Norplant® Guidelines for Family Planning Service Programs

A Problem-Solving Reference Manual

Editors
Noel McIntosh
Penelope Riseborough
Chris Davis
NORPLANT® GUIDELINES
for FAMILY PLANNING
SERVICE PROGRAMS

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(January 1993)
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The purpose of this manual is to provide clinicians (physicians, nurses and midwives) essential information on how to use Norplant safely. The material is arranged sequentially according to the usual way in which clients are cared for - starting with general counseling, client assessment, instructions on how to insert Norplant capsules, management of side effects and health problems, and concluding with how to remove the capsules and the basics of organizing and managing Norplant services. Moreover, it is provided in concise modules for ease in learning and recall. Finally, key points are repeated in several sections to emphasize their importance.

Specific objectives are to:

- Describe the basic process of counseling clients about using Norplant
- Explain the indications and precautions for Norplant use
- Define the items necessary to include in the assessment of a potential Norplant acceptor
- Detail easy-to-use, inexpensive infection prevention practices which minimize disease transmission for clients and health care staff
- Describe a step-by-step procedure for insertion of Norplant capsules
- Describe the important elements in the follow-up of Norplant users
- Provide a guide to the management of possible side effects and complications of Norplant use
- Describe a step-by-step procedure for Norplant removal
- Describe the management skills needed to organize and provide quality Norplant services

Successful Norplant programs are those in which the staff exhibit:

- Good clinical judgment in selecting acceptors
- Care, sensitivity and thoroughness in informing the client about Norplant and its common side effects
- Skill in inserting (and removing) the subdermal implants
- Knowledge and ability to recognize real or potential problems
- Capability to take appropriate clinical action in response to these problems, including knowing when (and where) to refer clients with serious complications
INTRODUCTION TO NORPLANT

BACKGROUND

Norplant is an effective, long-lasting, reversible contraceptive that provides protection for up to five years. Six thin, flexible capsules made of a soft rubber-like material and filled with a synthetic hormone are inserted just under the skin of a woman's upper arm by means of a minor surgical procedure. Although contraceptive protection is provided within hours of insertion, normal fertility rapidly returns when the implants are removed.

The history of Norplant may be thought of in four stages:

- **Research** that resulted in the concept of implant contraception
- **Development** of the Norplant method
- **Introduction** of Norplant to family planning and health care systems around the world
- **Incorporation** of the method into family planning programs worldwide

The research and development program that produced Norplant began in 1966 in The Population Council's Center for Biomedical Research. A series of laboratory investigations was conducted on the release of various steroid hormones from silicone rubber (i.e., Silastic®) tubes. Results in animals showed that continuous release of hormones at fairly constant blood levels could be sustained for long periods of time. Furthermore, it was shown that the suppressive effects of these hormones on fertility in animals could be maintained for over a year. The results formed the basis of the Norplant concept (i.e., that an appropriate contraceptive steroid, stored under the skin in silicone rubber capsules, could provide effective contraception for many years, and that a single act of contraceptive acceptance could replace more than 1,800 days of pill taking).

By 1974, the progestin component was narrowed down to three candidates. Subsequently, levonorgestrel was selected on the basis of its effectiveness, its long-acting characteristics and its proven safe use in combination oral contraceptives. The system is composed of six capsules and was named Norplant. Pre-introductory trials of Norplant, designed to evaluate the effectiveness, safety and acceptability of the method under local conditions in developing countries, began in 1980.

With the safety and efficacy trials progressing satisfactorily, The Population Council began to address some of the issues critical to the introduction of the method. An agreement was completed with Leiras Oy Pharmaceuticals, an international company based in Finland, to manufacture and distribute the implants. In 1983, Finland became the first country to give regulatory approval to the Norplant method. At present 27 countries, including the United States, have approved Norplant.
COMPOSITION

Each of the six flexible Norplant capsules (Figure 1-1) is 3.4 centimeters (cm) long, with a diameter of 2.4 millimeters (mm), and contains an average of 36 milligrams (mg) of levonorgestrel, a synthetic progestin, in dry crystalline form. The capsule is sealed at each end with Silastic Medical Grade Adhesive. (Silastic is polydimethyl-siloxane).

Norplant is not made of new ingredients. Levonorgestrel is widely used in combined oral contraceptives (COCs) and in the progestin-only minipill. Moreover, the Silastic tubing has been used in surgical applications of various kinds in humans without adverse effects since the 1950s. What is new about Norplant is the way it delivers the contraceptive drug into the body; namely, the progestin diffuses through the walls of the capsules in a continuous low dose.

Figure 1-1. Norplant Capsule, Actual Size


RELEASE AND PHARMACOKINETICS

A blood level of levonorgestrel sufficient to prevent conception is reached within 24 hours after placement of the implants and is maintained at an effective level for at least five years (Leiras. 1989). Initially the six-capsule system has a relatively high release rate, about 85 micrograms (mcg)/day during the first few weeks of use. This decreases to about 50 mcg/day by nine months and to 35 mcg/day by 18 months, followed by a further decline to a steady level of 30 mcg/day.

Although the mean concentration of levonorgestrel declines relatively rapidly during the first weeks of Norplant use to a mean level between 0.25 and 0.4 nanogram (ng)/milliliter (ml) by six months, this level is still sufficient to prevent pregnancy. A slight decline, but still within this range of mean values, occurs for the remainder of Norplant use.

Circulating concentrations of levonorgestrel among individual users differ by a factor of several fold and many values fall outside the mean ranges stated above. Several factors account for the variation among subjects. One is the subject-to-subject variation in the rate of levonorgestrel metabolism. Another is variation in the weight of individuals, especially in women over 70 kilograms (kg). Yet another is variability in the levels of sex hormone binding globulin (SHBG) which circulates in the blood stream. Because levonorgestrel has a high affinity for circulating SHBG, it suppresses SHBG production. Suppression of SHBG, however, is not the same in all women. As a consequence, the level of free (unbound) levonorgestrel may vary from one individual to another. Finally, there is evidence that two local factors may affect levonorgestrel release from the implants. These factors
are: the thickness of the fibrous sheath formed around each capsule and the vascular patterns and amount of fatty tissue surrounding the capsules.

Following removal of the implants, plasma levonorgestrel becomes unmeasurable within a few days. (The time required for one-half the levonorgestrel to be cleared from the body after removal of the implant is approximately 40 hours.)

MECHANISM OF ACTION

Pregnancy is prevented through a combination of mechanisms. The two major ways are:

- Inhibition of ovulation so that eggs will not be produced regularly
- Production of thick scanty cervical mucus which prevents sperm penetration

Other mechanisms which may add to these contraceptive effects include:

- Suppression of endometrial growth
- Decrease in progesterone secretion during the luteal phase in those cycles when ovulation does occur

EFFECTIVENESS

The effectiveness of a contraceptive method is usually the most important factor both for the individual (or couple) trying to choose a method and for the family planning provider involved in counseling them. Potential users also need to know how reliable a given method is, while family planning providers need to know how much they can depend on the various methods to prevent pregnancies.

