can be reasonably sure the woman is not pregnant — see Appendix A).	a) With appropriate technique, IUDs can be safely inserted post-abortion (spontaneous or induced). Expulsion rates vary greatly depending on both the IUD type and provider. To minimize risk of expulsion, only providers with proper training (according to relevant national or institutional standards) and experience should insert IUDs. Clients should be carefully trained to detect expulsions. Fertility returns almost immediately post-abortion (spontaneous, or induced): within 2 weeks for first trimester abortion and within 4 weeks for second trimester abortion. Within 6 weeks of abortion, 75% of women have ovulated. 1) Lähteenmaki P, Ylöstalo P, Sipinen S, Toivonen J, Ruusuvaara L, Pikkola P, Nilsson CG, Luukkainen T. Return of ovulation after abortion and after discontinuation of oral contraceptives. <i>Fertility and Sterility</i> 1980;34(3):246-249.
b) IUDs should not be inserted in the following situations: <ul style="list-style-type: none">• With confirmed or presumptive diagnosis of infection (signs of unsafe or unclean induced abortion, signs and symptoms of sepsis or infection, or inability to rule out infection), do not insert IUD until risk of infection has been ruled out or infection has fully resolved (approximately 3 months).• With serious trauma to the genital tract (uterine perforation, serious vaginal or cervical trauma, chemical burns), do not insert IUD until trauma has healed.• With hemorrhage and severe anemia, IUDs (inert or copper-bearing) are not advised until hemorrhage or severe anemia is resolved. However, progestin-releasing IUDs can be used with severe anemia (they decrease menstrual blood loss).• Post-abortion IUD insertion after 16 weeks gestation requires special training of the provider for correct fundal placement. If this is not possible, delay insertion for six weeks.	b) After 16 weeks gestation, the uterine cavity will be too enlarged for post-abortion IUD placement to be accomplished by routine IUD insertion techniques. Only providers trained to do postpartum IUD insertion should perform immediate post-abortion IUD insertion for post-abortion clients after 16 weeks gestation. 1) Maternal adaptation to pregnancy, in Pritchard JA, Macdonald PC (eds): <i>Williams Obstetrics</i> , 16th edition. New York, Appleton-Century-Crofts, 1980, p 223. 2) Leonard AH, Ladipo OA. Postabortion family planning: Factors in individual choice of contraceptive methods. <i>Advances in Abortion Care</i> . 1994;4(2):1-4.

Q.4. What is an appropriate follow-up schedule after IUD insertion?

Recommendations	Rationales
<p>a) There should be one follow-up visit approximately one month after insertion; thereafter, there is no need for a fixed follow-up schedule.</p> <p>b) The client should be strongly encouraged to come to the clinic anytime she has questions or problems, particularly if she has:</p> <ul style="list-style-type: none">• late period (possible pregnancy),• prolonged or excessive abnormal spotting or bleeding,• abdominal pain or pain with intercourse,• infection exposure (such as gonorrhea), abnormal vaginal discharge or pelvic pain especially with fever, or• string missing or string seems shorter or longer. <p>c) Visits are encouraged for other preventive reproductive health care as available, including provision of condoms, when appropriate.</p>	<p>a-c) A follow-up visit at 3 to 6 weeks is prudent as the peak incidence of PID post-IUD insertion is at one month. Thereafter, there is no need for a fixed follow-up schedule. The best quality of care is to focus clinic resources and attention on those women who come back to the clinic with complaints or problems.</p> <ol style="list-style-type: none">1) Farley TM, Rosenberg MJ, Rowe PJ, Chen JH, Meirik O. Intrauterine devices and pelvic inflammatory disease: An international perspective. <i>The Lancet</i> 1992;339:785-788.2) Janowitz B, Dighe NM, Hubacher D, Petrick T. Assessing the impact of IUD revisits. Family Health International. Presented at a meeting of the American Public Health Association in San Francisco, California, October 1992.

Q.5. Is there a need for a routine pre-exam (a separate visit) before IUD insertion?

Recommendations	Rationales
a) No. If at all possible, handle all counseling and screening the same day as the insertion.	a) There is no medical need for a pre-exam (separate visit); it may be difficult for a woman to make two visits, and she may be at risk of pregnancy during this interval.

Q.6. Is there a minimum or maximum age to receive IUDs?

Recommendations	Rationales
<p>a) There is no minimum or maximum age, as long as the woman is at risk of pregnancy.</p> <p>b) To receive an IUD, all women, especially young women, should be at low risk of STDs and receive careful counseling in order to understand potential risk of PID/infertility (possibly due to infection during IUD insertion and/or lack of protection against pelvic infection when exposed to STDs).</p>	<p>a-b) The risk of PID is higher, statistically, among younger women. IUDs, in comparison to all other modern contraceptive methods, increase the risk of PID when a woman is infected with an STD. In addition, poor aseptic procedure during IUD insertion may introduce bacteria into the upper genital tract, which may lead to PID. Clients must be informed of these facts before choosing IUDs.</p> <ol style="list-style-type: none">1) Farley TM, Rosenberg MJ, Rowe PJ, Chen JH, Meirik O. Intrauterine devices and pelvic inflammatory disease: An international perspective. <i>The Lancet</i> 1992;339:785-788.2) Lee NC, Rubin GL, Ory HW, Burkman RT. Type of intrauterine device and the risk of pelvic inflammatory disease. <i>Obstetrics and Gynecology</i> 1983;62:1-6.3) Lee NC, Rubin GL, 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):1-6.4) Cramer DW, Schiff I, Schoenbaum SC, et al. Tubal infertility and intrauterine device. <i>The New England Journal of Medicine</i> 1985;15:941-6.5) Darling JR, Weiss NS, Voigt LF, McKnight B, Moore DE. The intrauterine device and primary tubal infertility. Letter to <i>The New England Journal of Medicine</i> 1992;326(3):203-4.6) Darling JR, Weiss NS, Metch BJ, Chow WH, Soderstrom RM, Moore DE, Spadoni LR, Stadel BV. Primary tubal infertility in relation to use of an intrauterine device. <i>The New England Journal of Medicine</i> 1985;312(15):937-41.7) Task Force on Intrauterine Devices, Special Programme of Research, Development and Research Training in Human Reproduction, World Health Organization. PID associated with fertility regulating agents. <i>Contraception</i> 1984;30(1):1-21.

Q.7. Can nulliparous women receive IUDs?

Recommendations	Rationales
<p>a) Yes. However, IUDs should not be the first choice of contraception in nulliparous women. To receive IUDs, all women, especially young women, should not be at risk of STDs and need careful counseling to understand potential risk of PID/infertility (possibly due to poor infection prevention practices during IUD insertion and/or lack of protection against pelvic infection when exposed to STDs). Therefore, it is appropriate to warn women that the IUD has an increased risk of STD-associated PID and infertility.</p>	<p>a) Because nulliparous women are typically young and may have patterns of sexual activity that lead to STD risk, the relative risk of PID for nulliparous IUD users may be high.</p> <ol style="list-style-type: none">1) Task Force on Intrauterine Devices, Special Programme of Research, Development and Research Training in Human Reproduction, World Health Organization. PID associated with fertility regulating agents. <i>Contraception</i> 1984;30(1):1-21.2) Petersen KR, Brooks L, Jacobsen B, Skouky SO. Intrauterine devices in nulliparous women. <i>Advances in Contraception</i> 1991;7(4):333-8. <p>Additionally, nulliparous women receiving IUDs may be at higher risk for expulsion, bleeding and pain.</p> <ol style="list-style-type: none">1) Petersen KR, Brooks L, Jacobsen B, Skouky SO. Intrauterine devices in nulliparous women. <i>Advances in Contraception</i> 1991;7(4):333-8. <p>The degree to which the 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 sexually transmitted disease. IUDs fail to protect women against PID.</p> <ol style="list-style-type: none">1) Angle MA, Brown LA, Buekens P. IUD protocols for international training. <i>Studies in Family Planning</i> 1993;24(2):125-31. <p>Nevertheless, women should be allowed to make their own choice (e.g., an older nulliparous woman who is sure she does not want children may be a reasonable IUD candidate).</p>

- Q.8. a) Is there a need for a "rest period" with IUDs after a certain period of use?**
b) Are there medical reasons for removal of an IUD?

