Chapter 6

Progestin-Only Injectable Contraceptives

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Guidelines for Clinical Procedures in Family Planning: A Reference for Trainers, Chapter 6: Progestin-Only Injectable Contraceptives

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CHAPTER 6

PROGESTIN-ONLY INJECTABLE CONTRACEPTIVES

This chapter focuses on the clinic-based administration of progestin-only injectable contraceptives. For both clinic-based and (where applicable) community-based administration of progestin-only injectables, the principles of informed choice, screening for method appropriateness, and careful infection prevention procedures must be followed. Where progestin-only injectables are provided through non-clinic-based programs, the distributor should have checklists to assure that these procedures are followed and that clients are referred as necessary to a clinic for further evaluation or management of side effects. These referred clients, as well as clients who prefer to use clinic-based services, are the clients discussed in this chapter.

The two most commonly available progestin-only injectable contraceptives are DMPA (depo-medroxyprogesterone acetate, Depo Provera®), and NET-EN (norethindrone enanthate, Noristerat®). Some parts of this chapter give slightly more emphasis to DMPA because of the greater amount of published research data on its use.

STEP 1
Discuss the client's past experience with progestin-only injectable contraceptives

If the client has <u>ever</u> used progestin-only injectable contraceptives, such as DMPA (Depo Provera®) or NET-EN (Noristerat®):

- how long did the client use progestin-only injectable contraceptives?
- was the client satisfied with progestin-only injectable contraceptives (e.g., availability, convenience, side effects or other problems, pregnancy)?
- why did the client stop using progestin-only injectable contraceptives?

If the client has <u>never</u> used progestin-only injectable contraceptives:

- has the client ever discussed progestin-only injectable contraceptives with her partner or friends or relatives?
- does the client know anyone using progestin-only injectable contraceptives?
- does the client think her partner or other persons would disapprove? If so, would this keep her from accepting progestin-only injectable contraceptives?

If the client has heard rumors about progestin-only injectable contraceptives, the following may help correct mistaken ideas:

RUMOR: A woman who uses progestin-only injectables will not be able to get pregnant again.

FACT: On average, it will take about 4 months longer for a woman who has stopped using DMPA to get pregnant than for a woman who has stopped using pills, IUDs, or barrier methods. However, in a few cases it can take longer, up to 1 to 2 years. Despite possible delay, reversibility is total.

RUMOR: Progestin-only injectable contraceptives cause cancer.
FACT: Current research does **not** show that progestin-only injectables cause cancer. In fact, DMPA prevents cancer of the uterine lining.

RUMOR: The milk of mothers who use progestin-only injectable contraceptives is harmful to babies.
FACT: The milk of mothers using progestin-only injectables has been shown in several studies to have such a tiny amount of hormone in it that it is considered very safe for babies age 6 weeks and older. Moreover, quality and quantity of milk remains normal, and babies develop normally.

RUMOR: A woman who has used progestin-only injectable contraceptives for a long time should take a "rest" between doses because the contraceptive "builds up" in the body and is not healthy.
FACT: Injectable progestins are slowly released from the injection site. They always slowly pass out of the body, and are usually completely gone by 9 months after the last injection. No rest is needed.

Adapted from: 1) Lisken L: Hormonal Contraception: New Long Acting Methods. *Population Reports* Series K 1987;3(March-April);K57-K58; 2) Winikoff B, Semeraro P, Zimmerman M: *Contraception During Breastfeeding: A Clinician's Sourcebook.* New York, The Population Council, 1988; and 3) Technical Guidance Working Group: *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*. Chapel Hill NC, INTRAH Program, University of North Carolina at Chapel Hill School of Medicine, 1994, p 34.

STEP 2
Discuss how progestin-only injectable contraceptives work

Encourage the client to examine a vial of the progestin-only injectable contraceptive while you talk. Explain how injectable progestins work. Do this in a culturally appropriate way using words and visuals the client can understand. Encourage the client to ask questions or to ask for clarification about any of the information you provide.

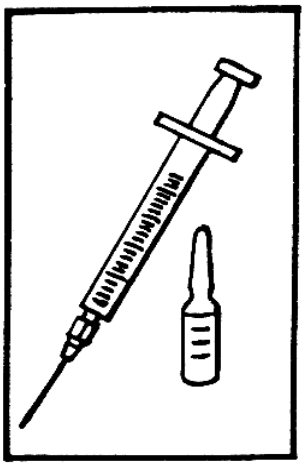

Illustration source: Barcelona DR, et al: *Contraception: A Guide to Birth Planning Methods*. Chicago, The Community and Family Study Center, 1981, p 31.

Progestin-only injectable contraceptives contain synthetic (man-made) progestins, similar to the hormone progesterone produced by the woman's body. After being injected into the muscle, the progestin is slowly released. Injectable progestins act chiefly in two ways to prevent pregnancy:

- They suppress ovulation (an egg is not released by the woman's body).
- They cause cervical mucus to become too thick for sperm to pass through (sperm cannot reach the uterus).

In addition, progestin-only injectables also cause the endometrium (lining of the uterus) to become less rich in blood vessels, which would make it more difficult for an egg to implant if ovulation did occur and if sperm did get through the thick cervical mucus.

Amenorrhea (absent menses; in the case of hormonal contraceptives, amenorrhea is more correctly called absent withdrawal bleeding) often occurs with progestin-only injectables; this is because the injectable progestins prevent the lining of the uterus from building up, so there is little lining to be shed. This is a normal effect of progestin-only contraceptives, which many women appreciate.

Injections need to be given every 2 or 3 months. The two most commonly available progestin-only injectables are DMPA (depo-medroxyprogesterone acetate, Depo Provera®), and NET-EN (norethindrone enanthate, Noristerat®). The following are some of the similarities and differences between DMPA and NET-EN:

	DMPA	**NET-EN**
Frequency and dose of injection	150 mg every 3 months (12 weeks).	200 mg every 2 months (8 weeks).
Time the next injection is allowed to be late.	2 (to 4) weeks.	1 (to 2) weeks.
Administration	Deep intra muscular (IM) injection into the deltoid (arm) or gluteal (buttock) muscle.	Deep intra muscular (IM) injection into the deltoid (arm) or gluteal (buttock) muscle.
Amenorrhea (absent withdrawal bleeding)	Slightly more common than NET-EN (55% of women by the end of the first year).	Slightly less common than DMPA (30% of women by the end of the first year).
Typical failure rate (for correct use)	About 3 in 1000 women per year will get pregnant (0.3%).	About 4 in 1000 women per year will get pregnant (0.4%).
Return to fertility (delay to conception)	On average, after stopping DMPA (3 months after the last injection), the delay is 4 months longer than for a woman who stops using pills, IUDs or barrier methods.	Suspected to cause less delay in return to fertility than DMPA.
Diabetes	Promotes some mild glucose intolerance, but is often used with good results for diabetic women.	Has NO effect on glucose tolerance. May be a slightly better option for known diabetics.

Adapted from: 1) Lisken L: Hormonal Contraception: New Long-Acting Methods. *Population Reports* Series K 1987;3(March-April);K57-K87; 2) Kleinman RL, ed: *Hormonal Contraception*. London, IPPF Medical Publications, 1990, p 84; 3) *Injectable Contraceptives: Their Role in Family Planning Care. Geneva* Switzerland, The World Health Organization, 1990; 4) Trussell J, Kost K: Contraceptive Failure in the United States: A Critical Review of the Literature. *Studies in Family Planning* 1987;18(5):237-283; 5) Fotherby K, Koetsawang S, Mathrubutham M: Pharmacokinetic Study of Different Doses of Depo-Provera. *Contraception* 1980;22(5):527-536; and 6) Technical Guidance Working Group: *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*. Chapel Hill NC, INTRAH Program, University of North Carolina at Chapel Hill School of Medicine, 1994, pp 36-39.

STEP 3
Describe the characteristics of progestin-only injectable contraceptives

In this section, advantages and disadvantages of progestin-only injectable contraceptives are referred to as "characteristics" because what one client considers an advantage (e.g., absent menses, given by injection, estrogen-free) may be considered a disadvantage to another client.

While you describe the characteristics (advantages and disadvantages) of progestin-only injectable contraceptives, encourage the client to raise questions or share any doubts or apprehensions she has.

CHARACTERISTICS

Effectiveness

- Very effective (99.6%).
- Long acting.
- Effectiveness continues even if the client is 1 or 2 weeks late for her return visit.
- Since they are long-acting, cannot be easily discontinued or removed from the body if complications develop or if pregnancy is desired.

Use

- Offer privacy to user.
- Appealing to those who like shots better than pills.
- Nothing to remember beyond returning for follow-up visit.
- Do not interfere with sexual intercourse.

Medical benefits

- May help decrease anemia.
- In women with sickle cell anemia, DMPA may decrease painful sickling crises.
- In women with seizures, DMPA may decrease the frequency of seizures.
- Prevent cancer of the uterine lining (endometrium), and may prevent ovarian cancer.

