

Summary of:

**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*

March 1995

This document is a summary of *Recommendations for Updating Selected Practices in Contraceptive Use: Results of a Technical Meeting, Volume I: Combined Oral Contraceptives, Progestin-Only Injectables, NORPLANT® Implants, and Copper-Bearing Intrauterine Devices*, which is the product of a technical meeting of representatives of many USAID Cooperating Agencies, who convened to draft initial recommendations on selected procedural and service guidelines. The initial draft was subsequently reviewed and augmented by numerous international experts in family planning.

The document recommends procedural steps for administration of selected hormonal methods and IUDs based on the current clinical and epidemiological evidence.

These recommendations are intended to provide guidance for persons and organizations who are developing, updating or revising family planning procedural and service guidelines.

While the attached summary includes only the questions and recommended responses for many procedural issues for contraceptive use, the complete document includes detailed rationales and citations to support these recommendations.

Copies of the complete document are available in Spanish (courtesy of JHPIEGO through USAID funds) and in French and English (courtesy of INTRAH through USAID funds).

This summary 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.

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.
- 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.

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

March 1995

* 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.

Table of Contents

	Page
III. Combined Oral Contraceptives (COCs).....	1
IV. Progestin-Only Injectables.....	9
V. NORPLANT® Implants.....	17
VI. Copper-Bearing Intrauterine Devices (IUDs).....	25
Appendix A: How to Be Reasonably Sure the Woman Is Not Pregnant.....	33

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

- 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).

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

- 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.

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
- a back-up method (or abstinence) should be used for 7 days.

(For information concerning need for back-up method see Q.7.)

- 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.

Q.2.
When can COCs be started postpartum?

Recommendations

For Breastfeeding Women: (These restrictions do not apply to women who are only doing token, i.e., minimal, breastfeeding.)

- 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.

(continued on next page)

Q.2.
When can COCs be started postpartum?
(continued)

Recommendations

- 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).
 - 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.
- ** In breastfeeding women, bleeding in the first 56 days (8 weeks) postpartum is NOT considered "menstrual" bleeding, because it is not preceded by ovulation.
- 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).

For Non-Breastfeeding Women:

- a) If not breastfeeding, a woman can begin COCs after the second to third postpartum week.

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

Recommendations

- 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).
- b) If a client has a history or current indication of excessive clotting (coagulopathy), COCs should **not** be recommended.

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

Recommendations

- 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.
- 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.
- 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.
- 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.**
- 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.

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

Recommendations

- 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 *optimal*, if she has a reliable alternative method.

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

Recommendations

COCs may be used at any age at which the woman is at risk of pregnancy (e.g., past menarche and through menopause).

- a) Women over age 40 can take COCs, provided other risk factors have been considered (e.g., smoking, high blood pressure, diabetes).
- b) Use of COCs does not compromise future fertility.

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

Recommendations

- a) If the client is taking **antibiotics**?
No — except rifampin or griseofulvin (an antifungal medication).
- b) If the client is taking **anticonvulsants** (except valproic acid)?
Use of one of the following may be necessary:
- 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).
- 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.
- 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).
- 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).
- f) If the client is taking **anti-malarial medication**?
No back-up is needed.

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

Recommendations

a) No.

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).

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.

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.

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

- 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).
- 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).
- 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 initiation and Q.3. for post-abortion initiation.)

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

Recommendations

For Breastfeeding Women:

- 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).

* 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.

- b) If she does not want to rely on LAM, ideally wait at least 6 weeks postpartum to initiate injectable progestins.

For Non-Breastfeeding Women:

- 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).

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).

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

Recommendations

- 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.

Older Women:

- b) Injectable progestins may be used by women through menopause. Risks for use of injectable progestins for older women appear minimal.

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.

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

Recommendations

- 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.

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

- 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.

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

Recommendations

- 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.
- 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.)

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

Recommendations

- a) For DMPA (150 mg), on a 3-month schedule, it is acceptable to give the next injection:
- 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.
- b) For NET-EN, on a 2-month schedule, it is acceptable to give the next injection:
- 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.

(continued on next page)

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

Recommendations

- 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 *in utero* 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).

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

Recommendations

Not usually. Irregular and prolonged bleeding episodes are common and expected in the first 3 to 6 months of use.

- 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.

If counseling and reassurance are not sufficient for the woman and she wishes to continue the method, the following management approaches may be tried:

- 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.

- 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.
- c) If suspected, abnormal conditions which cause prolonged or heavy bleeding should be evaluated and treated as appropriate.
- d) Some prolonged or heavy bleeding may fail to be corrected and injections may need to be discontinued.

(continued on next page)

14

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

Recommendations

- e) Evaluate and address anemia if indicated. Give nutritional advice on the need to increase the intake of iron-containing foods.
- 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

- 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.

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

Recommendations

- a) No.
All sites providing progestin-only injectable contraceptives should consistently follow basic infection prevention measures, including:
 - 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.

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

- 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).
- 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).
- 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.)

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

Recommendations

For Breastfeeding Women:

- 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).

* 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.

- 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.

(continued on next page)

Q.2.
Are progestin-only
injectables appropriate for
use immediately post-
abortion?
(continued)

Recommendations

- 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).

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

Recommendations

- 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).

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

Recommendations

- 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).

Older Women:

- b) NORPLANT® Implants may be used by women through menopause.

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.

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

Recommendations

- a) No:
- If possible, handle all counseling and screening on the same day as the insertion.
 - A routine system of pre-exam visits is not necessary.

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

Recommendations

- a) **Encourage** the client to call or return to local provider if problems arise.
- b) A visit within the first 1 to 3 months may be advised if additional counseling is necessary or to check the insertion site.
- 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.
- d) Visits are encouraged for other preventive reproductive health care as available, including provision of condoms, when appropriate.