Recommendations	Rationales
<p>a) If a woman wants a new IUD when an old one has expired, no rest period is needed.</p> <p>b) IUD removal is indicated if:</p> <ul style="list-style-type: none"> • the woman requests removal, • the woman develops precautions/contraindications, or • the effective life of the IUD is reached (e.g., the full effective life of the CuT 380A is currently 10 years). 	<p>a-b) The removal and reinsertion of an IUD exposes a woman to a small risk of introduction of vaginal or endocervical canal microorganisms into the upper genital tract. For this reason, long-acting IUDs are preferred. The Copper T 380A has been shown to be effective for at least 10 years.</p> <ol style="list-style-type: none"> 1) Farley TM, Rosenberg MJ, Rowe PJ, Chen JH, Meirik O. Intrauterine devices and pelvic inflammatory disease: An international perspective. <i>The Lancet</i> 1992;339:785-788. 2) Kjaer A, Laursen K, Thormann L, Barggaard O, Lebech P. Copper release from copper intrauterine devices removed after up to 8 years of use. <i>Contraception</i> 1993;47(4):349-350. 3) Copper T 380A intrauterine device is effective for 10 years. News Release, The Population Council, New York, NY, September 27, 1994.

Q.9. Following removal of an IUD (for reasons of partial expulsion without infection, or expiration of the IUD), should one wait to insert another?

Recommendations	Rationales
<p>a) If the client wants to continue the method, do not wait to reinsert a new IUD after old IUD removal, provided pregnancy has been ruled out, and no new precautions/contraindications have developed (see Q.1.).</p> <p>b) Make sure removal of the first IUD is indicated (i.e., for reasons of partial expulsion without infection or expiration of the IUD).</p>	<p>a-b) Even with proper technique, the removal and reinsertion of an IUD exposes a woman to the risk of introduction of vaginal and endocervical canal microorganisms into the upper genital tract. Therefore, removal and insertion at the same time avoids two separate exposures.</p> <p>1) Farley TM, Rosenberg MJ, Rowe PJ, Chen JH, Meirik O. Intrauterine devices and pelvic inflammatory disease: An international perspective. <i>The Lancet</i> 1992;339:785-788.</p> <p>In an interval between removal of one IUD and insertion of another, the woman will not be protected against pregnancy by the method of her choice.</p>

Q.10. If a woman is at low risk of STDs based on history, may IUDs be inserted without any lab tests if there is no mucopurulent endocervical discharge or clinically apparent PID or cervicitis?

Recommendations	Rationales
<p>a) Yes, if the woman has no current risk factors for STDs (by history and on exam) and she has no apparent clinical signs or symptoms of infection (including normal bimanual exam).</p> <p>b) If PID, mucopurulent endocervical discharge, cervicitis or clinically apparent vaginitis is present, do not insert IUD, but treat for infection. Consider other contraceptive methods, if an STD* is suspected.</p> <p>* NOTE: Not all clinically-apparent vaginal infections are due to STDs.</p>	<p>a-b) Currently available lab tests may be impractical and often unaffordable (even in the developed world) to rule out endocervical colonization by infectious agents capable of ascending and causing PID. Most chlamydia tests are only 80 to 90% sensitive, tests for mycoplasma and ureaplasma are not routinely available, and cervical gram stain is less sensitive for gonorrhea. However, where gonorrhea culture and chlamydia tests are affordable, negative test results provide reassurance to corroborate the woman's history.</p> <ol style="list-style-type: none"> 1) Kramer D, Brown S. Sexually transmitted diseases and infertility. <i>International Journal of Gynaecology and Obstetrics</i> 1984;22:19-27. 2) Bell TA, Grayston JT. Centers for Disease Control guidelines for prevention and control of Chlamydia trachomatis infections. <i>Annals of Internal Medicine</i> 1986;104:524-526. 3) Nasello M, Callihan D, Mempus M, Steighigel R. A solid-phase enzyme immunoassay (gonozyme®) test for direct detection of Neisseria gonorrhoeae antigen in urogenital specimens from patients at a sexually transmitted disease clinic. <i>Sexually Transmitted Diseases</i> 1985;(October-December):198-202.

Q.11. Should an IUD be removed if the partner complains about the string?

Recommendations	Rationales
<p>Not necessarily.</p> <p>a) Counsel – explain to the woman and/or her partner what the partner is feeling and recommend they try again.</p> <p>b) Describe to the client her other options (and their disadvantages):</p> <ul style="list-style-type: none">• The string can be cut short so that it does not protrude from the cervical os; inform the woman that she would not be able to feel the string and that, at the time of IUD removal, narrow forceps will be needed to remove the IUD (this entails a small additional infection risk). If a string is cut flush with the cervix, record in the chart and tell the woman that the string is located at the opening of the os for future removal. <p>OR</p> <ul style="list-style-type: none">• Offer to remove the IUD, if other options are not acceptable. <p>c) If partner complaints occur frequently, the service provider's technique should be reviewed. Strings should be cut approximately 3 cm from the external os.</p>	<p>a-c) For IUD services, the woman's preferences are the service provider's appropriate focus.</p>

Q.12. If the cervix is red due to eversion of the squamo-columnar junction (ectopy/ectropion), may the IUD be inserted without further investigation?

Recommendations

Rationales

a) Yes, the IUD may be inserted for clients with cervical ectopy/ectropion, if not at risk of STDs and the pelvic exam is normal (no cervicitis).

a) Cervical ectropion (the presence on the ectocervix of columnar epithelial cells from the endocervix) is a normal condition in adolescents and in pregnancy, and is distinct from cervical infection.

1) Paavonen J, Koutsky LA, Kiviat N. Cervical neoplasia and other STD-related genital and anal neoplasias, in Holmes KK, Mårdh P, Sparling PF, Wiesner PJ, Cates W, Lemon SM, Stamm W (eds). *Sexually Transmitted Diseases*. New York, McGraw-Hill Book Co., 1984, pp 561-592.

IUD insertions and continued use of the IUD have no relation to risk of cervical carcinoma.

1) Lassise 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):865-870.

Since chlamydia is an intracellular parasite of columnar epithelial cells, women with ectropion may be more likely to have positive chlamydia tests.

1) Harrison HR, Costin M, Meder JB, Bowds LM, Sim DA, Lewis M, Alexander ER. Cervical chlamydia trachomatis infection in university women: Relationship to history, contraception, ectopy and cervicitis. *American Journal of Obstetrics and Gynecology* 1985;153(3):244-51.

Q.13. If a woman complains of heavier menses or bleeding between menses, is there a medical basis for the IUD to be removed?