Special usefulness for certain clients

- Estrogen-free, thus especially helpful for women who cannot take estrogen-containing pills (due to smoking, migraines, or history of blood clotting or heart disease).
- Do not significantly affect breastmilk supply or quality, and have been shown to be safe for breastfeeding babies age 6 weeks and older.
- Useful for women who want no more children, but prefer not to have sterilization.
- Safe for women over 35 years of age.

Effects on menstrual cycle and fertility

- May cause absent menses (amenorrhea), which some clients appreciate.
- DMPA often causes a delayed return to fertility (after stopping DMPA, i.e., 3 months after the last injection, the average time delay to conception is about 4 months **longer** than the average time it takes for women who discontinue COCs, IUDs or barrier methods to conceive).
- May **decrease** symptoms of pre-menstrual syndrome, severe dysmenorrhea, ovulatory pain (Mittelschmertz) and endometriosis.

Possible minor side effects:

- prolonged or heavy vaginal bleeding (sometimes occurs during the first 1 to 2 months after taking the injection; bleeding can usually be controlled by ibuprofen, by short-term use of pills containing estrogen, and possibly by getting the next injection early).
- amenorrhea (often occurs after first injection and should be expected after 9 to 12 months of use),
- acne (rarely),
- slight weight gain (due to increased appetite),
- breast tenderness (mild, not common).

Protection against STDs

- **Do not protect against most STDs, including AIDS.**
- Provide some protection against pelvic inflammatory disease (progestins make cervical mucus thicker, so infection in the vagina or the cervix is less likely to reach the uterus and tubes).

Adapted from: 1) Hatcher RA, et al: *Contraceptive Technology 1994-1996*. New York, Irvington Publishers, Inc., 1994, pp 310-323; 2) *Family Planning Methods and Practice: Africa.* Atlanta, Centers for Disease Control, 1983, p 165; 3) Gray RH: Reduced Risk of PID with Injectable Contraceptives. *The Lancet* 1985;(May 4):1046; 4) Mattson RH et al: Treatment of Seizures with Medroxyprogesterone Acetate: Preliminary Report. *Neurology* 1984;34:1255-1258; 5) Technical Guidance Working Group: *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*. Chapel Hill NC, INTRAH Program, University of North Carolina at Chapel Hill School of Medicine, 1994, p 34; and 6) WHO Collaborative Study of Neoplasia and Steroid Contraceptives; Depo-medroxyprogesterone acetate (DMPA) and Risk of Endometrial Cancer. *International Journal of Cancer* 1991;49:186-190.

NOTE: Other forms of injectable contraceptives are being studied. These include monthly injections that contain estrogen and progestin. Two of these combined estrogen-progestin injectables (Mesigyna and Cyclofem) have already been approved for use by the World Health Organization. These estrogen-progestin injectables produce a more regular monthly bleeding pattern than progestin-only injectables. Medical eligibility criteria for these combined injectables differ from those listed in this chapter, due to the presence of estrogen in these monthly injectables.

STEP 4
Explore the appropriateness of progestin-only injectable contraceptives for the client through history and, if appropriate, physical exam

PROCEDURE

- Refer below to the list of conditions for restricting the use of progestin-only injectable contraceptives (WHO Medical Eligibility Criteria).
- Refer to local guidelines on general female reproductive history, and if physical examinations are offered as options for clients at your service site, refer to local guidelines on general physical exam, breast exam, abdominal exam and pelvic exam.
- Refer below to the history and, if appropriate, the physical exam checklists which are specific to progestin-only injectable contraceptives.
- If progestin-only injectable contraceptives are not appropriate, help the client make an informed choice of an appropriate method and follow that method's procedure.
- If any of the conditions for restricting the use of progestin-only injectables apply to the client and no other method is acceptable or available to her, discuss with her whether or not the benefits of progestin-only injectable contraceptives outweigh her risks from using them.

CONDITIONS for RESTRICTING the use of progestin-only injectables: WHO Medical Eligibility Criteria

In 1994-1995, the World Health Organization (WHO) developed "medical eligibility criteria" for use of various contraceptive methods. If the client has a specific physical "condition", the suitability for use of progestin-only injectable contraceptives can be determined by consulting the following category system developed by WHO.

WHO Category	Definition	What to do
4	A condition which always represents an unacceptable health risk.	Progestin-only injectables **should not be used** when this condition is present.
3	A condition where the theoretical or proven risks **usually** outweigh the advantages of using the method.	• Progestin-only injectables should **usually not be used unless other more appropriate methods are not available or are not acceptable**. • A woman having a condition assigned as Category 3 requires careful clinical judgment and probably follow-up to ensure that in the woman's case the benefits of progestin-only injectables outweigh any risks, taking into account the severity of the condition and the availability, practicality and acceptability of alternative methods. It might be the method of last choice.
2	A condition where the advantages of using the method **generally** outweigh the theoretical or proven risks.	Progestin-only injectables **can generally be used** in this situation. However, knowing a woman has a condition assigned as Category 2 may influence the selection of the method.
1	A condition for which there is no restriction for the use of the contraceptive method.	If preferred by a woman with this condition, progestin-only injectables are an appropriate contraceptive method.

Adapted from: World Health Organization Division of Family and Reproductive Health: *Improving Access to Quality Care in Family Planning. Eligibility Criteria for Initiating Use of Selected Methods of Contraception.* WHO/FRH/FPP/96.9.

The conditions for restricting the use of progestin-only injectables are organized and discussed in the following pages according to the medical eligibility category system developed by WHO. While WHO has published an extensive list of conditions affecting use of contraceptives, those listed below are the

ones encountered in routine clinical practice. The rationales given are adapted from the WHO rationales. (See World Health Organization Division of Family and Reproductive Health: *Improving Access to Quality Care in Family Planning. Eligibility Criteria for Initiating Use of Selected Methods of Contraception.* WHO/FRH/FPP/96.9.)

WHO Category 4: An Unacceptable Health Risk	**Rationale**
Progestin-only injectables ***should not be used*** by a woman who:	
4.1. Has a known or strongly suspected **pregnancy** (suggested by history, symptoms, signs or positive pregnancy test). (See Appendix A: "How to Be Reasonably Sure the Woman is Not Pregnant".)	4.1. a) Current data do <u>NOT</u> show that current hormonal contraceptives taken during pregnancy cause significant increase in the risk of birth defects, because the dose is so low. b) However, since exposing the fetus to any medication could in theory cause birth defects, hormonal contraceptives should not be given to pregnant women. Adapted from: 1) Simpson JL, Phillips OP: Spermicides, Hormonal Contraception and Congenital Malformations. *Advances in Contraception* 1990;6:141-147; 2) Bracken MB et al: Meta-analysis of the Risk of Birth Defects with Oral Contraceptives. *Obstetrics and Gynecology* 1990;76:552-557; 3) Connell EB, Tatum HJ: *Reproductive Health Care Manual.* Durant OK, Creative Infomatics, Inc., 1986, p 64; 4) Stewart FH, et al: *Understanding Your Body.* Toronto, Bantam Books, 1987, p 301; 5) Wilson ESB: Injectable Contraceptives, in Loudon N, (ed): *Handbook of Family Planning.* Edinburgh, Churchill Livingstone, 1985, pp 114-128; 6) *Depo Provera for Contraception: Review of Medical Use and Considerations*. Kalamazoo, The Upjohn Co, 1984; 7) Rosenfield A: Injectable Contraception in Corson SL, Derman RJ, Tyrer LB, (eds): *Fertility Control.* Boston, Little Brown & Co., 1985, p 192; 8) Mishell DR, Goebelsmann U: Disorders of Sexual Differentiation, in Mishell DR, Davajan V (eds): *Infertility, Contraception and Reproductive Endocrinology*, 2nd ed. Oradell, Medical Economics Books, 1986, p 214-215; 9) Technical Guidance Working Group: *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*. Chapel Hill NC, INTRAH Program, University of North Carolina at Chapel Hill School of Medicine, 1994, p 29; and 10) World Health Organization Division of Family and Reproductive Health: *Improving Access to Quality Care in Family Planning. Eligibility Criteria for Initiating Use of Selected Methods of Contraception.* WHO/FRH/FPP/96.9.