Presenting meaningful information regarding failure (pregnancy) rates for couples choosing a contraceptive method is difficult. For valid comparisons to be made among the methods, failure rates must be presented both for couples who use the method consistently and correctly and for typical users of the method. Data presented in this way for the first year of use for a number of contraceptive methods are shown in Figure 1-2.

Norplant is one of the most effective reversible contraceptive methods. Although no contraceptive is 100% effective, the average annual pregnancy rate over a five-year period for Norplant is less than 1%. In comparison, pregnancy (failure) rates that have been experienced with other methods of family planning during the first year of use are depicted in Figure 1-2. Another consideration is that, except for voluntary sterilization and the IUD, efficacy of the other methods depends, in part, on how reliably they are used. By contrast, the efficacy of Norplant does not depend on client compliance.

The relationship of user weight to pregnancy rates is shown in Table 1-1. Presently available data indicate that Norplant may be less effective in preventing pregnancy in heavier women. (For example, the five-year gross cumulative pregnancy rate is 8.5 per 100 users in women weighing 70 kg or more.) Recent studies, however, suggest that using a softer and less dense type of Silastic capsule may increase effectiveness, especially in heavier women (i.e., those over 70 kg). To confirm this, a large clinical study has been undertaken to provide sufficient data for stratification by weight. Until the results of this new study are available, only the pregnancy rate data in Table 1-1 can be cited.
Introduction

Figure 1-2. Estimated Range of Failure Rates for Major Contraceptive Methods Under Use Worldwide

![Diagram showing estimated range of failure rates for major contraceptive methods.]


Table 1-1. Gross Cumulative Pregnancy Rates per 100 Continuing Users Through Five Years

<table>
<thead>
<tr>
<th>Weight</th>
<th>Year</th>
<th>Cumulative</th>
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<tr>
<td>&lt;50 Kg</td>
<td>0.2</td>
<td>0.5</td>
</tr>
<tr>
<td>50-59 Kg</td>
<td>0.5</td>
<td>0.4</td>
</tr>
<tr>
<td>60-69 Kg</td>
<td>0.5</td>
<td>1.6</td>
</tr>
<tr>
<td>&gt;70 Kg</td>
<td>0.1</td>
<td>5.1</td>
</tr>
<tr>
<td>All</td>
<td>0.2</td>
<td>1.2</td>
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Source: Adapted from the United States Food and Drug Administration (USFDA): Norplant System (Levonorgestrel Implants): Prescribing Information. USFDA, December 1990.
Pregnancy also may be more likely in Norplant users who take medications which increase the production of liver enzymes that metabolize (break down) hormones such as levonorgestrel (Angle et al, 1991). This increased metabolism can lead to reduced levels of the hormone. Medications which fall into this category include rifampin for treatment of tuberculosis; anti-epilepsy (seizure disorder) drugs such as barbiturates (e.g., phenobarbital), phenytoin (e.g., Dilantin®) and carbamazepine (e.g., Tegretol®) but not valproic acid; and phenylbutazone (e.g., Butazolidin®), an anti-inflammatory drug.

**Remember:** Before inserting the capsules, the health care provider should ask the client what medications, if any, she is taking.

**CONTINUATION**

Continuation rates observed with Norplant have been high in the clinical studies and field trials conducted to date. For example, the net continuation rate in 816 acceptors analyzed in the centrally monitored Population Council studies was 77.1% at one year and 35% at five years. It approached 49% at five years in a later cohort of users.

**SIDE EFFECTS**

**Menstrual Bleeding Patterns**

The predominant side effect observed during the use of Norplant is the disruption of the menstrual cycle. Increased bleeding is experienced by some Norplant users and decreased bleeding by others. Patterns of increased bleeding, during the first 90 days of use as reported in one study are presented in Table 1-2. For comparison, five days of bleeding is considered usual.

It should be noted that the incidence of increased bleeding decreased in frequency over the next three 90-day periods. This may be due, at least in part, to the termination of Norplant use by the most affected acceptors, who thereby removed themselves from further analysis.

**Management of Bleeding Irregularities**

Despite the fact that there is no recommended medical treatment for prolonged and/or heavy menstrual bleeding, many clinicians treat these clients in an attempt to correct the bleeding pattern and to improve continuation rates. To date, only one study has been published which addresses this issue (Diaz et al, 1990). In that study, levonorgestrel (30 mcg, twice daily), ethinyl estradiol (EE) (50 mcg, daily) and ibuprofen (800 mg, three times daily) were compared to a placebo. Treatment was initiated only after eight days of bleeding. Duration (number of days) of total bleeding was determined after treatment with one of the three drugs or with the placebo. All three treatment groups performed better than the placebo. Ethinyl estradiol reduced bleeding over a one-year period by 52 days; ibuprofen, a non-steroidal anti-inflammatory agent, reduced bleeding over a one-year period by 35 days; and levonorgestrel by 28 days. In this study, EE was given for 20 days on average 2.2 times during the one-year study period; ibuprofen was given for only five days on average 2.7 times over the year.

The advantages of using ethinyl estradiol in the management of prolonged bleeding in Norplant users should be weighed carefully against potential disadvantages. For example, treatment may conflict with the reason the client selected Norplant (e.g., because it is an estrogen-free method).
Additionally, gastric intolerance to EE ied 5 out of 45 subjects to discontinue the treatment method.

Clearly, additional research is necessary on this topic since irregular bleeding is the most common reason for discontinuation, and because of the strong desire and tendency of clinicians to want to treat irregular bleeding. It should be noted that in the above study the effects of these treatment regimens on continuation rates were not assessed. Therefore, along with evaluating the effect of various medical treatments, a comparison should be made of the effect on continuation of good counseling alone versus medical treatment.

Table 1-2. Manifestation of Increased Bleeding (per 90 days)

<table>
<thead>
<tr>
<th>Manifestation</th>
<th>Percentage</th>
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<tr>
<td>Frequent bleeding (5+ episodes)</td>
<td>21%</td>
</tr>
<tr>
<td>Prolonged bleeding (8+ days per episode)</td>
<td>35%</td>
</tr>
<tr>
<td>Numerous bleeding days (21+)</td>
<td>27%</td>
</tr>
<tr>
<td>Numerous bleeding and spotting days (31+)</td>
<td>36%</td>
</tr>
</tbody>
</table>

Note: Some women had more than one manifestation of increased bleeding.

Source: Adapted from the United States Food and Drug Administration (USFDA): Norplant System (Levonorgestrel Implants): Prescribing Information. USFDA, December 1990.

OTHER SIDE EFFECTS

In addition to menstrual bleeding problems, women using Norplant occasionally develop enlarged ovarian follicles which usually cause no symptoms and are discovered only incidentally at pelvic examinations. Generally they regress spontaneously and rarely require surgical treatment. Finally, several other conditions that may or may not be associated with Norplant use have been reported. They include headache, breast tenderness and/or discharge, weight gain, increased body or facial hair (hirsutism) and vaginitis. (See Chapter 7 for a complete listing of side effects.)