Recommendations	Rationales
<p>Not necessarily.</p> <p>a) As in pre-method choice counseling, women should be informed that menses are normally heavier with the IUD and intermenstrual bleeding may occur, especially in the first few months. Inert IUDs should not be the first choice, for this reason.</p> <p>Give nutritional advice on the need to increase the intake of iron-containing foods.</p> <p>b) For mild to moderate bleeding and pain in the first month post-insertion, with no evidence of clinically apparent pelvic infection, and if reassurance is not sufficient but the woman wants to keep the IUD, a short course of a non-steroidal anti-inflammatory agent other than aspirin (e.g., ibuprofen) may be given.</p> <p>c) Bleeding generally decreases over time. If bleeding is heavy or the woman is anemic, treatment using oral iron can improve hemoglobin levels.</p> <p>d) If bleeding or pain is severe, or the client wishes to discontinue use, remove the IUD.</p> <p>e) If suspected, abnormal conditions which cause prolonged or heavy bleeding should be evaluated and treated as appropriate.</p> <p>f) If pelvic infection is diagnosed, remove the IUD, and treat with antibiotics. (In the case of mild uterine tenderness without any other evidence of pelvic infection, broad spectrum antibiotics or chemotherapeutics may solve the problem; use clinical judgement regarding whether or not to remove the IUD).</p>	<p>a) In general, IUDs (especially inert IUDs) commonly increase the amount of menstrual blood loss, according to IUD type, particularly in the first few months post-insertion.</p> <p>1) Cohen B, Gibor Y. Anemia and menstrual blood loss. <i>Obstetrical and Gynecological Survey</i> 1980;35(10):597-618.</p> <p>Copper IUDs may increase normal menstrual blood loss by 50%, which may be clinically significant for women who are already anemic. (Progestin-releasing IUDs decrease menstrual blood loss; the more progestin an IUD releases, the more effectively it decreases menstrual blood loss.)</p> <p>1) Andrade A, Pizarro E. Quantitative studies on menstrual blood loss in IUD users. <i>Contraception</i> 1987;36(1):129-144.</p> <p>b) Non-steroidal anti-inflammatory drugs (e.g., ibuprofen*) decrease uterine bleeding and cramping.</p> <p>1) Drug facts and comparisons. St. Louis, MO, <i>Facts and Comparisons</i> 1993, p 251.</p> <p>* NOTE: Nonsteroidal anti-inflammatory drugs (e.g., ibuprofen) should be used instead of aspirin because of aspirin's stronger and longer-lasting inhibitory effects on platelet aggregation (aspirin promotes bleeding).</p> <p>1) <i>American Hospital Formulary Service Drug Information</i>. Bethesda, MD, American Society of Hospital Pharmacists, 1994, p 1208.</p> <p>2) Field CS. Dysfunctional uterine bleeding. <i>Primary Care</i> 1988;15(3):561-574.</p>

Q.14. Can IUDs be safely inserted by trained nurses and midwives?

Recommendations	Rationales
a) Yes, IUDs (including immediate postpartum and post-abortion insertion) can be safely inserted by nurses and midwives, who are appropriately trained according to relevant national or institutional standards.	a) Nurses or midwives have been shown to have equal or superior competence in IUD insertion when compared to doctors. 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;14:43-47.

Q.15. How much time should elapse between STD treatment and insertion? What about previous STD incidence?

Recommendations	Rationales
<p>a) If the client will not be at high risk of an STD in the future, treat the STD today and insert the IUD when the infection is resolved (for acute PID, wait 3 months).</p> <p>If she remains at increased risk of PID, advise against IUD use.</p>	<p>a) PID may take several weeks to resolve clinically, and, in the case of severe PID, waiting several months, in theory, allows healthy tissues (free of micro-abscesses) to form.</p> <p>1) Sweet RL, Draper DL, Hadley WK. Etiology of acute salpingitis: Influence of episode number and duration of symptoms. <i>Obstetrics and Gynecology</i> 1981;58:62-68.</p> <p>Women with prior PID are at increased risk of repeat PID. A woman who has had an episode of upper reproductive tract infection may be at increased risk of repeat episodes of non-sexually transmitted PID regardless of IUD use. Theoretically, a previous episode of upper reproductive tract infection may result in tubal damage increasing susceptibility of the fallopian tubes to opportunistic lower genital tract flora.</p> <p>1) Weström L, Mårdh P. Acute pelvic inflammatory disease (PID), in Holmes KK, Mårdh P, Sparling PF, Wiesner PJ, Cates W, Lemon SM, Stamm W. (eds). <i>Sexually Transmitted Diseases</i>, 2nd edition. New York, McGraw-Hill Information Services Company, Health Professions Division, 1990, pp 596-613.</p> <p>2) Keith L, Berger GS. The etiology of pelvic inflammatory disease. <i>Research Frontiers in Fertility Regulation</i> 1984;3(1):1-16.</p>

Q.16. Should IUDs be provided if infection prevention measures cannot be followed?

Recommendations	Rationales
<p>a) No.</p> <p>All sites inserting and/or removing IUDs should follow basic infection prevention measures, including:</p> <ul style="list-style-type: none"> • aseptic technique (including appropriate handwashing by the provider and careful preparation of the cervix), • sterile (or high-level disinfected) IUDs and equipment, • correct decontamination of instruments, and • safe disposal of contaminated disposables. 	<p>a) The potential for infection in IUD users is increased in areas where genital tract infections (GTI) such as gonorrhea and chlamydia are prevalent. By following recommended infection prevention processes, however, health workers can minimize the risk of post-IUD insertion infection to clients and the danger of transmitting infections, even hepatitis B or AIDS, to their clients, their co-workers or themselves.</p> <p>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, p 168.</p> <p>Sterilization is the safest and most effective method for processing instruments which come in contact with the bloodstream, tissue beneath the skin or tissues which are normally sterile. When sterilization equipment is either not available or not suitable, high-level disinfection (HLD) is the only acceptable alternative. HLD destroys all microorganisms, including viruses causing hepatitis B and AIDS, but does not reliably kill all bacterial endospores. For example, in family planning facilities, either sterilization or HLD are acceptable for processing instruments and gloves used for pelvic exams and IUD insertion and removal, since problems with endospores (<i>Clostridia</i> species) have not been reported with IUD use. Regardless of the method selected, however, HLD can only be effective when used (soiled) instruments and gloves are first decontaminated, thoroughly cleaned and rinsed before disinfection.</p> <p>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, p 34.</p> <p>Contaminated wastes may carry high loads of microorganisms which are potentially infectious to any persons who contact or handle the waste. Incineration provides high temperatures and destroys microorganisms; therefore, it is the best method for disposal of contaminated wastes. Incineration also reduces the bulk size of wastes to be buried. If incineration is not possible, all contaminated wastes must be buried to prevent scattering the waste materials.</p> <p>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, p 97.</p>

Classification of Selected Procedures for Intrauterine Devices (IUDs)

Procedure	Class	Rationale
Pelvic examination (speculum and bimanual)	A	<ul style="list-style-type: none"> • Bimanual and speculum exams are mandatory before IUD use, to rule out contraindications: pregnancy, PID and endocervical infection, 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 abortion¹. • 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 PID¹. The woman and her partner(s) must be treated before considering IUD insertion.
Blood pressure	C	<ul style="list-style-type: none"> • IUD use does not affect blood pressure². • Screening for high blood pressure is part of optimal preventive health care.
Breast examination	C	<ul style="list-style-type: none"> • For all women of reproductive age or beyond, a breast exam is recommended for optimal health care. • IUD use does not cause (nor increase the risk of) breast cancer.
STD screening by history	A	<ul style="list-style-type: none"> • Assessment of STD risk by personal history and socio-demographic risk factors is an important method of identifying women at risk of PID. • Assessment of STD risk permits empiric therapy of client and presumptive treatment of partner.