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WHO Category 4: An Unacceptable Health Risk	Rationale
4.2. Has **unexplained abnormal uterine bleeding (suspicions for serious underlying condition) before evaluation**, i.e., irregular uterine bleeding during the last three months, between menstrual periods or after intercourse, which is **suspicious** for infection, pelvic malignancy or pregnancy (intrauterine or ectopic) and which has not been evaluated. **NOTES**: • If pregnancy or an underlying abnormality (such as pelvic cancer) is suspected, it must be evaluated; after evaluation, the category should be adjusted. • For an irregular menstrual pattern with heavy bleeding, see WHO Category 2, in which the benefits from using progestin-only injectables usually outweigh the risks.	4.2. a) Causes of irregular bleeding include: intrauterine and ectopic pregnancy; pelvic inflammatory disease; endometrial, ovarian or cervical cancer; fibroids, other gynecologic problems; early or premenopause; breastfeeding; and hypo- or hyper-thyroidism. None of these conditions are worsened (and some are prevented) by progestin-only injectables. Specifically, injectable progestins provide significant protection against endometrial cancer. b) However, since initiating the use of progestin-only injectables is likely to cause irregular bleeding in many women, it would be optimal to determine the cause of the woman's bleeding and to treat any serious problems before she starts to use injectable progestins, if she can use another reliable method in the meantime. c) The major risk of giving hormonal contraceptives to a woman with unexplained bleeding is the risk of masking the signs of endometrial, ovarian or cervical cancer. However, 90% of endometrial cancers occur after the age of 50, and both endometrial and ovarian cancers are much less common in the developing world than in industrialized countries. Therefore, the chances of masking endometrial or ovarian cancer, particularly in a woman under the age of 35, is extremely small. In contrast, cervical cancer is more common than endometrial or ovarian cancer among young women and among women in the developing world. In Africa, every year about 2 out of every 10,000 women develop cervical cancer. Adapted from: 1) Speroff L, Glass RH, Kase NG: *Clinical Gynecologic Endocrinology and Infertility,* 5th ed. Baltimore, Williams & Wilkins, 1994, pp 439, 473-475; 2) Herbst AL, et al: *Comprehensive Gynecology.* St. Louis, Mosby-Year Book, 1992, pp 1082-1083; 3) Parazzini F, et al: The Epidemiology of Endometrial Cancer. *Gynecologic Oncology* 1991;41:1-16; 4) Pike MC: Age-related Factors in Cancers of the Breast, Ovary, and Endometrium. *Journal of Chronic Disease* 1987;40;Suppl2:59S-69S; 5) Sadaan O, et al: Is it Safe to Prescribe Hormonal Contraception and Replacement Therapy to Patients with Premalignant and Malignant Uterine Cervices. *Gynecologic Oncology* 1989;34:159-163; 6) Parkin DM, Laara E, Muir CS: Estimates of the Frequency of 16 Major Cancers in 1980. *International Journal of Cancer* 1988;41:184-187; and 7) World Health Organization Division of Family and Reproductive Health: *Improving Access to Quality Care in Family Planning. Eligibility Criteria for Initiating Use of Selected Methods of Contraception.* WHO/FRH/FPP/96.9.

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WHO Category 4: An Unacceptable Health Risk	Rationale
4.3. Has current known **cancer of the breast**. **NOTE**: For an undiagnosed breast mass, see WHO Category 2 in which the benefits from using progestin-only injectables usually outweigh the risks.	4.3. Progestin-only injectables do NOT cause breast cancer. Lumps that are suspicious for cancer should be evaluated. Hormonal treatment may cause such lumps to grow. (However, pregnancy causes much higher hormonal levels in the woman's body than most hormonal contraceptives do.) Adapted from: 1) *Injectable Contraceptives: Their Role in Family Planning Care*. Geneva Switzerland, The World Health Organization, 1990, p 69; 2) WHO Collaborative Study of Neoplasia and Steroid Contraceptives. Breast Cancer and depot-medroxyprogesterone acetate: a multinational study. *The Lancet*:1991;338:833-838; and 3) World Health Organization Division of Family and Reproductive Health: *Improving Access to Quality Care in Family Planning. Eligibility Criteria for Initiating Use of Selected Methods of Contraception.* WHO/FRH/FPP/96.9.

WHO Category 3: Risk Usually Outweighs Advantages	Rationale
Progestin-only injectables should usually not be used (unless other, more appropriate methods are unavailable or unacceptable) for a woman who:	
3.1. Has a current or past history of ischemic heart disease or stroke.	3.1. a) Manufacturers routinely list blood clotting disorders and heart disease as contraindications to progestin-only methods. However, current progestin-only contraceptives have no significant effect on blood clotting, blood pressure, or development of diabetes, and have not been shown to increase a woman's risk of cardiovascular disease. b) There is some evidence that use of injectable progestins may cause a slight decrease in high-density lipoprotein (HDL) levels. This may be a concern for clients with current or past history of heart disease or stroke. c) Women with past or current ischemic heart disease are at greatly increased risk of pregnancy complications, and should be counseled to consider voluntary surgical contraception (VSC). If VSC is not acceptable, the IUD, NORPLANT® Implants, or injectable contraceptives should be considered, because of their high efficacy.

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WHO Category 3: Risk Usually Outweighs Advantages	Rationale
	3.1. d) For a woman with a history of cardiovascular or thromboembolic disease who cannot or will not use other reliable methods, a progestin-only method is a better choice than combined oral contraceptives. (All current hormonal contraceptives are always safer than pregnancy for women in the developing world.) Adapted from: 1) Stadel BV: Oral Contraceptives and Cardiovascular Disease. *New England Journal of Medicine* 1981;305(12):672-675; 2) Hatcher RA, et al: *Contraceptive Technology* 1990-1992. New York, Irvington Publishers, Inc., 1990, p 319; 3) *NORPLANT® Levonorgestrel Implants: A Summary of Scientific Data.* Monograph, New York, The Population Council, 1990; 4) Wilson ESB, et al: A Prospective Controlled Study of the Effect on Blood Pressure of Contraceptive Preparations Containing Different Types and Dosages of Progestogen. *British Journal of Obstetrics and Gynecology* 1984;91:1254-1260; 5) *Injectable Contraceptives: Their Role in Family Planning Care.* Geneva Switzerland, The World Health Organization, 1990, pp 68-69; 6) Fotherby K: The Progestin-Only Pill and Thrombosis. *The British Journal of Family Planning* 1989;15:83-85; 7) *Implantable Contraceptives: Managerial and Technical Guidelines. Geneva* Switzerland, The World Health Organization, 1990; 8) *NORPLANT® System Counseling Manual*. Philadelphia, Wyeth-Ayerst Laboratories, 1990; 9) Oyelola OO, Thomas KD, Olusi SO: Steroidal Contraceptives and Changes in Individual Plasma Phospholipids: Possible Role in Thrombosis. *Advances in Contraception* 1990;6:193-206; and 10) World Health Organization Division of Family and Reproductive Health: *Improving Access to Quality Care in Family Planning. Eligibility Criteria for Initiating Use of Selected Methods of Contraception.* WHO/FRH/FPP/96.9.
3.2. Has severe hypertension (≥180/110) and/or hypertensive vascular disease. Hypertensive vascular disease includes kidney failure (nephropathy), vision loss (retinopathy) and cardiovascular disease.	3.2. There is some evidence that use of progestin-only injectables may cause a slight decrease in high-density lipoprotein (HDL) levels, which may be of some concern for those with moderate hypertension (with or without vascular disease). Additionally, there is a theoretical concern that the marked ovarian suppression caused by DMPA could produce an estrogen deficient state, which would remove the normal premenopausal beneficial effects of estrogen on atherosclerosis and on arterial wall contraction. Adapted from: 1) World Health Organization Division of Family and Reproductive Health: *Improving Access to Quality Care in Family Planning. Eligibility Criteria for Initiating Use of Selected Methods of Contraception.* WHO/FRH/FPP/96.9; 2) Sarrel PM, et al: Angina and Normal Coronary Arteries in Women: Gynecologic Findings. *American Journal of Obstetrics and Gynecology* 1992;167(2):467-471; 3) Reis SE, et al: Ethinyl Estradiol Acutely Attenuates Abnormal Coronary Vasomotor Responses to Acetylcholine in Postmenopausal Women. *Circulation* 1994;89(1):52-60; 4) Espeland MA, et al: Estrogen Replacement Therapy and Progression of Intimal-Medial Thickness in the Carotid Arteries of Postmenopausal Women. *American Journal of Epidemiology* 1995;142(10):1011-1019; and 5) Williams JK, et al: Short-Term Administration of Estrogen and Vascular Responses of Atherosclerotic Coronary Arteries. *Journal of American College of Cardiology* 1992;20(2):452-457.