OUTCOME OF PREGNANCIES

The use of Norplant does not appear to increase the incidence of ectopic pregnancy, in part because of the effectiveness of the method. In pooled studies, the ectopic pregnancy rate was 1.3 per 1,000 woman-years of use. Because ectopic pregnancy rates vary greatly among cultures, it is difficult to evaluate the effect of Norplant use. For example, the ectopic rate in the USA among women who are non-contraceptive users was 1.4 per 1,000 woman-years in the 1980s.

To date, there has been only one known instance of a birth defect among women using Norplant. A boy delivered by a woman in a pre-introductory study was born with ambiguous genitalia (undeveloped penis, rudimentary scrotum, one testis absent). It is unlikely that these defects were due to Norplant use.

RETURN OF FERTILITY

There is no evidence that prolonged use of Norplant impairs subsequent fertility. Once the implants are removed, the contraceptive effect ceases almost immediately. Return to previous fertility is usually prompt. For
example, in a recent study of women who had Norplant removed and wished to become pregnant, 40% conceived within 3 months of removal, 63% within 6 months, 76% by 1 year and 90% within 24 months. These rates are similar for women using no contraception.

**CLINICAL PHARMACOLOGY**

Indicators of change in organ function in women using Norplant have been monitored in several studies. No clinically important changes were found in liver, kidney, adrenal or thyroid functions.

**Carbohydrates**

Norplant use has been associated with a slight increase in serum glucose concentrations; however, the changes did not increase in magnitude with time and are not clinically significant.

**Lipoproteins**

Studies of the effects of Norplant use on lipoproteins have yielded conflicting results. Total cholesterol was significantly decreased in six studies. High-density lipoprotein (HDL) cholesterol was, however, significantly increased in three studies and significantly decreased in three studies. The total cholesterol to HDL cholesterol ratio was not significantly increased in any of the six studies and was significantly decreased in two. HDL₂ was decreased in the single study in which it was measured. The clinical importance of these findings is not yet clear.

**Clotting Factors**

Studies of effects of Norplant use on clotting factors also have yielded differing results. There was a significant decrease in Factor VII in two studies and significant increases in a third. Factor X showed no change in one study and significant increases in two.

Antithrombin III activity was not significantly changed. Fibrinogen was measured in two studies; there was no change in one, and a small but statistically significant increase in the other. Again, the clinical importance of these changes has not been determined.

**Endocrine Changes**

Estradiol levels during Norplant use have shown irregular patterns, with base values of 30-70 picograms (pg)/ml and occasional values between 200 and 400 or, infrequently, peaks to approximately 600 pg/ml.

Statistically significant decreases in circulating total testosterone and androstenedione have been the predominant finding among Norplant users. They were accompanied by corresponding decreases in SHBG. Since testosterone is highly bound to SHBG, the decreased SHBG concentrations would predict the slightly lower testosterone concentrations. Unbound testosterone concentrations, however, were essentially unchanged. These studies provide evidence that the effect of Norplant on androgens is not likely to be of clinical significance.

**Uterine Endometrium**

The endometrial suppression associated with the use of Norplant has not been associated with pathological processes. Several studies have shown that Norplant use does not represent a special hazard to the endometrium (lining cells of the uterine.
Introduction

cavity). The effect of duration of use on endometrial patterns also has been examined, and there is no convincing evidence of any adverse changes.

SHELF LIFE AND EFFECTIVE LIFE

The sterile packages of Norplant capsules have a shelf life of five years from the date of manufacture (expiration date stamped on each box). The Norplant package has been designed to maintain the sterility of the product for that period of time provided that the pouch is not damaged or opened.

If inserted anytime prior to the expiration date (shelf life), Norplant is effective in preventing pregnancy for up to five years. The implants should be removed by the end of the fifth year (effective life). A new set of implants may be inserted at that time if desired.

REFERENCES


TWO

COUNSELING

BACKGROUND

There are various reasons why individuals and couples decide to start, continue or stop practicing family planning. Some people may wish to delay the birth of their first child, while others may want to space the birth of their children, and some may want to ensure that only a desired number of children are born. There is another group of people who may wish to use family planning services not so much for protection from unplanned or unwanted pregnancy, but for other reasons, including achieving pregnancy or for the protection of their reproductive and sexual health.

CLIENT RIGHTS

Any member of the community who is of reproductive age should be considered a potential client of family planning services. All individuals in the community have a right to information about family planning for themselves and their families, regardless of their ethnic origin, socio-economic status, religion, marital status or political belief. All persons also have a right to decide freely whether or not to practice family planning.

Family planning programs should assist people in the practice of informed free choice by providing unbiased information, education and counseling, as well as an adequate range of contraceptive methods. Clients should be able to obtain the method they have decided to use provided the method is available.

A client’s concepts of acceptability and appropriateness change with circumstances. Therefore, the client has the right to decide when to start, stop or switch methods.

Clients also have the right to discuss their concerns in an environment in which they feel confident. The client should be aware that her conversation with the counselor or service provider will not be listened to by other people.

When a client is undergoing a physical examination it should be carried out in an environment in which her right to bodily privacy is respected. The client’s right to privacy also includes the following aspects related to quality of services:

- When receiving counseling or undergoing a physical examination, the client should be informed about the role of each individual inside the room (e.g., service providers, individuals undergoing training, supervisors, instructors, researchers, etc.).

- A client should know in advance the type of physical examination which is going to be undertaken. The client also has a right to refuse any particular type of examination if she doesn’t feel comfortable with it.

A client should feel comfortable when receiving family planning services. To a certain extent this is related to the adequacy of service delivery facilities (e.g., proper ventilation, lighting, seating and toilet facilities). Moreover, the time the client spends at the premises to receive requested services should be reasonable.
The service provided to a client should not be discontinued unless a decision is made jointly between the provider and the client. In particular, a client's access to other services should not depend on the continuation or refusal of contraceptive services. Additionally, referral and follow-up are two other important aspects of a client's right to continuity of services.

Finally, the client has a right to express her views about the service she receives. Her opinions on the quality of services, either thanks or complaint, together with her suggestions for changes in the service provision, should be viewed positively in a program's ongoing effort to monitor, evaluate and improve its services.

COUNSELING PROCESS

Counseling is a vital, though often poorly performed, component of family planning services that helps clients arrive at an informed choice of reproductive options, including pregnancy and contraceptive use. If the client chooses to use a family planning method, counseling also should help the client select a method she is satisfied with and prepare the client to use the method effectively.

Counseling is an ongoing process integrated into all aspects of family planning services. The medical and technical information important to effective counseling should not just be presented and discussed at one point in the provision of services. Rather, good counseling techniques should be applied and appropriate technical information provided and discussed in an interactive and culturally appropriate manner throughout the client's visit.

Counseling enables the client to make a voluntary informed choice. Moreover, clients who have made an informed choice of method are more likely to be satisfied with it and, by talking about their positive experience, become the most effective means of promoting it.