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KEY:

Class A = essential and mandatory in all circumstances, for safe use of the contraceptive method

Class B = medically/epidemiologically rational in some circumstances to optimize the safe 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 related to safe use of the contraceptive method

Class D = not only unnecessary, but irrelevant to the safe use of the contraceptive method

Classification of Selected Procedures for Intrauterine Devices (IUDs) (continued)

Procedure	Class	Rationale
STD screening by lab tests (for asymptomatic persons)	C	<ul style="list-style-type: none"> • 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. • For those clients with a personal history or with socio-demographic risk factors which suggest high risk, the client who still makes an informed choice of an IUD must understand she may have an STD without any signs or symptoms. While negative STD lab tests would be reassuring in this circumstance, they will not alter the client's future STD risk.
Cervical cancer screening	C	<ul style="list-style-type: none"> • Cervical cancer screening is indicated for women at risk of cervical carcinoma, and is recommended for optimal preventive health care for women of reproductive age or beyond (particularly women at risk of STDs). <p>NOTE: Cervical cancer screening is advised for optimal preventive care for all women at risk of cervical cancer (e.g., smokers, women with partners having multiple partners, women with young age at first intercourse, etc.). All women at risk should ideally have access to a practical method of cervical cancer screening, treatment and follow-up.</p> <ul style="list-style-type: none"> • IUD insertions and continued IUD use have no known relation to the risk of acquiring cervical carcinoma³.
Routine, mandatory lab tests (e.g., cholesterol, glucose, liver function tests)	D	Irrelevant to the use of copper-releasing IUDs for contraception.

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KEY:

- Class A** = essential and mandatory in all circumstances, for safe use of the contraceptive method
- Class B** = medically/epidemiologically rational in some circumstances to optimize the safe 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 related to safe use of the contraceptive method
- Class D** = not only unnecessary, but irrelevant to the safe use of the contraceptive method

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Classification of Selected Procedures for Intrauterine Devices (IUDs) (continued)

Procedure	Class	Rationale
STD screening by lab tests (for asymptomatic persons)	B	<ul style="list-style-type: none">• 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. Although STD lab tests may not be practical or affordable in many settings, in some cases it may be reasonable to supplement screening by history and physical exam with certain lab tests, especially where the client or the provider is concerned that the client may be at risk for STDs (clients with current signs or symptoms of STDs are not eligible for IUDs). When feasible, negative test results provide reassurance to corroborate the woman's history. It is important to try to avoid the imposition of additional visits in weighing the value of such tests.• For those clients with a personal history or with socio-demographic risk factors which suggest high risk, the client who still makes an informed choice of an IUD must understand she may have an STD without any signs or symptoms.

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Classification of Selected Procedures for Intrauterine Devices (IUDs) (continued)

Procedure	Class	Rationale
<ul style="list-style-type: none"> • General counseling: <ul style="list-style-type: none"> - efficacy - common side effects - correct use of method - signs and symptoms for which to return to the clinic - STD protection (when/as appropriate) 	A	<ul style="list-style-type: none"> • Accurate client education is essential for maximum quality of family planning services. • Appropriate counseling about common contraceptive side effects at the time of method selection can lead to improved client satisfaction and contraceptive continuation⁴.
<p>Specific counseling points related to IUDs:</p> <ul style="list-style-type: none"> • Counseling concerning change in menses, including increased bleeding with copper-bearing IUDs. • High risk behavior. • Counseling about condom use for women who, under certain circumstances, might become at high risk for STDs. <p>NOTE: Women who are currently at high risk for STDs, in general should not receive IUDs.</p>	A	<ul style="list-style-type: none"> • As in pre-method choice counseling, the women should be informed that menses are normally heavier with the IUD and intermenstrual bleeding may occur, particularly post insertion. Inert IUDs approximately double normal menstrual blood loss and copper IUDs may increase it by 50%, which may be clinically significant for women who are already anemic. The more progestin an IUD releases, the more effectively it decreases menstrual blood loss⁵. • Women at risk should be counseled on high risk behavior for contracting STDs and potential complications from IUD use. Women should be instructed to return to the clinic for: abdominal pain, pain with intercourse, abnormal vaginal discharge or pelvic pain, especially with fever, or if the IUD string is missing or appears to be longer or shorter or if the client is not pleased with the method. • When condoms are used as a back-up method, counseling should be given to increase correct use and compliance. • Condoms offer the greatest potential for preventing STD spread among persons at risk for STDs. • Counseling sessions providing skill training may increase the rate of condom use.

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KEY:

- Class A** = essential and mandatory in all circumstances, for safe use of the contraceptive method
- Class B** = medically/epidemiologically rational in some circumstances to optimize the safe 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 related to safe use of the contraceptive method
- Class D** = not only unnecessary, but irrelevant to the safe use of the contraceptive method

Classification of Selected Procedures for Intrauterine Devices (IUDs) (continued)

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Appendices

Appendix A

How to Be Reasonably Sure the Woman Is Not Pregnant

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:

- has not had intercourse since last normal menses, or
- has been correctly and consistently using another reliable method, or
- is within the first 7 days after normal menses, or
- is within 4 weeks postpartum (for NON-lactating women), or
- is within the first 7 days post-abortion, or
- is fully breastfeeding, amenorrheic, and less than 6 months postpartum (see "Relying on Lactational Amenorrhea," below).

History of symptoms for pregnancy

- absent (or altered) menses,
- nausea (with or without vomiting),
- fatigue (persistent),
- breast tenderness (and breast enlargement),
- increased frequency of urination,
- 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 6 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)¹⁻³. The effectiveness of LAM in the second 6 months postpartum is under study².

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 no clinical symptoms of pregnancy. When an accurate pregnancy test is not easily available or

(continued on next page)

* "Fully" breastfeeding includes exclusive or almost exclusive breastfeeding (only occasional tastes of foods or water) day and night¹⁻³. "Nearly fully" breastfeeding means that supplemental feedings are given but comprise a minimal part of the infant's diet¹⁻³.

Appendix A (continued)

affordable, and a woman more than 6 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 8 weeks (56 days) postpartum is NOT considered "menstrual" bleeding in breastfeeding women⁴.

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- 4) Bellagio Consensus Conference on Lactational Infertility. Bellagio consensus statement in the use of breastfeeding as a family planning method. *Contraception* 1989;39(8):477-496.

** 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/day or more, or who gives more than 80% of her infant's meals as breastfeeds, is at less risk of being fertile². Breastfeeding before giving each supplement is optimal.

Appendix B
List of Abbreviations

Appendix B

List of Abbreviations

AIDS	acquired immune deficiency syndrome
CBD	community-based distribution
COC	combined oral contraceptive
CuT 380A	Copper T 380A intrauterine device
DMPA	depo-medroxyprogesterone acetate (Depo-Provera®)
EE	ethinyl estradiol
FP	family planning
GTI	genital tract infection
HIV	human immunodeficiency virus
HLD	high-level disinfection
IUD	intrauterine device
LAM	Lactational Amenorrhea Method
NET-EN	norethindrone enanthate (Noristerat®)
PID	pelvic inflammatory disease
POP	progestin-only pill
STD	sexually transmitted disease

Appendix C
Elements of Informed Choice

Appendix C

Elements of Informed Choice

Counseling is an interactive process, where the provider listens to the client's needs, tries to elicit the client's concerns, and offers relevant information to better enable the client to make decisions. The process ideally includes the provider giving a balanced presentation of the advantages and disadvantages of each method and asking the client what she understands about the choices available to her. **WHO and others have stipulated the importance of providers NOT coercing or overly emphasizing certain methods over others.**

The following is a summary of recommendations made by the International Planned Parenthood Federation based on their evaluation of the association between counseling, quality of care, and method continuation:

- 1) Counseling on contraception should be focused mainly on the essential information and discussions needed by the client to make an adequate contraceptive choice and for using the method properly and consistently.
- 2) Counseling should be restricted to the number of issues that can be properly discussed within the available time.
- 3) The amount of information provided during a counseling session should be in accordance with what the client can understand and retain in her memory. We must remember that the process of learning should be a continuous one, and that no one should be expected to learn in one counseling session more than what is reasonably possible.
- 4) Service providers must remember that every client has different needs and levels of knowledge and understanding of family planning. Therefore the focus of counseling, the counseling technique and the time spent with the client should be tailored according to the characteristics and needs of the individual client.