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WHO Category 3: Risk Usually Outweighs Advantages	Rationale
3.3. Has diabetes with vascular disease, or has had diabetes for 20 or more years. Diabetic vascular disease includes kidney failure (nephropathy); vision loss (retinopathy) and cardiovascular disease.	3.3. Women with severe or prolonged diabetes or other vascular disorders are at increased risk of heart disease or stroke (particularly women who smoke). DMPA causes minor alterations in carbohydrate and lipid metabolism. Few data have been published on the metabolic effects of NET-EN, but its effect on most metabolic functions appears to be similar to that of DMPA. There is an unproven, but theoretical concern that these metabolic effects of injectables might affect the progression of diabetic nephropathy, retinopathy, or other diabetic vascular diseases. Adapted from: 1) *Injectable Contraceptives: Their Role in Family Planning Care. Geneva* Switzerland, World Health Organization, 1990, p 78 and 2) World Health Organization Division of Family and Reproductive Health: *Improving Access to Quality Care in Family Planning. Eligibility Criteria for Initiating Use of Selected Methods of Contraception.* WHO/FRH/FPP/96.9.
3.4. Has severe, active liver disease (including symptomatic, active viral hepatitis or severe, decompensated cirrhosis) or has benign or malignant liver tumors. **NOTE**: Mild, compensated cirrhosis of the liver is WHO Category 2, in which the benefits from using progestin-only injectables usually outweigh the risks.	3.4. a) There is no good evidence that progestin-only injectables cause liver tumors, or liver or gall bladder disease. b) Women with severe, active, liver disease should not become pregnant, and should preferably not use estrogen-containing contraceptives. This is because estrogens and, to lesser degree, progestins, affect the general functioning of the liver. It is not clear if progestin use contributes to an increased risk of liver tumors. If non-hormonal methods are not acceptable, progestin-only methods would be safer than pregnancy. Adapted from: 1) Hatcher RA, et al: *Contraceptive Technology 1994-1996.* New York, Irvington Publishers, Inc., 1994, p 311; 2) McEwan J: Contraception for Women with Liver Disease. *The British Journal of Family Planning* 1983;9:53-57; 3) Royal College of General Practitioners Oral Contraceptives Study: Oral Contraceptives and Gall Bladder Disease. *The Lancet* 1982;(October 30):957-959; 4) WHO Collaborative Study of Neoplasia and Steroid Contraceptives. *International Journal of Cancer* 1989;43:254-259; 5) *NORPLANT® Levonorgestrel Implants: A Summary of Scientific Data.* Monograph. New York, The Population Council, 1990; 6) Goldzieher JW: *Hormonal Contraception: Pills, Injections & Implants*. Dallas, Essential Medical Information Systems, Inc., 1989, pp 194-196; 7) Davis M, Williams R: Hepatic Disorders, in Davies DM (ed): *Textbook of Adverse Drug Reactions*, 4th ed. Oxford, Oxford Medical Publications, 1991, p 269; and 8) World Health Organization Division of Family and Reproductive Health: *Improving Access to Quality Care in Family Planning. Eligibility Criteria for Initiating Use of Selected Methods of Contraception.* WHO/FRH/FPP/96.9.

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WHO Category 3:
Risk Usually Outweighs Advantages

Rationale

3.5. Is breastfeeding before 6 weeks postpartum.

3.5. There is a theoretic concern that exposure of the newborn to synthetic progestins could be detrimental to mental or physical development. Limited information from animal studies and the fact that human newborns normally experience a predictable rise, followed by an important predictable fall, in their levels of human sex hormones in the first 6 weeks of life, indicate it may be prudent to wait to initiate progestin-only contraceptives until a breastfeeding woman is at least 6 weeks postpartum.

Adapted from: 1) Harlap S: Exposure to Contraceptive Hormones through Breastmilk - Are There Long-term Health Consequences? *International Journal of Gynaecology and Obstetrics* 1987;25(Suppl):47-55; 2) Ward RM: Pharmacologic Principles and Practicalities, in Taeusch HW, Ballard RA, Avery ME (eds): *Diseases of the Newborn*. Philadelphia, WB Saunders Company, 1991; 3) World Health Organization Division of Family and Reproductive Health: *Improving Access to Quality Care in Family Planning. Eligibility Criteria for Initiating Use of Selected Methods of Contraception.* WHO/FRH/FPP/96.9; and 4) Technical Guidance Working Group: *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*. Chapel Hill NC, INTRAH Program, University of North Carolina at Chapel Hill School of Medicine, 1994, p 31.

WHO Category 2:
Advantages Generally Outweigh Risks

Rationale

Progestin-only injectables can generally be used even by a woman who:

2.1. Has an undiagnosed breast mass.

NOTE: For current known breast carcinoma, see WHO Category 4 in which the risks from using progestin-only injectables are considered unacceptable.

2.1. Progestin-only injectables do not cause breast cancer. Furthermore, use of injectable progestins is not a concern for women with benign breast disease. Breast masses suspicious for cancer should be referred for evaluation. While any hormonal treatment may in theory cause lumps (of any cause) to grow, pregnancy causes much higher hormonal levels; therefore, an undiagnosed breast mass is not a reason to restrict the use of progestin-only methods.

Adapted from: World Health Organization Division of Family and Reproductive Health: *Improving Access to Quality Care in Family Planning. Eligibility Criteria for Initiating Use of Selected Methods of Contraception.* WHO/FRH/FPP/96.9.

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WHO Category 2: Advantages Generally Outweigh Risks	Rationale
2.2. Has **diabetes - non-insulin or insulin dependent**.	2.2. Although injectable progestins slightly decrease carbohydrate tolerance, this does not clinically worsen diabetes.
2.3. Has **moderate hypertension** (below 180/110), without vascular disease. **NOTE:** For severe hypertension (≥180/110) or hypertensive vascular disease, see WHO Category 3.	2.3. There is some evidence that use of progestin-only injectables may cause a slight decrease in high-density lipoprotein (HDL) levels, which may be of some concern for those with moderate hypertension (with or without vascular disease). However, progestin-only injectables are a very safe and appropriate method for women with mild to moderate hypertension. Rationales for 2.2 and 2.3 adapted from: World Health Organization Division of Family and Reproductive Health: *Improving Access to Quality Care in Family Planning. Eligibility Criteria for Initiating Use of Selected Methods of Contraception.* WHO/FRH/FPP/96.9.
2.4. Is **age 15 years or under**.	2.4. Use of progestin-only injectables generally leads to amenorrhea (with DMPA, about half of women by the end of the first year and in about two thirds of women by the end of the second year are amenorrheic). 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 oriental, 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. Adapted from: 1) Technical Guidance Working Group: *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*. Chapel Hill NC, INTRAH Program, University of North Carolina at Chapel Hill School of Medicine, 1994, p 34; 2) Bonjour JP et al: 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; 3) Theintz G et al: 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; 4) Dhuper S et al: Effects of Hormonal Status on Bone Density in Adolescent Girls. *Journal of Clinical Endocrinology and Metabolism* 1990;71:1083-1088; 5) World Health Organization Division of Family and Reproductive Health: *Improving Access to Quality Care in Family Planning. Eligibility Criteria for Initiating Use of Selected Methods of Contraception.* WHO/FRH/FPP/96.9; and 6) Technical Guidance Working Group: *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*. Chapel Hill NC, INTRAH Program, University of North Carolina at Chapel Hill School of Medicine, 1994, p 35.

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WHO Category 2:

Advantages Generally Outweigh Risks	Rationale
2.5. Experiences severe, **recurring headaches (including migraines)** with or without focal neurological symptoms. **NOTE:** If a client develops severe headaches **with** focal neurologic symptoms **while using** injectable progestins, this is WHO Category 3.	2.5. For some clients, headaches (including migraines) may intensify with use of injectables. Because injectables cannot be promptly discontinued once administered, a client with a history of severe headaches may wish to try progestin-only pills (or non-hormonal methods) first. Adapted from 1) World Health Organization Division of Family and Reproductive Health: *Improving Access to Quality Care in Family Planning. Eligibility Criteria for Initiating Use of Selected Methods of Contraception.* WHO/FRH/FPP/96.9.
2.6. Has an **irregular menstrual pattern with or without heavy bleeding**. **NOTES**: • If the client has both clinically-apparent anemia and a history of heavy bleeding, this is WHO Category 3 for use of progestin-only injectables. • For unexplained abnormal uterine bleeding suspicious for infection, malignancy or pregnancy, see WHO Category 4 in which use of progestin-only injectables is always an unacceptable health risk.	2.6. **Initiation of progestin-only injectables**: a) If, prior to initiating progestin-only injectables, abnormal conditions are suspected (such as infections, malignancy, or pregnancy -- ectopic or uterine) which could cause prolonged or heavy bleeding, these should be evaluated and treated as appropriate. b) A number of women (especially teenagers) have an atypical pattern of irregular (anovulatory) menstrual cycles (due to various benign causes). Progestin-only injectables may be safely used in such women. For all women, however, when injectable progestins are first started, irregular and prolonged bleeding episodes are common and expected in the first 3 to 6 months of use. **Heavy bleeding** (greater than normal menstruation) is uncommon. By the end of the first year of progestin-only injectables use, 50% of women experience amenorrhea. By the end of the second year, 66% of progestin-only injectable users experience amenorrhea. **Continuation of progestin-only injectables:** Some women may still require stopping the use of injectable progestins due to medical reasons for excessive bleeding, or due to the client's preference. Adapted from: 1) Technical Guidance Working Group: *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*. Chapel Hill NC, INTRAH Program, University of North Carolina at Chapel Hill School of Medicine, 1994, pp 40-41; 2) World Health Organization Division of Family and Reproductive Health: *Improving Access to Quality Care in Family Planning. Eligibility Criteria for Initiating Use of Selected Methods of Contraception.* WHO/FRH/FPP/96.9; 3) Belsey EM and Task Force on Long-Acting Systemic Agents for Fertility and Regulation: Menstrual Bleeding Patterns in Untreated Women and With Long-Acting Methods of Contraception. *Advances in Contraception* 1991:257-270; 4) *Injectable Contraceptives: Their Role in Family Planning Care*. Geneva, World Health Organization, 1990; 5) Diaz S et al: Clinical Assessment of Treatments for Prolonged Bleeding in Users of NORPLANT® Implants. *Contraception* 1990; 42(1):97-109; and 6) 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. *Contraception* 1983; 28(1):1-20.