To counsel clients effectively, health workers must be properly informed about the contraceptive methods offered and potential users must be able to make an informed choice from the methods available. Information should be given to aid client choice, not to persuade, press or induce a person to use a particular method. Furthermore, the decision to refuse a method offered must be based on adequate information just as much as a decision to accept it. This implies an understanding not only of the effectiveness of that method, but also of the risks involved and the alternative choices available. To achieve this objective, a variety of interpersonal skills are essential. All health workers dealing with family planning clients must be trained in counseling techniques and appropriate educational materials must be produced for both literate and non-literate clients.

In reviewing contraceptive alternatives with clients, all available contraceptive methods should be discussed. Health workers should be aware of a number of factors that may be of relevance, depending on the method in question. These include:

- Reproductive goals of the woman (spacing or timing births)
- Subjective factors associated with the use of any services required, and the time, travel costs, pain or discomfort likely to be experienced
• Accessibility and availability of other products that may have to be procured to use the method

• Advantages and disadvantages of the method

• Reversibility

• Long- or short-term side effects

Family planning counseling is a function that should be integrated into all phases of the client's interaction with clinic staff. (See Appendix A.1 for details of the counseling process.)

**TYPES OF COUNSELING**

Several types of counseling are needed by Norplant users. Because the information preferably should come from more than one source, clinic staff need to work as a team.

To encourage the client to express her views, several verbal and non-verbal techniques that may be used are:

• Listening attentively when the client speaks

• Nodding (or other non-verbal gestures as appropriate) to encourage the client to continue

• Paraphrasing what the client says to make it more specific but without changing its meaning

• Reflecting the feelings expressed by the client back to her in a non-judgmental way

• Asking questions in such a way that the client is not simply reduced to answering "yes" or "no"

• Ensuring that control of the discussion is not entirely in the hands of the health worker

**Initial counseling** (or education) prior to a decision on Norplant use is intended to familiarize the client with all contraceptive methods and other health care services provided by the clinic. When objectively provided, initial counseling helps clients select an appropriate method of contraception.

Counseling in waiting areas with individuals or groups provides:

• The right atmosphere for services through a warm and personalized welcome

• Education about all available contraceptive methods

• Education about the effectiveness of breastfeeding as a contraceptive method for postpartum clients

• Explanation about what the client should expect during the clinic visit

Guidelines for conducting group sessions can be found in Appendix A.2

**Method-specific counseling** provides the client with an opportunity to:

• Ask questions about specific contraceptives in which she is interested and discuss her experience

*Norplant Guidelines for Family Planning Service Programs* 11
Counseling

- Be given more detailed information about available contraceptives in which she is interested.
- Be helped to choose a suitable method.
- Receive further explanation about how to use the method safely, effectively, and with satisfaction.

If she chooses Norplant, counseling should provide specific information about:

- How it prevents pregnancy.
- Advantages and disadvantages including side effects, particularly those related to changes in the menstrual cycle (irregularities), and other problems.
- Insertion/removal procedure and the five-year effective life of Norplant.
- Timing of insertion and which contraceptive method to use if insertion is delayed.
- Freedom of the client to discontinue the method whenever desired.
- No delay in return of fertility after removal.

Post-insertion counseling is usually given immediately after Norplant insertion; however, some elements of this type of counseling should be given earlier and reinforced at this time (e.g., post-insertion care). Post-insertion counseling should focus on the need for follow-up and on warning signs for a quick return to the clinic, if problems occur, such as infection at the insertion site.

Follow-up counseling should reinforce information given post-insertion. Counselors need to listen attentively and be prepared to answer questions about any problems the client has encountered. Answering questions helps a client to cope with any problem or side effect. Again, counselors should reassure clients that removal is available on demand.

RUMORS AND FACTS

Correcting false rumors and misinformation is an important job of family planning providers. When you talk to the client about rumors and misinformation, do not just say that what they have heard is not true. Always explain politely or show why it is not true, and explain what is true. Be careful not to embarrass the client because she has a mistaken idea or belief. The following are some of the more common mistaken ideas:

False Rumor: Norplant weakens the woman.
Response: No, the implants cannot weaken the woman in any way.

False Rumor: The implants move around within the woman's body.
Response: No, they remain under the skin in her arm, where they were placed, until they are removed.

False Rumor: The procedure of inserting Norplant is painful.
Response: Because a local anesthetic is used, there will be little or no pain. There may be a slight stinging sensation when the local anesthetic is injected.
False Rumor: Norplant is implanted permanently.

**Response:** It can be removed at any time and must be replaced after five years.

False Rumor: Norplant never needs to be replaced.

**Response:** It needs to be replaced every five years.

To help the client understand and remember the most important facts about Norplant, be sure to explain them to her clearly and simply, and repeat them several times. Answers to common questions about Norplant can be found in Chapter 7.

**Advantages**

- Very effective (while no contraceptive method is 100% effective, Norplant is one of the most effective reversible methods)

- Easy to use (once Norplant is inserted, the woman only has to return to the clinic for follow-up visits and to have the implants removed)

- Provides continuous protection for up to five years

- Convenient (does not interfere with normal activities, sexual desire or intercourse)

- Reversible

- Comfortable and usually not visible under the skin

- Few side effects

**Disadvantages**

- Insertion and removal are minor surgical procedures which require trained personnel

- Risks similar to any minor surgery (infection, bleeding or hematoma)

- Implants may be visible under the skin

- Client cannot discontinue the method on her own

**Side Effects**

Most women can expect some change in their menstrual cycles. Changes include:

- Prolonged bleeding (i.e., during the first months of use she may have bleeding or spotting for more days than usual)

- Bleeding or spotting between periods

- No bleeding at all for several months (amenorrhea) or, for a few women, for a year or longer

- A combination of these patterns

**Less common side effects**

- Headaches

- Change in weight (both increase and decrease)

- Depression or nervousness
WHO SHOULD DO COUNSELING?

Every health worker who talks to women (or couples) about contraception should understand why counseling is important and the role it plays in increasing the user's satisfaction with a family planning method. The importance of the provider being sensitive to the needs of users is heightened with Norplant because this method is dependent upon the provider for both insertion and removal. Because use and discontinuation of this method require the cooperation of medical personnel whose cultural backgrounds, social positions, and often gender may distinguish them from their clients, special efforts must be made to ensure that clients make informed, free choices.

Even though only a few staff may be involved in Norplant insertion or counseling, other staff will probably be curious about the method. If they also are given information about Norplant, they will be able to talk knowledgeably about the method in the clinic and the community.

**Remember:** The more people who have accurate information about Norplant, the less likely it is that incorrect rumors will develop and spread.

Good counseling of potential clients helps to ensure that users will be satisfied and also reduces unnecessary returns to the clinic or discontinuation due to misunderstanding of the method. **By taking the time to train your staff to counsel effectively now, you will benefit your program in the future.**

BEING AN EFFECTIVE COUNSELOR

A good counselor understands the perceptions of the client and her partner and takes a few minutes to put them at ease and allow the beliefs and feelings about contraceptive methods to emerge. Producing such an atmosphere will be cost-effective in the long run. For example, when counseling is done effectively, clients will be more satisfied with their choices and less likely to discontinue use after a short period of time or because of unexpected menstrual bleeding changes.