Further elements of informed choice have been defined by the Cooperating Agencies Task Force on Informed Choice. The following report summary is taken from: Cooperating Agencies Task Force on Informed Choice. *Informed Choice: Report of the Cooperating Agencies Task Force*. Baltimore MD, The Johns Hopkins University, 1989.

INFORMED CHOICE: REPORT OF THE COOPERATING AGENCIES TASK FORCE

July 1989

For more information or copies of this report, contact:
Dr. Phyllis T. Piotrow, Chairperson of the CA Task Force
Director
Center for Communication Programs
The Johns Hopkins University
527 St. Paul Place
Baltimore, MD 21202, USA

REPORT OF THE COOPERATING AGENCIES TASK FORCE ON INFORMED CHOICE

Executive Summary

The Cooperating Agencies Task Force on Informed Choice, consisting of representatives of 17 organizations working in international family planning programs, met in April and November 1988 and in February 1989. The following recommendations represent the consensus of the CA Task Force members regarding the most important actions needed to promote informed choice in developing countries:

Recommendation No. 1

Expanded Definition of Informed Choice

Informed choice is effective access to information on reproductive choices and to the necessary counseling, services and supplies to help individuals choose and use an appropriate method of family planning, if desired. The Cooperating Agencies Task Force broadened the definition of informed choice from a choice of family planning methods to encompass various reproductive choices, including the possibility of choosing pregnancy. Thus, informed choice begins prior to the choice of a particular method, at the time when a person first learns that there is a way to control his or her fertility.

Recommendation No. 2

Continual Process

Informed choice should be seen as a continual process as new acceptors try out one method and then shift to other methods or nonuse as their needs or preferences change.

Recommendation No. 3

Method Choices

Within each given service area, an appropriate range of contraceptive methods should be available to meet the needs of various types of contraceptive users. Available methods should include male and female methods, some reversible methods which are temporary as well as long-acting ones, and permanent methods. Program administrators should strive for "effective access," which means that, at a minimum, major groups of contraceptive methods are available in each regional area of a country.

Recommendation No. 4

Referrals

Providers that offer only one or a limited range of family planning methods should tell clients where

alternative methods are available, regardless of how distant they may be. Referral systems should be established and coordinated with providers at the local level, using written materials as appropriate.

Recommendation No. 5

Clinic Education

To complement counseling, service providers should seek to improve client education by using waiting areas for visual displays, lectures and audio-visual presentations and by providing client counselors with visual aids and audio-visual and print materials. Client education materials should be accurate, appropriate to their intended audience, and understandable.

Recommendation No. 6

Client Counseling

Each local institution should ensure that client counseling is done sensitively and effectively. The goal of counseling is to have the client arrive at a choice that he/she is satisfied with and, if the choice is to use contraception, to prepare the client to use his/her chosen method effectively. Counseling should be a two-way interaction, based on a positive relationship.

Recommendation No. 7

Monitoring and Evaluation

CAs and local institutions should build information needed for monitoring and evaluation of informed choice into their standard reporting requirements. Such information might include indicators that client counseling guidelines have been followed and service statistics on method mix and referrals (as appropriate). Evaluations should look at the structure of services, the actual delivery of services and service outcomes to assess the extent of informed choice. While CAs can provide technical support, local institutions must take primary responsibility for promoting informed choice and for monitoring service delivery sites to ensure that the appropriate steps are being taken.

Recommendation No. 8

Public Outreach

Family planning agencies should make more use of culturally sensitive mass media to reach not only potential and current contraceptive users but also others who influence reproductive decisions

such as spouses, other relatives, and policy-makers. All modes of public education such as television, radio, press, magazines, group meetings, exhibits, cultural events, folk theatre, all types of entertainment, field worker visits, inserts in contraceptive packages and point-of-purchase displays should be expanded. Whenever feasible, they should include information about specific methods.

Recommendation No. 9

Protocols for Service Delivery

Both public and private agencies in developing countries should develop national or regional guidelines on family planning methods and the client education process. Emphasis should be placed on continuous support of clients, not simply the first contact.

Recommendation No. 10

Training

Service delivery staff need to be trained in client counseling and interpersonal communication, since good counseling and a positive relationship with the client are essential to informed choice. Counseling staff should receive on-site training, assistance, supervision, and periodic evaluations. Each agency should develop or adapt from other agencies a portion of a training module specifically on informed choice. Trainers should encourage service providers to be attentive to the client's needs and life situation.

Recommendation No. 11

Male Involvement

Family planning programs need to pay more attention to the role of men in reproductive decisions and to expand male outreach programs. Many programs focus mainly on women, even though men have a major role in making family reproductive choices in many countries.

Recommendation No. 12

Family Planning and STDs, Including AIDS

The prevention and treatment of sexually transmitted diseases (STDs) is important to reproductive health. Family planning providers should offer basic STD services. In view of the widespread concern regarding acquired immune deficiency syndrome (AIDS), family planning providers should seek assistance from various sources for programs to prevent transmission of the virus that causes AIDS. These programs may include staff training, counseling, peer group activities, condom promotion and distribution, the development

of communication strategies and materials, and HIV testing (where appropriate).

Recommendation No. 13

Research Needs

More research should be conducted on various elements of informed choice, including method availability, referrals, counseling, public and clinic education, and training. Operations research can be useful to assess the most effective ways of promoting informed choice.

Recommendation No. 14

Informed Consent Requirements

While clients should make informed decisions for any contraceptive, written informed consent should be required only for voluntary sterilization, because it is intended to be (and effectively is) permanent.

Recommendation No. 15

The Role of Cooperating Agencies

CAs should review their policies and procedures in regard to informed choice, provide adequate staff training, and adopt appropriate monitoring and evaluation procedures. CAs preparing international guidelines should seek input from service providers in developing countries.

Recommendation No. 16

AID Support to CAs

AID should provide CAs with up-to-date, accurate information pertaining to informed choice, especially in key areas such as contraceptive safety and efficacy and AIDS prevention.

The Task Force concluded that much progress has been made in promoting informed choice and that future initiatives may depend upon correcting erroneous assumptions about informed choice. In fact, the stereotypical activities associated with informed choice—boring lectures, lengthy forms and rigid guidelines—may have little to do with helping the client to make and implement choices, to understand and remember pertinent information, and to feel comfortable seeking additional information or services, as needed.

Family planning and health care professionals need to understand that implementation of programs to promote informed choice will make their job easier, not harder. Satisfied users are not only the key to high continuation rates but also the most effective promoters of family planning.