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WHO Category 2: Advantages Generally Outweigh Risks	Rationale
2.7. Has history of **hypertension** but blood pressure (BP) cannot be measured today.	2.7. No significant changes in blood pressure have been found with use of progestin-only contraceptives, thus they may safely be administered to a woman with a history of hypertension. However, this history deserves follow-up, and the woman should also be referred for BP evaluation. Adapted from: World Health Organization Division of Family and Reproductive Health: *Improving Access to Quality Care in Family Planning. Eligibility Criteria for Initiating Use of Selected Methods of Contraception.* WHO/FRH/FPP/96.9.
2.8. Has cervical intraepithelial neoplasia or **cervical, endometrial, or ovarian cancer**, or has another diagnosed pelvic malignancy.	2.8. While there is a theoretical concern that use of progestins might affect progression of cervical intraepithelial neoplasia or cervical cancer, there is no evidence for this. (The main concern is masking of the symptom of irregular bleeding due to cervical cancer, because women on progestin-only injectables would attribute the irregular bleeding to their method.) There is no evidence that injectable progestins worsen endometrial or ovarian cancer. Adapted from: 1) WHO Collaborative Study of Neoplasia and Steroid Contraceptives: DMPA and Risk of Invasive Squamous Cell Cervical Cancer. *Contraception* 1992;45(4):229-312; 2) OBerle MW et al: Cervical Cancer Risk and Use of Depot-Medroxyprogesterone Acetate in Costa Rica. *International Journal of Epidemiology* 1988;17(4):718-723; 3) Liang AP et al: Risk of Breast, Uterine Corpus, and Ovarian Cancer in Women Receiving Medroxyprogesterone Injections. *Journal of the American Medical Association* 1983;249(21):2909-2912; 4) Mishell DR. Long-Acting Contraceptive Steroids: Postcoital Contraceptives and Antiprogestins, in Mishell DR, Davajan V, Lobo RA (eds): *Infertility, Contraception, and Reproductive Endocrinology*, 3rd ed. Boston, Blackwell Scientific Publications, 1991, p 878; and 5) World Health Organization Division of Family and Reproductive Health: *Improving Access to Quality Care in Family Planning. Eligibility Criteria for Initiating Use of Selected Methods of Contraception.* WHO/FRH/FPP/96.9.

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WHO Category 2: Advantages Generally Outweigh Risks	Rationale
2.9. Is taking rifampin/rifampicin or griseofulvin or anti-coagulants or anti-seizure (anti-convulsant) **medications**.	2.9. a) Use of non-hormonal (including back-up) contraceptive methods should be encouraged for women who are on long term use of any of these drugs. However, injectable contraceptives are more appropriate than COCs, POPs, or NORPLANT® Implants. While rifampin, griseofulvin and anti-convulsants (except valproic acid) interfere with low dose hormonal contraceptives (i.e., COCs, POPs, or NORPLANT® Implants), there is less evidence that these medications measurably interfere with injectables. b) Progestin-only methods may be associated with prolonged bleeding in the first three months of use. It is unknown if anti-coagulants aggravate the bleeding. Adapted from: 1) Mattson RH et al: Treatment of Seizures with Medroxyprogesterone Acetate: Preliminary Report. *Neurology* 1984;34(9):1255-1258; 2) Mattson RH, Rebar RN: Contraceptive Methods for Women with Neurologic Disorders. *American Journal of Obstetrics and Gynecology* 1993;168:2027-2032; and 3) World Health Organization Division of Family and Reproductive Health: *Improving Access to Quality Care in Family Planning. Eligibility Criteria for Initiating Use of Selected Methods of Contraception.* WHO/FRH/FPP/96.9.

CHECKLISTS for History-taking and Physical Examination

A physical examination is **NOT** mandatory for the safe use of hormonal methods. Some programs may be able to offer, and some women may prefer, physical examinations as a preventive health service. Regardless of whether a physical examination is done, it is always important to **screen by history**, both for conditions which may affect the use of hormonal methods, and for the woman's reproductive health.

History Checklist for Progestin-only Injectable Contraceptive Users

Service Provider's Questions **Ask the client the following questions:**	**NO**	**YES**	**Service Provider's Instructions** **If "YES", follow the instructions below:**
1. Do you think you are pregnant? (e.g., unprotected intercourse? last period more than 4 weeks ago?)	☐	☐	1. Do **NOT** give progestin-only injectables until you can be reasonably sure that the woman is not pregnant. Offer condoms (and/or spermicides) until you are reasonably sure she is not pregnant (see Appendix A: "How to Be Reasonably Sure the Woman is Not Pregnant").
2. a) Are you breastfeeding a child less than **6 months** old at present? b) Are you still free of your menstrual periods since your delivery? (Bleeding during the first 8 weeks following delivery is not considered a menstrual period in a breastfeeding woman.) c) Are you **fully or nearly fully** breastfeeding (not regularly substituting food or drink for breastfeeding meals)?	☐	☐	2. If the answer is "yes" to all three questions, the Lactational Amenorrhea Method (LAM) alone provides sufficient contraception for **6 MONTHS**. If additional contraception is needed or will be needed soon, offer progestin-only injectables. Even for the woman who is only partially breastfeeding, there is no need to begin progestin-only injectables before the **6 WEEKS** postpartum visit, because the risk of pregnancy is **extremely** low.
3. Do you think you have breast cancer, or have you ever been told that you have had breast cancer?	☐	☐	3. If you strongly suspect cancer, DO NOT give progestin-only injectables. Refer as necessary. Help the client make an informed choice of a non-hormonal method. Explain that progestin-only injectables DO NOT cause breast cancers, but women who already have cancer should not take hormones.
4. Have you noticed any bleeding between periods or after intercourse, or any bleeding that is heavier than usual over the last 3 months?	☐	☐	4. These symptoms should be evaluated before hormonal contraceptives are begun. Help her make an informed choice of a non-hormonal method.

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History Checklist for Progestin-only Injectable Contraceptive Users (continued)

Service Provider's Questions Ask the client the following questions:	NO	YES	Service Provider's Instructions If "YES", follow the instructions below:
5. To your knowledge, do you have any liver disease now? or: • Have you ever been told you had a tumor of the liver? • Have you been told that you now have active hepatitis or gallbladder disease?	☐	☐	5. If yes to any question, try to confirm this history on physical exam (jaundice? painful or enlarged liver?). If there is active liver disease or a liver tumor, refer as appropriate. In all cases, help the client make an informed choice of a reliable non-hormonal method until the liver problem is resolved.
6. Have you had diabetes for 20 years or more, or do you have severe diabetes with damage to your vision or to your kidneys?	☐	☐	6. If the client has diabetes with damage to kidneys or eye sight, or other vascular disease, or diabetes of 20 years or more duration, she is at high risk for complications during pregnancy and should strongly consider voluntary surgical contraception (VSC), or a reliable progestin-only method like NORPLANT® Implants, or an IUD. If these are not acceptable, the risks associated with progestin-only injectables are almost certainly lower than the risks associated with pregnancy.
While question 7 does NOT relate to non-eligibility by the WHO criteria, it is an important question for the woman's reproductive health.			
7. a) Have you ever had a severe pelvic infection with fever, chills, pain in womb area, and discharge, or do you now? b) Reassure client of your confidentiality before asking the following question: Have either you or your partner recently had other sex partners?	☐	☐	7. If yes to either question, this client is at risk for STDs, including AIDS. Give progestin-only injectables because of effectiveness, but also advise the client to use condoms (or to use spermicides if condoms are unacceptable) to protect herself against STDs, including AIDS. Look for evidence of STDs on exam.

Checklists to Use When Physical Examinations are Indicated

Physical examinations (general, speculum, bimanual) may be useful to evaluate questions raised by the client's history (such as a history of high blood pressure, breast lumps or liver disease). For clients who have a "negative" history for conditions in WHO Categories 3 and 4, physical examinations may be appropriate for good preventive health care, but are not necessary for safe use of the contraceptive method.