A good counselor should provide information and reassurance to clients or couples so that they can make their own decisions about contraception and feel comfortable with their decisions. Sound knowledge and good communication skills are essential if the counselor is to discuss Norplant (and other methods) appropriately.

These skills also help reduce method discontinuation due to ignorance or unnecessary anxiety. The counselor must recognize the potential importance of the views of other members of a client's family and should help the client deal with them. Finally, the counselor should present the relevant information clearly and concisely. Overly technical information and academic language and jargon should be avoided. Questions, particularly about the negative aspects of the method, should be answered honestly.
Counseling

A good counselor has:

- Understanding and respect for client’s rights
- A sensitivity that earns the trust of the client
- A good understanding of all available family planning methods in addition to Norplant
- An understanding of the cultural and psychological factors that affect a woman’s (or a couple’s) decision to use Norplant or another family planning method
- A non-judgmental approach, treating the client with respect and kindness
- Ability to present information in an unbiased, client-sensitive manner
- A way of encouraging clients to ask questions
- Ability to listen actively to the client’s concerns
- Ability to recognize when he or she cannot sufficiently help a client and to refer the client to someone who can
- Appreciation of non-verbal communication (body language)

TIPS ON GOOD COUNSELING

- Listen effectively
- Answer questions objectively
- Reinforce important information on side effects, danger signs, etc.
- Let the client make her own decision

Counseling on Norplant use can be done in small groups or individually. When possible, counseling should be done in privacy or at least in an area set aside for that purpose. Although there may be other staff in your clinic who counsel family planning clients, do not assume that sufficient Norplant-specific counseling already has been provided.

If a client expresses an interest in knowing more about Norplant, let her examine the sterile package containing the Norplant capsules while you explain general information about its use and insertion. Demonstrate to her on a model training arm how Norplant is inserted. Tell her that Norplant must be inserted and removed by a trained health care provider (physician, nurse or midwife).

Remember: Counseling should be integrated into each interaction with the client.

COUNSELING AND CONTINUATION: REALISTIC EXPECTATIONS

Though the rationale for some nations’ family planning programs is the desire to limit their population growth, service providers must put the interests of individual users before other concerns. It is both ethically and programmatically important that providers pay close attention to individual needs.

Although continuation rates with Norplant generally have been high - from 87 to 95% after one year, and from 66 to 92% after two years - it should be remembered that a high continuation rate alone does not necessarily reflect user satisfaction. The most valid continuation rates are those achieved where clients have adequate access to removals.
A summary of the steps in counseling family planning clients is diagrammed in Appendix A.3.

CLIENT SCREENING

An important component of the counseling process is screening the client to determine:

- Indications for Norplant use
- Whether any conditions requiring precautions for use exist
- Whether there are any special medical problems needing more frequent follow-up

In screening clients, a checklist often is useful to see if Norplant is medically appropriate. Use of a checklist, such as the sample presented in Appendix B, helps ensure that no important information is left out. This checklist is intended only as a guide. The health care provider, in conjunction with the client, should make the final decision as to the appropriateness of using Norplant.

REFERENCES


BACKGROUND

A contraindication is a condition or a disease that makes a drug or treatment unsafe or inadvisable for a client. In the past, to protect the client from contraceptive complications, lists of contraindications have been developed for each contraceptive method. Although such lists are produced with the best interest of the client in mind, potentially serious, but often rare, complications are over-emphasized. As a consequence, clients often are prevented arbitrarily from choosing their preferred contraceptive method rather than guided in their decision-making.

Another disadvantage is that while contraindications change over time, the lists tend to become set in stone. (The same is true to a certain extent for lists of indications.) Moreover, what may be an appropriate contraindication in one country, when applied to another setting with different reproductive health characteristics, may not be appropriate. For example, in countries where maternal mortality rates are high, there may be less concern about the very low risk of cardiovascular or venous thromboembolic complications associated with use of the newer combination oral contraceptives (COCs) currently available. Finally, in many countries, new information is slow in arriving and the contraindication list remains "the word" for many years.

A partial solution to this problem is to require that every list of indications and contraindications be dated, and state clearly the country or setting for which the list was intended. Beyond this, one could consider alternatives to the use of the word contraindication, which carries such dire implications.

In this manual, we have chosen to replace contraindications with precautions. Making this change, however, does not solve the problem entirely. Therefore, in addition to listing the indications and those conditions requiring precautions for Norplant, a brief statement is included explaining the reason(s) for categorizing the condition as such. Finally, to minimize confusion, the list of precautions is limited to those conditions on which there is universal agreement. For these conditions, service providers need to assess the appropriateness of Norplant use for each client, not only in terms of her special needs but also in relation to the health care climate in which she lives.
**INDICATIONS FOR USE**

Norplant is an appropriate method for a woman who:

<table>
<thead>
<tr>
<th>SITUATION</th>
<th>RATIONALE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prefers a method which does not require taking contraceptive action daily</td>
<td>Once the Norplant capsules are inserted, the client does not need to do anything except return to the clinic for follow-up visits and have the implants replaced every five years.</td>
</tr>
<tr>
<td>or before sexual intercourse. (This includes women who have trouble using</td>
<td></td>
</tr>
<tr>
<td>barrier methods or remembering to take a pill every day.)</td>
<td>Norplant is a highly effective, long-term contraceptive. It can be used indefinitely provided the client develops no serious medical problems and replaces the implants on schedule every five years.</td>
</tr>
<tr>
<td>Wants long-term birth spacing (two years or more) or has the number of</td>
<td></td>
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<tr>
<td>children she wants but does not want a permanent method (voluntary sterilization) at this time.</td>
<td>Breastfeeding is not affected by the use of Norplant. Although hormonal methods should not be the first choice for breastfeeding women, the level of levonorgestrel in breast milk causes no clinically important effects on infant health or growth when used after six weeks postpartum. At present, there are no data available about possible fetal effects when used before six weeks postpartum; thus, Norplant is a reasonable option.</td>
</tr>
<tr>
<td>Is breastfeeding and needs a contraceptive.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>If a client is fully breastfeeding, insertion can be delayed for six months provided she:</td>
</tr>
<tr>
<td></td>
<td>• remains amenorrheic (no vaginal bleeding), and</td>
</tr>
<tr>
<td></td>
<td>• gives no supplementary feeding.</td>
</tr>
<tr>
<td>Prefers not to use contraceptives that contain estrogen or has developed</td>
<td>Many of the side effects of COCs are due to the estrogen component. Since Norplant contains only a progestin (levonorgestrel), this method may be a suitable alternative to COCs.</td>
</tr>
<tr>
<td>estrogen-related complications while taking combined oral contraceptives</td>
<td></td>
</tr>
<tr>
<td>(COCs).</td>
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</tr>
</tbody>
</table>
PRECAUTIONS FOR USE

Several of the precautions given below are based on experience with COCs. Combined oral contraceptives contain a progestin such as levonorgestrel as well as estrogen, another type of sex hormone. Although some rare but potentially serious problems (e.g., blood clots) have been associated with use of COCs, it is unknown whether these side effects are associated with a progestin-only contraceptive like Norplant. In addition, because the hormone in Norplant is released at such a low rate, it is expected that if any risk exists it will be much lower than with COCs.