Appendix D

- 1) ***Participants' and Reviewers' Organizations**
- 2) ***The Subgroup Responsible for Incorporating Reviewers' Feedback**
- 3) ***Participants in the November 24, 1992 Meeting**
- 4) ***Reviewers**

NOTE: This document was greatly enriched and informed by the diversity of view points expressed by the 33 participants who attended the November 1992 meeting, and by the 61 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 by the 14 members of a subgroup responsible for incorporating this input. As with any endeavor involving such a large number of experts, unanimity on every point was impossible. Overall, the concepts of the original 1992 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

Participants' and Reviewers' Organizations

ACNM = American College of Nurse Midwives
ARHP = Association of Reproductive Health Professionals
AVSC International
BIRPERHT, Bangladesh
CARE
CARE International
CDC = Centers for Disease Control and Prevention
CEDPA = The Centre for Development and Population Activity
CONRAD
CPFH = Center for Population and Family Health, Columbia University
Family Planning Program, Emory University
FHI = Family Health International
FPASL = Family Planning Association of Sri Lanka
Futures Group/Options Project
ICMER = Instituto Chileno de Medicina Reproductiva, Chile
Instituto Nacional de la Nutrición, México
Instituto Nacional de Perinatología, México
INTRAH, UNC-CH = Program for International Training in Health, University of North Carolina at Chapel Hill, USA, Kenya and Togo
IPAS = International Projects Assistance Services
IPPF = International Planned Parenthood Federation
IPPF WHR = International Planned Parenthood Federation - Western Hemisphere Region
IRH = Institute for Reproductive Health, Georgetown University
JHPIEGO
The R.W. Johnson Pharmaceutical Research Institute
Karolinska Hospital, Sweden
Ministry of Health, Uganda
National Family Planning Program, Ministry of Health, Tanzania
PATH = Program for Appropriate Technology in Health
Pathfinder International, USA and México
PIP = Population Information Program, Center for Communication Programs
The Population Council
The Population Council/CEMICAMP, Brazil

Participants' and Reviewers' Affiliations (continued)

Profamilia, Dominican Republic

The Profit Project, Boston University

Sborml Hospital and Maternity, Nigeria

School of Public Health, University of California at Berkeley

SEATS/JSI = Family Planning Service Expansion and Technical Support Program/John Snow, Inc., USA, Côte d'Ivoire, Rwanda, Zimbabwe

South to South Corporation in Reproductive Health, Brazil

UMATI, Tanzania

UNFPA = United Nations Population Fund

Universite Libre de Bruxelles, Belgium

University of California - San Francisco (UCSF), Schools of Medicine and Public Health

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

USFDA = United States Food and Drug Administration

WHO = World Health Organization

The Secretariat of the Technical Guidance Working Group wishes to thank the Division of Family Health and the Special Programme of Research, Development and Research Training in Human Reproduction of the World Health Organization (WHO) for their review of this document; all of the recommendations made by WHO which are within the scope of this document have been made. The recommendations in this document are also consistent with the WHO's August 1994 draft of Medical Eligibility Criteria*, which is the preliminary result of a WHO-led effort to update family planning medical eligibility criteria to reflect current clinical and epidemiologic knowledge.

* World Health Organization. *Improving Access to Quality Care in Family Planning; Eligibility Criteria for Initiating Use of Selected Methods of Contraception: Combined Oral Contraceptives, Progestogen Only Contraceptives, DMPA, Norplant and Copper IUDs*. Revised Draft August 8, 1994. Geneva, WHO, 1994.

The Subgroup Responsible for Incorporating Reviewers' Feedback

NOTE: Alphabetized by organizational
name

Rebecca Ponce de Leon, MD, PhD
**CDC (Centers for Disease Control
and Prevention)**
MS K34
4770 Buford Highway, NE
Atlanta, GA 30341-3724

Susan Allen, MD, MPH
CONRAD
1611 N. Kent Street
Suite 806
Arlington, VA 22209

Roberto Rivera, MD
Corporate Director of International Medical
Affairs
FHI (Family Health International)
P.O. Box 13950
Research Triangle Park, NC 27709

Marcia Angle, MD, MPH
Clinical Officer
**INTRAH, UNC-CH (Program for
International Training in Health)**
208 N. Columbia St.
Chapel Hill, NC 27514

Patricia Bright, MSPH
Research Assistant
INTRAH, UNC-CH
208 N. Columbia St.
Chapel Hill, NC 27514

Kathryn Curtis, MSPH
Research Assistant
INTRAH, UNC-CH
208 N. Columbia St.
Chapel Hill, NC 27514

Carlos Huezo, MD
Head, Medical Programmes
**IPPF (International Planned
Parenthood Federation)**
Regent's College
Inner Circle, Regent's Park
London, England NW1 4NS

Douglas Huber, MD, MSc
Director of Medical Services
Pathfinder International
Nine Galen Street
Watertown, MA 02172

Anibal Faúndes, MD
The Population Council/CEMICAMP
Caixa Postal 6181
13081/970
Campinas, SP, Brazil

Fernanda Kaplan, MD
The Profit Project/Boston University
Deloitte and Touche
The Waterview Building
1925 N. Lynn Street, Suite 601
Arlington, VA 22209

James Shelton, MD, MPH
Acting Deputy Director, Office of Population
**USAID/W (United States Agency for
International
Development/Washington)
G/RD/POP**
Room 820, SA-18
Washington, DC 20523-1819

Roy A. Jacobstein, MD, MPH
Chief, Communication, Management and
Training Division
USAID/W G/RD/POP/CMT
Room 811, SA-18
Washington, DC 20523

Anne Wilson, MSN
Senior Research Investigator, University of
Michigan
USAID/W G/RD/POP/FPSD
Room 809, SA-18
Washington, DC 20523-1819

Ms. Jennifer S. Smith
Family Health International Fellow
USAID/W G/RD/POP/R
Washington, DC 20523-1819

Participants in the November 24, 1992 Meeting

NOTE: Alphabetized by organizational name

Betty L. Farrell, CNM, MPH
ACNM (American College of Nurse Midwives)
818 Connecticut Avenue, NW
Washington, DC 20006

Amy Pollack, MD, MPH
Medical Director
AVSC International
79 Madison Avenue
New York, NY 10016

Cynthia Steele Verme, MA
Director of Special Programs
AVSC International
79 Madison Avenue
New York, NY 10016

Maurice Middleburg, MS
Population Consultant
CARE
151 Ellis Street
Atlanta, GA 30303

Herbert Petersen, MD, MPH
Chief of Women's Health & Fertility Branch
CDC (Centers for Disease Control and Prevention)
MS K34
4770 Buford Highway, NE
Atlanta, GA 30341-3724

Celia Woodfill, PhD
Medical Epidemiologist, EIS
CDC
Division of STD/HIV Prevention
1600 Clifton Road, Mail Stop E-63
Atlanta, GA 30333

Mary Luke, RN, MPH
Director of Programs
CEDPA (The Centre for Development and Population Activity)
1717 Massachusetts Avenue, NW
Suite 202
Washington, DC 20036

Khadijat Mojidi, MCP (MCH)
Deputy Director, Programs Division
CEDPA
1717 Massachusetts Avenue, NW
Suite 202
Washington, DC 20036

Allen Rosenfield, MD, MPH
Dean, School of Public Health
**CPFH (Center for Population and Family Health),
Columbia University**
60 Haven Avenue
New York, NY 10032

Robert Hatcher, MD, MPH
Professor, Department of Ob/Gyn
Director, **Family Planning Program,
Emory University School of Medicine**
69 Butler Street, SE
Atlanta GA 30303

Karen Hardee, PhD
Senior Research Associate
FHI (Family Health International)
P.O. Box 13950
Research Triangle Park, NC 27709

Susan Palmore, MA
Director
Division of Field Development and Training
FHI
P.O. Box 13950
Research Triangle Park, NC 27709

Roberto Rivera, MD
Corporate Director of International Medical Affairs
FHI
P.O. Box 13950
Research Triangle Park, NC 27709

Kokila Agarwal, MD
Senior Research Scientist
Futures Group/Options Project
1050 - 17th Street, Suite 100
Washington, DC 20005

Participants in November 24, 1992 Meeting (continued)

Marcia Angle, MD, MPH
Clinical Officer
**INTRAH, UNC-CH (Program for
International Training in Health,
University of North Carolina -
Chapel Hill)**
208 N. Columbia St.
Chapel Hill, NC 27514

Kate Curtis, MSPH
Research Assistant
INTRAH, UNC-CH
208 N. Columbia St.
Chapel Hill, NC 27514