When General Physical Examination is Indicated: Checklist for Progestin-only Injectable Contraceptive Users

Service Provider's Observations **Look for the abnormalities listed:**	**NO**	**YES**	**Service Provider's Instructions** **If "YES", follow the instructions below:**
1. Weigh the client. Is she underweight or overweight (according to local clinic guidelines)?	☐	☐	1. Progestin-only injectables are sometimes associated with weight gain. Establish a baseline weight for the client. If she is underweight or overweight, counsel accordingly.
2. Is her blood pressure (BP) elevated? (systolic over diastolic) • Mild to moderate high blood pressure (BP): under 180/110 • Severe high blood pressure (BP): 180/115 or above	☐	☐	2. If the BP is elevated, recheck, and refer for evaluation or manage BP according to local clinic guidelines. Encourage the client to make an informed choice of a reliable contraceptive method. For moderate high BP, NORPLANT® Implants, progestin-only injectables or POPs may be used since progestin-only methods are always far safer than pregnancy and are unlikely to worsen BP. For severe high BP, a reliable non-hormonal method is preferred.
3. Does she have lumps in her breast? Lumps that are benign (e.g., breast cysts or fibroadenomas) are usually smooth, clearly defined in shape, often occur at the same place in both breasts, and are freely moveable. These lumps may also swell slightly and become tender each month just before menses. There should be no firm or markedly enlarged lymph nodes in the underarm area. When in doubt, the client should be referred for evaluation.	☐	☐	3. Lumps that are suspicious for cancer are generally non-tender, unilateral, irregular in shape, with decreased mobility (feel "stuck" to skin or muscle). Enlarged lymph nodes in the underarm area may be present. Refer the client with lumps suspicious for cancer as appropriate. Help her make an informed choice of a non-hormonal method. If none are acceptable, offer POPs (POPs are low dose and are always safer than pregnancy). If lumps are not suspicious, provide progestin-only injectables.
4. a) Is she jaundiced? b) Does she have an enlarged or tender liver?	☐	☐	4. If you answer "yes" to either one of these questions, the client is likely to have active liver disease, or a liver tumor. Refer her as appropriate. Help her make an informed choice of a reliable non-hormonal method. If none are acceptable, offer POPs until the liver problem resolves.

When Speculum Examination is Indicated: Checklist for Progestin-only Injectable Contraceptive Users

Service Provider's Observations Look for the abnormalities listed:	NO	YES	Service Provider's Instructions If "YES", follow the instructions below:
1. Does she have: a) an abnormal vaginal or cervical discharge? or b) any genital ulcers? or c) other findings suspicious for STDs (such as genital warts)?	☐	☐	1. Evaluate and manage according to local clinic guidelines, including treatment of partner(s). Give progestin-only injectables. If a STD is suspected, advise the client to abstain until cured and then to use condoms for protection against STDs, including AIDS (or use spermicides if condoms are unacceptable).
2. Does she have tumors or ulcers or other changes on the cervix which are suspicious for cancer?	☐	☐	2. Evaluate and refer as appropriate, including pap smear where possible. Recommend a reliable contraceptive method. Hormonal methods are safe to use while awaiting evaluation and treatment.

When Bimanual Examination is Indicated: Checklist for Progestin-only Injectable Contraceptive Users

Service Provider's Observations Look for the abnormalities listed:	NO	YES	Service Provider's Instructions If "YES", follow the instructions below:
1. Does she have an enlarged, smooth, soft uterus?	☐	☐	1. Do **NOT** give progestin-only injectables until you can be reasonably sure that the woman is not pregnant, especially if she has other symptoms or signs. Offer condoms (and/or spermicides) until you are reasonably sure she is not pregnant (see Appendix A: "How to Be Reasonably Sure the Woman is Not Pregnant"). Advise her to use condoms for protection against STDs, including AIDS.
2. Does she have an enlarged but firm and irregular uterus?	☐	☐	2. She probably has benign uterine fibroid tumors. However, if irregular bleeding is also present, or if uterine size has rapidly increased (within 6 months), refer her as appropriate to verify the diagnosis before giving progestin-only injectables.

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When Bimanual Examination is Indicated: Checklist for Progestin-only Injectable Contraceptive Users (continued)

Service Provider's Observations Look for the abnormalities listed:	NO	YES	Service Provider's Instructions If "YES", follow the instructions below:
3. Does she have an adnexal mass?	☐	☐	3. She may have an ovarian cyst (including corpus luteum of pregnancy), an abscess, an ectopic pregnancy or, rarely, a tumor of the ovaries or tubes. Refer her as appropriate. Advise the client to use condoms for contraception and for protection against STDs, including AIDS (or use spermicides if condoms are unacceptable). If intrauterine pregnancy and cancer are unlikely, it is reasonable to begin progestin-only injectables and manage or refer for evaluation of the adnexal mass.
4. Does she have marked tenderness of the cervix, ovaries, tubes, or uterus?	☐	☐	4. She may have pelvic inflammatory disease (PID); manage according to local clinic guidelines, including treatment of partner(s). Give progestin-only injectables. Also advise the client to use condoms for protection against STDs, including AIDS (or to use spermicides if condoms are unacceptable).

STEP 5
Give injection

TIMING OF INJECTION

- Progestin-only injectable contraceptives may be given at any time during the menstrual cycle when you can be reasonably sure the client is not pregnant. If the injection is given after the 7th day of a normal menstrual cycle, ask the client to use a back-up method, such as condoms, for 7 days or to NOT have intercourse for 7 days.
- If the client is not at risk of pregnancy (abstaining, or using another effective method, or within one week post-abortion, or protected by LAM), she may begin progestin-only injectables any day of the month.
- If you are discharging a breastfeeding mother from the maternity service, advise her to have a 6 week postpartum check-up. Explain that she does not need to start the progestin-only injectables before **6 weeks** postpartum since the risk of pregnancy in the first 6 weeks postpartum in a woman who is even partially breastfeeding is extraordinarily rare. Explain that she will need progestin-only injectables **before** her menses return, and **before** she starts giving the infant other food or liquids in place of a breastmilk meal, and **before** her baby is 6 months old.

PREPARATION OF EQUIPMENT

- Review carefully local guidelines on disinfection and sterilization. Disposable needles and syringes (appropriately discarded) are preferred. Correct disposal of contaminated needles and syringes into puncture-proof disposable containers is crucial to protect providers, clients, and persons who handle garbage. If needles and syringes are to be used more than once, they **must be decontaminated, cleaned and then sterilized between every injection**.
- Assemble equipment needed for injection. (Prepare the equipment needed for the procedure **before** any needed physical examination, so the woman does not wait very long on the examining table while you get ready.)
  - DMPA or NET-EN,
  - **sterile** syringe (1 cc. size or larger; preferably disposable),
  - **sterile** needle for IM injection,
  - cotton wool,
  - locally-available **antiseptic as skin disinfectant**. Antiseptics include Betadine®, Hibitane®, pHisoHex, Savlon® and others.

EXPLANATION TO THE CLIENT

- Encourage the client to ask questions as you explain what you are going to do.
- Show the client the equipment that will be used, and tell her what you will be doing.
- Explain to the client that the syringes and needles have been carefully sterilized (or, if disposables are used, that they come presterilized in the package). Reassure her there is **NO** risk of disease from injections in your clinic, because you are very strict about using only properly sterilized instruments.
- Reassure the client after the injection.

GIVING THE INJECTION

The usual dosage is:

- 150 mg of DMPA (Depo-Provera®) deep IM every 3 months (12 weeks).
  Note: For client convenience, the next injection of DMPA can be safely given as much as 4 weeks early or 2 (to 4) weeks late (depending on local protocol).

OR

- 200 mg of NET-EN (Noristerat®) deep IM every 2 months (8 weeks).
  Note: For client convenience, the next injection of NET-EN can be safely given as much as 2 weeks early or 1 (to 2) weeks late (depending on local protocol).

Step 1: Wash your hands.
Step 2: Disinfect the injection site, using local antiseptic. For both DMPA and NET-EN, either the upper arm (deltoid) or the buttocks (upper outer quadrant in the gluteal muscle) may be used.
Step 3: For DMPA, shake vial vigorously before drawing into syringe. For NET-EN, warm the vial between your hands to make it easier to draw the thick oily solution into the syringe.
Step 4: Wipe top of vial with **disinfectant**, if necessary (glass vials to be broken do not require disinfection, see local guidelines for appropriate disinfection).
Step 5: Give injection (both DMPA and NET-EN are given as deep intramuscular injections).
Step 6: Do **not** massage injection site, and tell the client not to massage the site, since massaging may speed the release of progestin and thus shorten the period of efficacy.
Step 7: Wash your hands.

Adapted from: Long-Acting Progestins - Promise and Prospects. *Population Reports* Series K 1983;2(May):K18-K55.

STEP 6
Explain instructions for use of the progestin-only injectable contraceptive

INSTRUCTIONS TO THE SERVICE PROVIDER

- After explaining instructions to the client, ask the client to repeat the explanation to you in her own words. If she has misunderstood or omitted any instruction, go over that information again with her.
- Encourage the use of condoms (or spermicides if condoms are unacceptable), in addition to progestin-only injectables:
  - if there is a chance of the client or her partner being exposed to STDs, including AIDS or
  - if the client is late for her next injection.
- Give several condoms, according to local clinic guidelines. If necessary, demonstrate with samples and models the correct use of condoms and spermicides.