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

Recommendations

Not usually. Irregular and even prolonged bleeding episodes are common and expected especially in the first 3 to 6 months of NORPLANT® Implant use.

- 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.

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:

- short term (for 7 to 21 days) COCs or estrogen or
 - ibuprofen (or similar non-steroidal anti-inflammatories other than aspirin).
- 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.

(continued on next page)

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

Recommendations

- c) If suspected, abnormal conditions which cause prolonged or heavy bleeding should be evaluated and treated as appropriate.
- 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.
- e) Evaluate and address anemia, as appropriate. Give nutritional advice on the need to increase the intake of iron containing foods.
- f) **Do not** perform uterine evacuation unless another medical condition is suspected (vacuum aspiration is generally the preferred method of uterine evacuation).

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

Recommendations

- a) There are no known weight limits for NORPLANT® Implants use.

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

Recommendations

- 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.

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

Recommendations

a) No.

All centers inserting and/or removing NORPLANT® Implants should follow basic infection prevention measures, including:

- 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.

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

- 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).

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

The IUD is effective immediately.

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

Recommendations

An IUD may be inserted:

- a) Immediately post-placental, or during or immediately after a Cesarean-section (special training required).
- b) Prior to hospital discharge (up to 48 hours after delivery) (special training required).
- c) As early as 4 to 6 weeks postpartum, to accomodate 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.
- d) In breastfeeding women.

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

Recommendations

- 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).
- b) IUDs should not be inserted in the following situations:
- 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).

(continued on next page)

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

Recommendations

- 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.

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

Recommendations

- a) There should be one follow-up visit **approximately** one month after insertion; thereafter, there is no need for a fixed follow-up schedule.
- b) The client should be strongly encouraged to come to the clinic anytime she has questions or problems, particularly if she has:
 - 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.
- c) Visits are encouraged for other preventive reproductive health care as available, including provision of condoms, when appropriate.

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

Recommendations

- a) No. If at all possible, handle all counseling and screening the same day as the insertion.

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

Recommendations

- a) There is no minimum or maximum age, as long as the woman is at risk of pregnancy.
- 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).

Q.7.
**Can nulliparous
women receive
IUDs??**

Recommendations

- 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.

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

- a) If a woman wants a new IUD when an old one has expired, no rest period is needed.
- b) IUD removal is indicated if:
 - 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).

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

- 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.).
- b) Make sure removal of the first IUD is indicated (i.e., for reasons of partial expulsion without infection or expiration of the IUD).

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

- 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).
- 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.

* NOTE: Not all clinically-apparent vaginal infections are due to STDs.

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

Recommendations

Not necessarily.

- a) Counsel – explain to the woman and/or her partner what the partner is feeling and recommend they try again.
- b) Describe to the client her other options (and their disadvantages):
 - 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.

OR

(continued on next page)

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

Recommendations

- Offer to remove the IUD, if other options are not acceptable.
- 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.

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

- 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).

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

Not necessarily.

- 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.

Give nutritional advice on the need to increase the intake of iron-containing foods.
- 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.
- c) Bleeding generally decreases over time. If bleeding is heavy or the woman is anemic, treatment using oral iron can improve hemoglobin levels.
- d) If bleeding or pain is severe, or the client wishes to discontinue use, remove the IUD.

(continued on next page_

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

Recommendations

- e) If suspected, abnormal conditions which cause prolonged or heavy bleeding should be evaluated and treated as appropriate.
- 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).

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

Recommendations

- 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.

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

Recommendations

- 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).

If she remains at increased risk of PID, advise against IUD use.

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

Recommendations

- a) No.

All sites inserting and/or removing IUDs should follow basic infection prevention measures, including:

- 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.

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.

- 1) Lobbok M, Cooney K, Coly S. Guidelines: Breastfeeding, Family Planning, and the Lactational Amenorrhea Method - LAM. Washington, DC: Institute for Reproductive Health, 1994.
- 2) Lobbok MH, Perez A, Valdes V, Sevilla F, Wade K, Laukaran VH, Cooney KA, Coly S, Sanders C, Queenan JR. The Lactational Amenorrhea Method (LAM): A postpartum introductory family planning method with policy and program implications. *Advances in Contraception* 1994;10:93-109.
- 3) Lobbok M, Krasovec K. Toward consistency in breastfeeding definitions. *Studies in Family Planning* 1990;21:226-230.
- 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.

31

ORDER FORM

Recommendations for Updating Selected Practices in Contraceptive Use, Volume I: Combined Oral Contraceptives, Progestin-Only Injectables, NORPLANT® Implants, Copper-Bearing IUDS

Shipping information:

Name: _____

Organization: _____

Address: _____

Telephone: _____

Number of copies	Language	Unit Price*	Extended Price
	English	\$9.00	
	French	\$9.00	
	Spanish	\$9.00	
Total			

Ordering information:

*Single copies are free of charge to individuals and local agencies in developing countries from INTRAH or JHPIEGO (depending on the language you are requesting).

Copies are available to persons/organizations in developed countries for \$9.00 per copy. Price includes shipping and handling. Prepayment is required in US dollars. Make check or money order payable to:

UNIVERSITY of NORTH CAROLINA (for English and French editions) or
JHPIEGO Corporation (for Spanish edition)

Send orders to:

English and/or French edition	Spanish edition
INTRAH Publications Program University of North Carolina School of Medicine 208 N. Columbia St., CB #8100 Chapel Hill, NC 27514, USA Fax: 919-966-6816	JHPIEGO Corporation Materials Division Brown's Wharf 1615 Thames Street, Suite 200 Baltimore, MD 21231-3447, USA Fax: 410-614-0586

Thank you for your order

32 ✓