Carlos Huezo, MD
Head, Medical Programmes
**IPPF (International Planned
Parenthood Federation)**
Regent's College
Inner Circle, Regent's Park
London, England NW1 4NS

Miriam Labbok, MD, MPH
Director, International Breastfeeding
Collaborating Centre (WHO)
**IRH (Institute for Reproductive
Health),**
Georgetown University
Ob/Gyn Department, 3 PHC
3800 Reservoir Road, NW
Washington, DC 20007

Paul Blumenthal, MD
Medical Adviser
JHPIEGO Corporation
Brown's Wharf
1615 Thames Street, Suite 200
Baltimore, MD 21231

Monica Kerrigan, MPH
Associate Director for Africa
JHPIEGO Corporation
Brown's Wharf
1615 Thames Street, Suite 200
Baltimore, MD 21231

Noel McIntosh, MD, ScD
President
JHPIEGO Corporation
Brown's Wharf
1615 Thames Street, Suite 200
Baltimore, MD 21231

Douglas Huber, MD, MSc
Director of Medical Services
Pathfinder International
Nine Galen Street
Watertown, MA 02172

Ward Rinehart, MA
Editor, Population Reports
**PIP (Population Information
Program, Center for
Communication Programs)**
527 St. Paul Place
Baltimore, MD 21202-2284

Robert Miller, PhD
Associate, OR Dissemination
The Population Council
One Dag Hammarskjold Plaza
New York, NY 10017

Malcolm Potts, MD, MB, BChir, PhD
Professor of Population and Family Planning
Department of Social and Administrative
Health Sciences
International Health Office
School of Public Health,
University of California at Berkeley
Berkeley, CA 94704

Nancy Harris, MPH
Director, SEATS
**SEATS/JSI (Family Planning Service
Expansion and Technical Support
Project/John Snow, Inc.)**
1616 N. Fort Myer Drive, 11th Floor
Arlington, VA 22209

James Shelton, MD, MPH
Acting Deputy Director, Office of Population
**USAID/W (United States Agency for
International
Development/Washington)**
G/RD/POP
Room 820, SA-18
Washington, DC 20523-1819

Participants in November 24, 1992 Meeting (continued)

Roy A. Jacobstein, MD, MPH
Chief, Communication, Management and
Training Division
USAID/W G/RD/POP/CMT
Room 811 SA-18
Washington, DC 20523

Bonnie Pedersen, RN, CNM, MPH
Public Health Advisor,
USAID/W G/RD/POP/FPSD
Room 811 SA-18
Washington, DC 20523

Anne Wilson, MSN
Senior Research Investigator, University of
Michigan
USAID/W G/RD/POP/FPSD
Room 809, SA-18
Washington, DC 20523-1819

Felice M. Apter, PhD
AAAS Science, Engineering & Diplomacy
Fellow
USAID/W G/RD/POP/R
Room 820, SA-18
Washington, DC 20523-1819

Ms. Jennifer S. Smith
Family Health International Fellow
USAID/W G/RD/POP/R
Washington, DC 20523-1819

Lisa Rarick, MD
Medical Officer, Fertility and Maternal Health
Drugs
**USFDA (United States Food and
Drug Administration)**
Division of Metabolism and Endocrine Drug
Products
5600 Fishers Lane - HFD-510
Rockville, MD 20857-1706

Reviewers

NOTE: Alphabetized by organizational name

Betty L. Farrell, CNM, MPH
ACNM (American College of Nurse Midwives)
818 Connecticut Avenue, NW
Washington, DC 20006

Louise B. Tyrer, MD
Medical Director
ARHP (Association of Reproductive Health Professionals)
549 Lakeshore Boulevard, #7
Incline Village, NV 89451

Karen Beattie, MA
Quality Services Coordinator
AVSC International
79 Madison Avenue
New York, NY 10016

Amy Pollack, MD, MPH
Medical Director
AVSC International
79 Madison Avenue
New York, NY 10016

Gilberte Vansintejan, EdD, MPH, RN, MW
Medical Technology Advisor
AVSC International
79 Madison Avenue
New York, NY 10016

Cynthia Steele Verme, MA
Director of Special Programs
AVSC International
79 Madison Avenue
New York, NY 10016

Halida H. Akhter, MD
Director
BIRPERHT
25 Shymoli, Mirpur Road
GPO Box 279
Dhaka, 207 Bangladesh

Mary Vandembroucke, RN, MPH
CARE International
P.O. Box 6034
La Paz, Bolivia

Herbert Petersen, MD, MPH
Chief of Women's Health & Fertility Branch
CDC (Centers for Disease Control and Prevention)
MS K34
4770 Buford Highway, NE
Atlanta, GA 30341-3724

Mary Luke, RN, MPH
Director of Programs
CEDPA (The Centre for Development and Population Activity)
1717 Massachusetts Avenue, NW
Suite 202
Washington, DC 20036

Susan Allen, MD, MPH
CONRAD
1611 N. Kent Street
Suite 806
Arlington, VA 22209

Allen Rosenfield, MD, MPH
Dean, School of Public Health
**CPFH (Center for Population and Family Health),
Columbia University**
60 Haven Avenue
New York, NY 10032

Robert Hatcher, MD, MPH
Professor, Department of Ob/Gyn
Director, **Family Planning Program,
Emory University School of Medicine**
69 Butler Street, SE
Atlanta GA 30303

Karen Hardee, PhD
Senior Research Associate
FHI (Family Health International)
P.O. Box 13950
Research Triangle Park, NC 27709

Linda Potter, DrPH
Principal Research Scientist
Contraceptive Use and Epidemiology
Division
FHI
P.O. Box 13950
Research Triangle Park, NC 27709

Reviewers (continued)

Pamela Schwingl, PhD
Epidemiologist
FHI
P.O. Box 13950
Research Triangle Park, NC 27709

Sriani Basnayake, MD
Medical Director
**FPASL (Family Planning Association
of Sri Lanka)**
37/27 Bullers Lane
P.O. Box 365
Colombo 7, Sri Lanka

Horacio B. Croxatto, MD
**ICMER (Instituto Chileno de
Medicina Reproductiva)**
José Ramón Gutiérrez 295, Depto. 3
Correo 22, Casilla 96
Santiago, Chile

Kokila Agarwal, MD
Senior Research Scientist
Futures Group/Options Project
1050 - 17th Street, Suite 100
Washington, DC 20005

Rebecca Massai, MD
Associate Investigator
ICMER
José Ramón Gutiérrez 295, Depto. 3
Correo 22, Casilla 96
Santiago, Chile

Soledad Díaz, MD
Consultorio de Planificación Familiar
ICMER
José Ramón Gutiérrez 295, Depto. 3
Correo 22, Casilla 96
Santiago, Chile

Josué Garza-Flores, MD
Instituto Nacional de la Nutrición
Calle Vasco de Quiroga 15
Delegación Tlalpan
14000 México, D.F.