INSTRUCTIONS TO THE CLIENT

When the injection takes effect:

- The injection takes effect immediately if it is given between day 1 and day 6 of your cycle.
- If the first injection is given after the 7th day of your last period, you should either use condoms or spermicide as a back-up method for 7 days or you should NOT have intercourse for 7 days.

What to do if you are late for the next injection:

- If you are late for your next injection, you need to abstain or use another method of contraception (such as condoms) until you have your next injection.

Irregular bleeding and absent menstrual periods:

- Most women who use progestin-only injectables have changes in their periods. Especially with the first injection, you are likely to have frequent bleeding. This is NOT a true menstrual period. You may have heavy or irregular periods, spotting between periods, or no periods at all. These changes are normal with progestin-only injectables use and are not harmful to your health.
- After 9 to 12 months of use, your periods will probably be irregular or you may not have them at all. This is very safe.
- Some women worry that if they have no menses, they are pregnant, but injectables are very effective. If you receive your injections on time, pregnancy is extremely unlikely (3 in 1000 chance). Other women worry that if they have no menses something toxic ("bad blood") will build up inside. With injectables, menstrual bleeding is absent because **no blood** is building up inside.
- About 7 to 10 months after your last injection (on average) your old pattern of menstrual bleeding will return. If your pattern before using injectables was irregular, it will still be irregular after using injectables.

Weight gain:

- You should watch your diet, as your appetite may increase.

Injections and other medical care:

- Any time you make a medical visit, tell the physician or nurse that you are using progestin-only injectable contraceptives.

Risk of exposure to STDs, including AIDS:

- Use condoms in addition to progestin-only injectable contraceptives if you think there is any chance you or your partner are at risk of exposure for STDs, including AIDS. If condoms are unacceptable, use spermicides.

STEP 7
Plan for the return visit

INSTRUCTIONS TO THE SERVICE PROVIDER

- Make sure all points in the informed choice checklist (see Chapter 1) have been covered.

INSTRUCTIONS TO THE CLIENT

- If you have no problems, return to the clinic on time for your next injection. Clients receiving DMPA (Depo-Provera®) need to return every 3 months (12 weeks) for repeat injection. Clients receiving NET-EN (Noristerat®) need to return every 2 months (8 weeks).
- Return to the clinic if you or your partner are not satisfied with the method, or if you develop any side effects you feel are due to the method.
- Return at once if you experience any of the following signs/symptoms of serious conditions which may or may not be related to progestin-only injectable contraceptives use:
  - very heavy vaginal bleeding,
  - severe headaches, or
  - severe abdominal pain.
- Return to this clinic or a STD clinic if you think there is any chance you may have been exposed to a STD.

STEP 8
Follow procedures for the return visit

- Ask the client, and her partner if possible, whether she or they were satisfied with the progestin-only injectable contraceptive.
- Ask if there are any complaints or problems following the injection. If there are any side effects, see the chart below for management of side effects.
- Repeat the history checklist. If the client has any symptoms of pregnancy or complaints of pelvic pain, discharge, bleeding with intercourse or very heavy bleeding, repeat the bimanual and speculum examinations.
- If possible, check her blood pressure and weight (optional).
- If the client is **more than one month late** for her return visit, first determine whether she is already protected from pregnancy (abstinence? the lactational amenorrhea method? consistent use of condoms?). If she is at risk of pregnancy, check her for pregnancy by pelvic exam or, if available and affordable, by laboratory test. Ask the client to use a non-hormonal method for the next month and return for a repeat pelvic examination or pregnancy test to rule out pregnancy. If the exam is still negative, the client may receive her progestin-only injectable contraceptive that day.

- If the client has developed any conditions for restricting the use of progestin-only injectables, or the client finds progestin-only injectable progestins or their side effects unacceptable, help the client make an informed choice of another method.
- If the client is satisfied with the method and there are no conditions for restricting the use of progestin-only injectables, then:
  - give her the next injection and
  - remind her of the reasons to return to the clinic (side effects, signs/symptoms of serious conditions, dissatisfaction with the method, symptoms of STDs).
- Plan for a return visit in 3 months (12 weeks) for DMPA or 2 months (8 weeks) for NET-EN.

MANAGEMENT OF SIDE EFFECTS OF PROGESTIN-ONLY INJECTABLES

Note: For all of the side effects listed, if the client is using DMPA, and wishes to continue using progestin-only injectables, a change to NET-EN may improve the symptom.

Adapted from: 1) *NORPLANT® Prototype 5-Day Training Curriculum*. Washington DC, PATH, 1989; 2) *Guide to Effective Counseling About NORPLANT®*. New York, The Population Council, 1989; 3) *Child Spacing and Family Planning Clinical Procedure Manual*. Harare, Zimbabwe National Family Planning Council, 1985; 4) Odlind V: Hormonal Long-Acting Methods for Contraception. *The British Journal of Family Planning* 1991;16(Suppl No. 4):8-11; 5) Brache V, et al: Ovarian Endocrine Function Through Five Years of Continuous Treatment With Norplant Subdermal Contraceptive Implants. *Contraception* 41:169; 6) *NORPLANT®: A Summary of Scientific Data*. New York, The Population Council, 1990; 7) Hatcher RA, et al: Contraceptive Technology, 1990-1992. New York, Irvington Publishers Inc., 1990, pp 309-313; 8) Stewart GK: Update on the Norplant System. *Contraceptive Technology Conference 1991*. Washington DC, unpublished, March 1991, pp 34-38; 9) Diaz S, et al: Clinical Assessment of Treatments for Prolonged Bleeding in Norplant Implants Contraceptive Users. *Contraception 1990;*42(1);97-109; 10) Shoupe D, Mishell DR, Bopp BL: The Significance of Bleeding Patterns in Norplant Users. *Obstetrics and Gynecology* 1991;77:256-260; 11) Brown RC, Brown JE: *The Family Planning Clinic in Africa*. London, Macmillan Publishers, Ltd., 1987; 12) Fakeye O, Balaugh S: Effect of NORPLANT® Contraceptive Use on Hemoglobin, Packed Red Cell Volume and Menstrual Bleeding Patterns. *Contraception* 1989;39:265-274; 13) Klavon SL, Grubb G: Insertion Site Complications During the First Year of NORPLANT® Use. *Contraception* 1990;41(1):27-37; 14) Kleinman RL: *Hormonal Contraception*. London, IPPF Medical Publications, 1990; 15) Waller HT, Holmen J: Systolic and Diastolic Blood Pressure Valves Indicating Equivalent Risk. *The New England Journal of Medicine* 1991;35(August 8):434; 16) World Health Organization Division of Family and Reproductive Health: *Improving Access to Quality Care in Family Planning. Eligibility Criteria for Initiating Use of Selected Methods of Contraception.* WHO/FRH/FPP/96.9; and 17) Technical Guidance Working Group: *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*. Chapel Hill NC, INTRAH Program, University of North Carolina at Chapel Hill School of Medicine, 1994, pp 27-46.

Side Effects	Investigation Steps	Management
Heavy and/or Prolonged Bleeding	A. Determine what the woman's concerns are (fear of underlying disease? anemia? inconvenience? social problem surrounding "menstrual" bleeding? expense of sanitary supplies?).	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. Explain that the number of bleeding days decreases with months of injectable progestin use. Clarify that this is not "menstrual" bleeding (this distinction may be of social or religious importance to her).
	B. Determine by history whether other conditions are likely (i.e., tumors, pregnancy, abortion, PID and other gynecologic problems).	B. If suspected, abnormal conditions which cause prolonged or heavy bleeding should be evaluated and treated as appropriate.

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Side Effects	Investigation Steps	Management
Heavy and/or Prolonged Bleeding **(continued)**	C. Look for evidence of anemia. Evaluate and address anemia if indicated.	C. Give nutritional advice (if indicated) on the need to increase intake of iron-containing foods.
	D. Determine whether counseling and reassurance are sufficient to address the client's concerns.	D. 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 * NOTE: Nonsteroidal anti-inflammatory drugs (e.g., ibuprofen) should be used instead of aspirin because aspirin promotes bleeding. • since the above two treatments work differently, both may be tried together, because: – COCs/estrogen rebuild the endometrium and thus may stop bleeding, and – ibuprofen blocks prostaglandin synthesis and thus decreases uterine bleeding.
	E. Determine whether the prolonged spotting or bleeding has responded to treatment to the client's satisfaction.	E. Some prolonged or heavy bleeding may fail to be corrected and injections may need to be discontinued.
Extremely Heavy Bleeding (very uncommon with injectables)	A. Take a history and perform physical exam to evaluate possible causes, especially pregnancy (intrauterine, ectopic), recent abortion, fibroid or other tumors (leiomyomata).	A. Manage any underlying conditions according to local clinic guidelines and refer as appropriate. Do **NOT** perform uterine evacuation unless an underlying medical condition is suspected (vacuum aspiration is generally the preferred method of uterine evacuation).
	B. Evaluate and address anemia.	B. Give nutritional advice on the need to increase intake of iron-rich foods.