Precautions should be taken before inserting Norplant in a woman who:

<table>
<thead>
<tr>
<th>CONDITION</th>
<th>PRECAUTION</th>
<th>RATIONALE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Could be pregnant (by history, symptoms or signs)</td>
<td>The Norplant implants should not be inserted during pregnancy and should be removed immediately if intrauterine pregnancy is confirmed and will be carried to term.</td>
<td>Current data do not show that the low dose of levonorgestrel causes any significantly increased risk of birth defects. Even though the amount of hormone is small, the fetus should not be exposed to unnecessary hormones.</td>
</tr>
<tr>
<td>Has jaundice (active liver or gall bladder disease) or benign or malignant liver tumors</td>
<td>Clients with active liver or gall bladder disease should not have Norplant inserted until they fully recover.</td>
<td>There is no evidence that Norplant causes liver tumors or gall bladder disease. However, the levonorgestrel in Norplant may be poorly metabolized in women with impaired liver function.</td>
</tr>
<tr>
<td>Has active thromboembolic disorders (e.g., blood clots in the legs, lungs, or eyes)</td>
<td>Clients with active thromboembolic disorders should not have Norplant inserted until they fully recover.</td>
<td>Most experts now believe it is estrogens not progestins that cause blood clotting; therefore, women with a past history of thromboembolic disease can safely use a low-dose, progestin-only method such as Norplant.</td>
</tr>
<tr>
<td>Has undiagnosed vaginal bleeding</td>
<td>The cause of any persistent, unexplained vaginal bleeding (e.g., between menses or after intercourse) should be determined and, if necessary, treated before Norplant is inserted.</td>
<td>Because Norplant can cause intermenstrual spotting or bleeding, an underlying problem such as normal or ectopic pregnancy, cervicitis, and rarely cancer of the genital tract, may be masked.</td>
</tr>
</tbody>
</table>
## Indications and Precautions

### CONDITION

**Has breast lumps or known or suspected cancer of the breast**

**PRECAUTION**

Clients with breast lumps should be evaluated before inserting Norplant.

**RATIONALE**

Use of low-dose progestins does not cause breast cancer; therefore, Norplant can be safely used in women with benign breast lumps.

### OTHER PROBLEMS

Women who have any of these problems may need more frequent follow-up care.

<table>
<thead>
<tr>
<th>PROBLEM</th>
<th>PRECAUTION</th>
<th>RATIONALE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetes mellitus</td>
<td>Diabetics who elect to use Norplant should be carefully observed and followed up to be sure the disease is well controlled.</td>
<td>Recent studies indicate that there is no effect on blood glucose or glucose tolerance for users of Norplant.</td>
</tr>
<tr>
<td>Hypertension</td>
<td>Women with blood pressure over 160/90 at the time of insertion should be followed more closely than clients with normal blood pressure to be sure their hypertension is controlled.</td>
<td>Although there have been no statistically significant trends in Norplant users, increased blood pressure has been reported in some users of COCs.</td>
</tr>
<tr>
<td>Severe vascular or migraine headaches</td>
<td>Women with a history of severe vascular or migraine headaches should be carefully followed up.                            Data from controlled clinical trials suggest that one of the side effects of Norplant use may be headaches, although there is little or no information available on changes in severe headaches when Norplant is used.</td>
<td></td>
</tr>
<tr>
<td>Epilepsy (seizure disorders) or tuberculosis</td>
<td>Clients taking medication for these disorders should be carefully counseled about potential reduction in the efficacy of Norplant.</td>
<td>Medications for epilepsy (except valproic acid) and for tuberculosis (rifampin) cause the liver to metabolize progestins very quickly. Because blood levels of levonorgestrel are quite low to begin with, women using these medications may require more frequent follow-up and/or a back-up method (see Chapter 1).</td>
</tr>
<tr>
<td>PROBLEM</td>
<td>PRECAUTION</td>
<td>RATIONALE</td>
</tr>
<tr>
<td>------------</td>
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<td>---------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Depression</td>
<td>Women with a history of depression should be carefully followed when using Norplant and removal considered if depression worsens or recurs to a serious degree.</td>
<td>Depression may be drug related.</td>
</tr>
<tr>
<td>Smoking</td>
<td>Smokers who elect to use Norplant, especially women over 35, should be strongly advised not to smoke.</td>
<td>Cigarette smoking increases the risk of heart attacks and strokes in users of COCs. The risk increases with age, especially in women over age 35 who are heavy smokers (15 or more cigarettes a day). It is not known whether a similar interaction occurs with Norplant.</td>
</tr>
</tbody>
</table>

**REFERENCES**


BACKGROUND

Because Norplant contains only a progestin, one of the two types of steroid hormones present in combination oral contraceptives, it does not have estrogen-related side effects, and there are fewer precautions for its use.

Norplant may be appropriate for most but not all women. Therefore, clinic staff need to be familiar with these medical precautions and know how to screen out those women who:

- May need further evaluation before they can use Norplant
- Have medical conditions which may require more frequent follow-up care

MEDICAL SCREENING

The primary objectives of medical screening are to determine the indications for use, whether any conditions requiring precaution exist and whether there are any special problems that require further assessment. In particular, during the screening process every attempt should be made to be sure the client is not pregnant.

In assessing potential Norplant clients, clinic staff should:

- Screen clients for medical conditions that may be a precaution for Norplant use
- Further evaluate clients by medical history and/or physical examination if there are special problems
- Make sure that potential clients have been counseled about the method, its side effects and other contraceptive choices before selecting Norplant, and that they understand what to expect during the insertion

Health conditions which clients should be asked about and which may limit Norplant use include:

- Jaundice (active liver or gall bladder disease) or benign or malignant liver tumors
- Active thrombophlebitis or deep vein thrombosis (blood clots in the legs, lungs, or eyes)
- Undiagnosed vaginal bleeding (i.e., any persistent, unexplained vaginal bleeding)
- Breast lumps or known or suspected cancer of the breast

In addition, a client with any of the following problems may use Norplant but may require more frequent or special follow-up:
Client Assessment

- Diabetes
- Blood pressure above 160 mm (systolic) and/or 90 mm (diastolic)
- Severe vascular or migraine headaches
- Epilepsy (seizure disorders) or tuberculosis
- Mental depression
- Smoking

Absence of a history of any of the above-mentioned conditions is sufficient to permit provision of Norplant without further evaluation, assuming there is no suspicion of pregnancy.

Note: Clients do not always have exact information about these conditions. As a consequence, health workers must know how to assess the accuracy of the information, and if necessary, restate the question(s) in several different ways. Also they should take into account the social, cultural and religious factors that might influence how a client (and her partner) responds.