Ramon Aznar Ramos, MD
Jefe Depto. Planificación Familiar
Instituto Nacional de Perinatología
Montes Urales 800 Lomas de Virreyes
México, D.F. C.P. 11000

Martha Carlough, MD, MPH
Tri-County Community and Migrant Health
Center
Consultant, **INTRAH, UNC-CH**
208 N. Columbia St.
Chapel Hill, NC 27514

Grace Mtawali, RN, SCM, PHN
Clinical Program Officer
**INTRAH Regional Office for
Anglophone Africa**
P.O. Box 55699
Nairobi, Kenya

Manuel Pina, MD
Clinical Officer
**INTRAH Regional Office for
Francophone and Lusophone
Africa**
B.P. 12356
Lomé, Togo

Ann Leonard, RN, MSPH
Vice President for International Programs
**IPAS (International Projects
Assistance Services)**
P.O. Box 100
Carrboro, NC 27510

Judith Winkler, MEd
Director of Communications
IPAS
P.O. Box 100
Carrboro, NC 27510

Marcos Arévalo, MD
Quality of Care Advisor
**IPPF WHR (IPPF Western
Hemisphere Region)**
902 Broadway, 10th Floor
New York, NY 10010

Miriam Labbok, MD, MPH
Director, International Breastfeeding
Collaborating Centre (WHO)
**IRH (Institute for Reproductive
Health),
Georgetown University**
Ob/Gyn Department, 3 PHC
3800 Reservoir Road, NW
Washington, DC 20007

Reviewers (continued)

Paul Blumenthal, MD
Medical Adviser
JHPIEGO Corporation
Brown's Wharf
1615 Thames Street, Suite 200
Baltimore, MD 21231

Noel McIntosh, MD, ScD
Director
JHPIEGO Corporation
Brown's Wharf
1615 Thames Street, Suite 200
Baltimore, MD 21231

Gray S. Grubb, MD, MPH
Associate Director
**The R.W. Johnson Pharmaceutical
Research Institute**
Route 202, P.O. Box 300
Raritan, NJ 08869-0602

Professor Kerstin B. Hagenfeldt
Associate Professor
Department of Obstetrics & Gynaecology
Karolinska Hospital
104.01 Stockholm, SWEDEN

Florence A. Oryem-Ebanyat, MD
Assistant Commissioner for Medical
Services, MCH/FP
**Ministry of Health, Uganda and
Fellow, The Evaluation Project
Carolina Population Center**
University of North Carolina at Chapel Hill
CB # 8120, University Square
Chapel Hill, NC 27516-3997

A.T. Kapesa, MD
Obstetrician/Gynaecologist
c/o Miss Naomi Goko, INTRAH Resident
Trainer
**National Family Planning Program,
Ministry of Health**
Commission of Science & Technology Bldg.
Bagamsyo Road
Dar-es-Salaam, Tanzania

Elaine Murphy, PhD
Senior Program Advisor
Communications Department
**PATH (Program for Appropriate
Technology in Health)**
Suite 700, 1990 M Street, NW
Washington, DC 20036

Ms. Carol Corso
Director
Communications Department
PATH
Suite 700, 1990 M Street, NW
Washington, DC 20036

Carlos E. Cardenas, MD
Regional Medical Director for Latin America
Pathfinder International
Ximilpa #5 Esq. Congress
Thalpan México D.F. México

Martha Brady, MPH
The Population Council
One Dag Hammarskjold Plaza
New York, NY 10017
(reflects thoughts of Beverly Winikoff and
Barbara Mensch also)

Juan Diaz, MD
Associate
The Population Council
One Dag Hammarskjold Plaza
New York, NY 10017

Juan Diaz (second address)
Ruberley Boaretto da Silva 839
Bairro Cidade Universitaia
CEP 13083
Campinas, Sao Paulo, BRAZIL

Attn: Emma Ottolenghi, MD
(formerly Clinical Officer at
Development Associates, Inc.)
c/o Guatemala Pouch
The Population Council
GUA 107
P.O. Box 02-5368
Miami, FL 33102

Reviewers (continued)

Anibal Faúndes, MD
The Population Council/CEMICAMP
Caixa Postal 6181
13081/970
Campinas, SP, Brazil

Frank Alvarez, MD
Medical Director
Profamilia, Asociación Dominicana
Center for Biomedical Research
Pro-Bienestar de la Familia, Inc.
Calle Socorro Sánchez #64
Apartado Postal 1053
Gascué
Santo Domingo, Dominican Republic

Irogbenachi Ezuma, MBBS
Medical Director
Sborml Hospital and Maternity
Box 406
Anambra State, Nigeria

Nancy Harris, MPH
Director, SEATS
SEATS/JSI (Family Planning Service
Expansion and Technical Support
Project/John Snow, Inc.)
1616 N. Fort Myer Drive, 11th Floor
Arlington, VA 22209

Muteba Mwamba, MD
Resident Advisor
SEATS/JSI
17 BP 307
Abidjan, Cote d'Ivoire

Marcel Vekemans, MD
Resident Advisor
SEATS/JSI
ONAPO (National Office of Population)
Kigali, Rwanda

Ndungu Wamburu, MD
Medical Advisor
SEATS East/South Africa, JSI (John
Snow, Inc.)
(c/o Bonnie Pedersen)
Public Health Advisor,
USAID/W G/RD/POP/FPSD
Room 811 SA-18
Washington, DC 20523

Lynette Malianga, RN
Regional Training Specialist
SEATS East/South Africa, JSI
P.O. Box 308B
Harare, Zimbabwe

O.A. Ladipo, MD
Executive Secretary and Program Director
South to South Corporation in
Reproductive Health
Rua Caetano Moura 35, Federação
40210 Salvador
Bahia, Brazil

Adatus T. Kapesa, MD
Department of Obstetrics and Gynecology
UMATI
P.O. Box 65133
Dar-es-Salaam, Tanzania

Anatole D. Rukonge, MD
Obstetrician Gynecologist
UMATI
Corner of Samora Avenue and Zanaki Street
Box 1372
Dar-es-Salaam, Tanzania

Charlotte Gardiner, MD
Technical Officer, MCH/FP Branch
Technical and Evaluation Division
UNFPA (United Nations Population
Fund)
220 East 42nd Street
New York, NY 10017

Pierre Buekens, MD, PhD
Research Associate, National Fund for
Scientific Research
Universite Libre de Bruxelles
School of Public Health
Route de Lennik 808
B-1070 Brussels, Belgium

Philip D. Darney, MD, MSc, Prof. in
Residence
University of California - San
Francisco
San Francisco General Hospital, Ob/Gyn
Ward 6D, 1001 Potrero Avenue
San Francisco, CA 94110

Reviewers (continued)

Lucy Mize, RN, MPH
CTO, Communication, Management and
Training Division
**USAID/W (United States Agency for
International
Development/Washington)
G/RD/POP/CMT**
Room 811, SA-18
Washington, DC 20523

Bonnie Pedersen, RN, CNM, MPH
Public Health Advisor,
USAID/W G/RD/POP/FPSD
Room 811 SA-18
Washington, DC 20523

Lisa Rarick, MD
Medical Officer, Fertility and Maternal Health
Drugs
**USFDA (United States Food and
Drug Administration)**
Division of Metabolism and Endocrine Drug
Products
5600 Fishers Lane - HFD-510
Rockville, MD 20857-1706

Joseph Kierski, MD
Medical Officer
Division of Family Health
WHO (World Health Organization)
CH-1211 Geneva 27, Switzerland

Leila Mehra, MD, DMCW, MPH
Senior Advisor
Division of Family Health
WHO
20, Avenue Appia
CH-1211 Geneva 27, Switzerland

Catherine D'Arcangues, MD
Special Programme of Research,
Development and Research Training in
Human Reproduction
WHO
CH-1211 Geneva 27, Switzerland

Suman Mehta, MD
Medical Officer
Special Programme of Research,
Development and Research Training in
Human Reproduction
WHO
CH-1211 Geneva 27, Switzerland

Olaf Meirik, MD
Special Programme of Research,
Development and Research Training in
Human Reproduction
WHO
CH-1211 Geneva 27, Switzerland

Patrick Rowe, MBBS, FRCOG
Medical Officer
Special Programme of Research,
Development and Research Training in
Human Reproduction
WHO
CH-1211 Geneva 27, Switzerland

Appendix E
Acknowledgments

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Acknowledgments

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Appendix E (continued)

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