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Side Effects	Investigation Steps	Management
Extremely Heavy Bleeding (very uncommon with injectables) **(continued)**	C. Determine whether client wants high dose estrogen therapy to stop the bleeding.	C. Extremely heavy bleeding (much greater than normal menstruation) is uncommon; it can usually be controlled by administration of increased doses of estrogen (which may be given as COCs). Follow clinic protocol. Some clinicians begin with two COCs twice daily for seven days to stop unusually heavy bleeding; where available, higher dose estrogen may also be used. For heavy bleeding due only to injectable progestin use, do **not** perform uterine evacuation because if the bleeding is **only** due to the progestin-only injectable, increased doses of estrogen will stop it.
	D. Determine if heavy bleeding has been corrected.	D. Some women will require stopping the use of injectable progestins due to medical reasons for excessive bleeding or due to the client's preference.
Amenorrhea which Concerns the Client	A. Attempt to rule out pregnancy by menstrual history, symptoms, physical exam and, if available and affordable, by laboratory test. See Appendix A: "How to be Reasonably Sure the Woman is Not Pregnant."	A. If the client is definitely pregnant, refer her according to her preference. If she intends to continue the pregnancy, stop injections. When you are reasonably sure the woman is not pregnant, reassure the client that there is no evidence that DMPA causes fetal damage, and permit her to continue DMPA if she so chooses.

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Side Effects	Investigation Steps	Management
Amenorrhea which Concerns the Client **(continued)**	B. If there are no signs or symptoms of pregnancy, ask what it is about the absent menses that worries the client. Many women are worried they are pregnant, and may even note symptoms of pregnancy even when they are not pregnant. Others worry that, if they have no menses, something toxic is building up inside them, and that they need to menstruate to clean out "bad blood".	B. Reassure the client she is not pregnant. Explain that over 90% of all women on progestin-only injectables have absent menses for at least 3 months and that half of all DMPA users stop bleeding after the fourth injection. Explain that progestin-only injectables keep the lining of the uterus from building up: "Nothing toxic is building up. In fact, so little lining is building up that there is none to be shed now." Explain this is a safe condition which lasts only as long as she uses the injectable progestins.
	C. Determine if the client still finds lack of menses to be unacceptable, despite reassurance.	C. Offer the client COCs if estrogen-related "conditions" do not apply to her. If she has conditions in which estrogen should not be used, help her make an informed choice of a non-hormonal method.
Severe Lower Abdominal Pain	A. Take a history and perform physical exam to rule out possible intrauterine or ectopic pregnancy, acute PID, ovarian tumor, appendicitis, ovarian cysts, twisted ovarian follicles, or ruptured liver tumor.	A. 1) If the client presents with any of these causes, provide immediate medical attention and refer as appropriate. 2) If ovarian cysts are found, reassure the client that they are a normal and frequent occurrence. Most cysts disappear on their own without surgery. To verify the cyst is resolving, re-examine the client in 3 weeks or so if possible.
	B. Take a history and perform relevant physical exam (palpate abdomen; do rectal exam with glove) to rule out constipation.	B. For constipation, instruct on diet (plenty of roughage and water) and adequate exercise. Give milk of magnesium or other mild laxative.

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Side Effects	Investigation Steps	Management
High Blood Pressure (BP)	A. Re-check BP after the client has sat quietly for a few minutes. Use large adult cuff (if available) for women with large arms.	A. If the BP is under 180/110, but over 140/90, give the injection and repeat BP on two more occasions over the next 2 weeks. If BP remains over 140/90, refer the client for treatment, but reassure her she can continue the injectable progestins because they have little effect (positive or negative) on blood pressure. If systolic BP is 180 or higher, or diastolic BP is 110 or higher, this is severe hypertension. Give the next injection and refer the client as appropriate. In the future, the client may be best served by a very effective non-hormonal method (IUD, VSC).
Dizziness or Nausea (rare with injectables)	A. According to clinic ability, rule out other causes, such as anemia, high or low blood pressure, low blood sugar, pregnancy, viral illness, or neurologic disease.	A. Refer or treat according to local clinic guidelines. Reassure client that it is not common for progestin-only injectables to cause dizziness or nausea. If client wants to continue the method, provide injection.
	B. If no cause is found and dizziness or nausea is very slight.	B. If dizziness or nausea continues, and the client finds it unacceptable and attributes it to progestin-only injectables, help the client make an informed choice of a non-hormonal method.
	C. If no cause is found and dizziness or nausea is very severe or the client is convinced dizziness/nausea is due to injectables.	C. Refer the client as appropriate. Help the client make an informed choice of a non-hormonal method.
Depression	A. Ask about possible causes, e.g., family, financial, social problems, or recent losses.	A. Counsel accordingly and follow-up during her next return visit.

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Side Effects	Investigation Steps	Management
Depression **(continued)**	B. If no other cause is found, ask the client if she really believes the depression is due to the progestin-only injectables. Reassure her that injectables do not cause severe depression.	B. If the client is convinced her depression has worsened while using progestin-only injectables or is due to the method, help her make an informed choice of a non-hormonal method. If the progestin-only injectables have not caused an early depression to worsen or the client sees other causes, the progestin-only injectables can be continued, but follow-up on this matter during her next visit.
Significant Unwanted Weight Gain	A. Interview the client, inquiring about eating habits promoting weight gain, or lack of exercise.	A. Weigh the client and compare with her weight at her first visit. If her weight gain is less than 2 kilos, reassure her that this is negligible. If weight gain is more than 2 kilos, instruct her on diet and exercise.
	B. Rule out weight gain due to pregnancy. See Appendix A: "How to Be Reasonably Sure the Woman is Not Pregnant."	B If the client is pregnant, refer her according to her preference. If she intends to continue the pregnancy, do not give next injection.
	C. If the client denies poor eating habits, but complains of increased appetite or weight gain without apparent cause, ask if the weight gain is unacceptable.	C. If the weight gain is unacceptable, and the client is convinced it is due to the injectable help the client make an informed choice of another method, including a low dose combined oral contraceptive (COC), progestin-only pill (POP), or other acceptable method.
Headaches	A. Determine whether she has purulent nasal discharge and tenderness in sinus area.	A. Refer for treatment of sinusitis if present; continue progestin-only injectables.
	B. Ask whether she has ever had high BP.	B. Regardless of history, check the BP. If it is elevated, repeat BP. Give progestin-only injectable. See "High Blood Pressure (BP)," above.
	C. Ask the client whether her headaches have been worse since the injections began.	C. If headaches are definitely worse with progestin-only injectables, recommend she switch to a reliable non-hormonal method.

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Side Effects	Investigation Steps	Management
Headaches **(continued)**	D. Ask if she has had loss of speech, numbness, weakness or tingling, or visual changes associated with the headaches. These symptoms may suggest severe migraine headaches.	D. These symptoms may suggest threatened stroke (temporary inadequate blood flow to the brain). Promptly refer as appropriate. Be sure the client does not smoke (or help her stop smoking). Help the client make an informed choice of a reliable non-hormonal method. If none are acceptable, offer POPs or progestin-only injectables, which are always far safer than pregnancy.
	E. If there is no threatened stroke or sinus disease and the headaches are no worse on injectables, explore possible social, financial or physical causes of headaches.	E. Counsel accordingly; continue progestin-only injectables.
Acne **(rarely associated with injectables)**	A. Ask how and how often she cleans her face; rule out inadequate hygiene and use of creams that block pores.	A. Recommend cleaning face daily with water. An astringent, like lemon, may also help. Avoid heavy creams and creams with lanolin or perfumes.
	B. Ask if she is currently under great stress.	B. Counsel as appropriate.
	C. Ask if the client believes her acne has worsened with use of progestin-only injectables.	C. Explain that a few women have noticed worsening of acne with progestin-only injectables. This problem usually does NOT occur with estrogen-containing COCs (even low dose COCs improve acne in most women).
Loss of Libido **(sex drive)**	A. Ask if this is due to other causes, e.g., dry vagina, painful intercourse, or marriage problems.	A. Counsel or refer as appropriate.
	B. If no other cause is found, ask if the client is convinced this is a problem due to progestin-only injectables.	B. Help the client make an informed choice of another method (including COCs).

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 the start of normal menses, or
- is within 4 weeks postpartum (for NON-lactating women), or
- is within the first 7 days post-abortion, or
- is fully or nearly 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 study[2].

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

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

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 women[4].

1) Labbok M, Cooney K, Coly S. *Guidelines: Breastfeeding, Family Planning, and the Lactational Amenorrhea Method - LAM*. Washington, DC: Institute for Reproductive Health, 1994.
2) Labbok MH, Perez A, Valdes V, Sevilla F, Wade K, Laukaran VH, 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) Labbok 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 fertile[2]. Breastfeeding before giving each supplement is optimal.