The findings from the medical screening determine whether a physical examination is necessary (i.e., if the client's response suggests a precaution for Norplant use, a brief physical examination or further questioning may be necessary). Pelvic examinations, if possible, are recommended as good health care, but are not a requirement for provision of Norplant unless pregnancy is suspected.

When conducting the medical screening, it may be helpful for clinic staff to use a checklist so that no important information is left out. A Sample Client Screening Checklist is presented in Appendix B, and a Sample Physical Examination Checklist for clients needing further evaluation is provided in Appendix C.

REFERENCES


Providing a safe environment for the delivery of Norplant services, regardless of a facility's size and location, is essential. Soap, water and careful attention to detail are the hallmarks of good infection prevention practices. These, coupled with ingenuity in selecting effective, affordable methods or agents to decontaminate, clean and sterilize (or high-level disinfect) instruments and equipment, can minimize disease transmission for both clients and staff.

BACKGROUND

Although insertion and removal of Norplant subdermal implants are minor surgical procedures, aseptic technique, including good surgical technique, must be followed to prevent an increase in infections at the insertion site. Such infections, though usually mild, are one of the major reasons for early removal of the device. Infection also may result in spontaneous expulsion of the Norplant capsules.

Another concern is the increasing problem of transmission of hepatitis B or AIDS viruses to clients, health care providers and clinic staff. To minimize this risk, contaminated waste must be properly disposed of; and soiled instruments, gloves and other items must be decontaminated, thoroughly cleaned and sterilized or high-level disinfected (HLD) after every case.

The emphasis in this chapter is on the use of infection prevention procedures that are practical and feasible in any country. Instruments, reusable gloves, needles and syringes, and surgical drapes used for Norplant insertion or removal should be sterilized by autoclaving (steam) or dry heat. If sterilization is not possible, high-level disinfection by boiling or soaking in an approved chemical disinfectant is the only acceptable alternative.

**Remember:** Regardless of whether sterilization or high-level disinfection (HLD) of instruments and other items is used, thorough cleaning of the client’s arm and hand to remove soil and organic material is the most effective way to prevent infection.

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1 Adapted from Tietjen LG et al: *Infection Prevention for Family Planning Service Programs*. Durant, Oklahoma, EMIS, 1992.

2 Throughout this manual, when hepatitis B (HBV) is mentioned, hepatitis C (HCV) and Delta Hepatitis (HDV) are also referred to because their occurrence is worldwide and their modes of transmission/prevention are similar.
DEFINITIONS

Microorganisms are the causative agents of infection. They include bacteria, viruses, fungi and parasites. For infection prevention purposes, bacteria can be further divided into three categories: vegetative (staphylococcus), mycobacteria (tuberculosis) and endospores (tetanus), which are the most difficult to kill.

Infection prevention often relies on placing barriers between the host and the agent. Protective barriers are physical, mechanical or chemical processes which help prevent the spread of infectious microorganisms from client to client, clinic staff to client, or vice versa due to lack of infection prevention practices or from contaminated instruments or equipment.

The terms asepsis, antisepsis, decontamination, cleaning, disinfection and sterilization often are confusing. For the purposes of these guidelines, the following definitions will be used:

- **Asepsis** or aseptic technique are general terms used in health care settings to describe the combination of efforts made to prevent entry of microorganisms into any area of the body where they are likely to cause infection. The goal of asepsis is to reduce to a safe level, or eliminate, the number of microorganisms on both animate (living) surfaces (skin and tissue) and inanimate objects (surgical instruments).

- **Antisepsis** is the prevention of infection by killing or inhibiting microorganisms on skin and other body tissues.

- **Decontamination** is the process that makes objects safer to be handled by staff, especially cleaning personnel, before cleaning. Such objects include large surfaces (e.g., pelvic examination or operating tables) and surgical instruments and gloves contaminated with blood or body fluids during or following surgical procedures.

- **Cleaning** is the process that physically removes all visible blood, body fluids or any other foreign material such as dust or dirt from skin or inanimate objects.

- **Disinfection** is the process that eliminates most, but not all, disease-causing microorganisms. **High-level disinfection** (HLD), through boiling or the use of chemicals, eliminates all microorganisms except some bacterial endospores.

- **Sterilization** is the process that eliminates all microorganisms (bacteria, viruses, fungi and parasites) including bacterial endospores from inanimate objects.

WHICH PROCESS TO USE

As summarized in Table 5-1, decontamination is the first step in processing contaminated (soiled) surgical instruments, reusable gloves and other items. For example, soaking contaminated items in 0.5% chlorine solution for 10 minutes rapidly kills hepatitis B and AIDS viruses, thereby making the instruments safer to be handled during cleaning. Larger surfaces such as examination and operating tables, laboratory bench tops and other equipment, which may have come in contact with blood or other body fluids, also should be decontaminated. Wiping them down with a suitable disinfectant (e.g., 0.5% chlorine...
or 1-2% phenol) is a practical, inexpensive way to decontaminate these items.

Once surgical instruments and other items have been decontaminated, they need to be further processed by thorough cleaning and then either sterilized or high-level disinfected (HLD). As outlined in Table 5-1, which method (i.e., sterilization or HLD) is used depends on whether the instruments will touch only intact mucous membranes/broken skin or come in contact with the blood stream, tissue deep beneath the skin or tissue which normally is sterile.

When is sterilization absolutely essential? When can high-level disinfection (HLD) be an acceptable alternative?

Most authorities recommend that instruments and other items used for surgical contraceptive procedures, such as voluntary sterilization (minilaparotomy or vasectomy) or Norplant insertion/removal, should be sterile. Some guidelines are more flexible, however, and state that when sterilization equipment is not available, high-level disinfection (HLD) can be used. In fact, the sole use of sterilization is not possible or

### Table 5-1. Decontamination, High-Level Disinfection and Sterilization

<table>
<thead>
<tr>
<th>To Make Instruments/Items Safer to Contact</th>
<th>Appropriate Infection Prevention Process</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intact (unbroken) skin</td>
<td>Decontamination destroys viruses (such as HBV and HIV), bacteria, fungi and parasites</td>
<td>Contaminated instruments and gloves prior to cleaning; pelvic exam table or other surfaces contaminated by body fluids.</td>
</tr>
<tr>
<td>Intact mucous membranes or broken skin</td>
<td>High-level disinfection (HLD) destroys all microorganisms except some endospores*; HLD should be preceded by decontamination and cleaning</td>
<td>Uterine sounds, specula, IUDs (packed in bulk), IUD inserters, gloves for pelvic exams</td>
</tr>
<tr>
<td>Blood vessels or tissue beneath the skin</td>
<td>Sterilization destroys all microorganisms, including endospores; sterilization should be preceded by decontamination and cleaning</td>
<td>Instruments such as needles and syringes, scalpels, trocars for Norplant, reusable gloves for surgery.</td>
</tr>
</tbody>
</table>

* Bacterial endospores are forms of bacteria which are very difficult to kill because of their coating; types of bacteria which can produce endospores include the bacteria-causing tetanus and gangrene (Clostridia sp.). Bacterial endospores can be reliably killed only by sterilization.

practical in many service delivery sites, not only in developing countries, but also in developed ones. For example, laparoscopes, which would be damaged if submitted to either autoclaving or dry heat sterilization, usually are processed between cases by HLD. Sterilization, when correctly performed, is clearly the safest and most effective method for processing instruments; however, if it is neither available nor suitable, then HLD is the only acceptable alternative. (Figure 5-1.)

**Remember:** For either the sterilization or HLD process to be effective, decontamination and cleaning of instruments and other items must be done properly.

### PROTECTIVE BARRIERS

Placing a physical, mechanical or chemical "barrier" between microorganisms and an individual, whether a client or health worker, is an effective means of preventing the spread of disease (i.e., the barrier serves to break the disease transmission cycle). **Protective barriers** in infection prevention include:

- Handwashing
- Wearing gloves (both hands), either for surgery or when handling contaminated waste materials or used (soiled) instruments
- Using antiseptic solutions for cleaning wounds or prepping the skin prior to surgery
- Decontaminating, cleaning and sterilizing or high-level disinfecting surgical instruments, reusable gloves and other items

### HANDWASHING AND GLOVES

Thorough handwashing coupled with the use of protective gloves, when inserting or removing Norplant or handling contaminated waste materials, are key components in minimizing the spread of disease and in maintaining an infection-free environment.

Understanding when sterile or HLD gloves are required and, equally important, when they are not, can reduce costs while maintaining safety for both clients and staff.

**Handwashing may be the single most important procedure in preventing infection.** The vigorous rubbing together of all surfaces of lathered hands mechanically removes and often inactivates most organisms. To encourage handwashing, program managers should make every effort to provide a continuous supply of fresh water, either from the tap or a bucket, and soap.

For most activities, a brief handwashing with plain or antimicrobial soap for about 15 to 30 seconds followed by rinsing in a stream of water is sufficient.

Handwashing is indicated before:

- Examining (direct contact with) a client
- Putting on sterile or high-level disinfected gloves for Norplant insertion or removal
Figure 5-1. Processing Instruments, Gloves and Other Items

DECONTAMINATION
- Soak in 0.5% chlorine solution for 10 minutes

THOROUGHLY WASH AND RINSE
- Wear gloves, guard against injury from sharp objects

Preferred Methods

Sterilization

Autoclave
- 106 kPa pressure (15 lb/in²)
- 121°C (250°F)
- 20 min. unwrapped
- 30 min. wrapped

Dry Heat
- 170°C
- 60 minutes

Boil
- Lid on
- 20 minutes

Chemical
- Soak
- 20 minutes

HIGH-LEVEL DISINFECTION (HLD)

Acceptable Methods

COOL
- Ready for Use*

* Wrapped sterile packs can be stored for up to one week. Unwrapped items should be stored in a sterile or HLD container with a tight-fitting lid or used immediately.
Handwashing is indicated after:

- Any situation in which hands may be contaminated, such as:
  - Handling used (soiled) instruments and other items
  - Touching mucous membranes, blood or other body fluids (secretions or excretions)
  - Removing gloves

Wash hands after removing gloves because gloves may have invisible holes or tears.

Microorganisms grow and multiply in moisture and in standing water. Therefore:

- If bar soap is used, provide small bars and soap racks which drain
- Avoid repeatedly dipping hands into basins containing standing water, even with the addition of an antiseptic agent, such as Dettol® or Savlon®
- Choose from several options when no running water is available:
  - Use a bucket with a tap which can be turned off to lather hands and turned on again for rinsing, or a bucket and pitcher
  - An alcoholic handrub which does not require water
  - Dry hands with a clean towel or air dry; shared towels can become readily contaminated

- Collect used water in a basin and discard in the latrine if a drain is not available

When to Wear Gloves

As a precaution, gloves should be worn by all staff prior to contact with blood and body fluids from any client. A separate pair of gloves must be used for each client to avoid cross-contamination. Using new, single-use (disposable) gloves is preferable.

However, gloves can be washed and sterilized by autoclaving, or washed and high-level disinfected by boiling before reuse. Gloves may be made of latex, natural materials or synthetic materials such as vinyl.

Which Gloves to Use

- Clinicians: New, disposable gloves or sterile gloves should be used when inserting or removing Norplant. (When sterilization procedures are not available, gloves can be high-level disinfected by boiling. Remember: Boiling, even for 90 minutes or more, will not reliably kill bacterial endospores.)
- Cleaning Staff: Clean, thick household (utility) gloves should be used for cleaning instruments and equipment as well as contaminated surfaces.

Do not use gloves which are cracked, peeling, or have detectable holes or tears.

Because most clinic staff may not know how to high-level disinfect reusable gloves by boiling, or how to dry and store them safely, instructions are provided in Appendix D.
ANTISEPSIS

Infection following minor surgical procedures, such as Norplant insertion or removal, may be caused by microflora from the skin of the client or from the hands of the health care worker. Washing hands before each case (i.e., insertion or removal) and cleansing the client's skin with antiseptic solution helps prevent infection at the operative site.

Selection of Antiseptics

Antiseptics do not have the same killing power as the chemicals used for high-level disinfection (HLD). Thus antiseptic solutions never should be used to HLD inanimate (non-living) objects such as instruments and reusable gloves.

Many chemicals qualify as safe skin antiseptics. The following antiseptic solutions are commonly available in different parts of the world:

- Alcohols (60 to 90%) ethyl, isopropyl or "methylated spirit"
- Cetrimide and chlorhexidine gluconate, various concentrations (e.g., Savlon®)
- Chlorhexidine gluconate (4%) (e.g., Hibiclens®, Hibiscrub®, Hibitane®)
- Parachlorometaxylenol (PCMX or chloroxylenol), various concentrations (e.g., Dettol®)
- Hexachlorophene (3%) (e.g., Phisohex®)
- Iodines (1 to 3%), tincture and aqueous (e.g., Lugol's)
- Iodophors, various concentrations (e.g., Betadine®)

PROCESSING USED (SOILED) INSTRUMENTS, GLOVES AND OTHER ITEMS

In working to create an infection-free environment, it is important that the rationale for each of these recommended infection prevention processes (and their limitations) be clearly understood by clinic staff at all levels - from service providers to cleaning and maintenance staff.

With either Norplant insertion or removal, the infection prevention processes which should be used to reduce disease transmission from contaminated instruments, gloves and other items are:

- Waste disposal and decontamination,
- Cleaning and rinsing, and
- Sterilization, or
- High-level disinfection (HLD).

The sequence and details for performing each of these processes are summarized in Tables 5-2 and 5-3.
**Table 5-2: Infection Prevention Guidelines for Norplant Insertion or Removal**

### WASTE DISPOSAL AND DECONTAMINATION

**STEP 1:** After completing either Norplant insertion or removal, and while still wearing gloves, dispose of contaminated objects (gauze, cotton and other waste items) in a properly marked leak-proof container (with a tight-fitting lid) or plastic bag.

**STEP 2:** Fully immerse all metal instruments in a plastic bucket containing 0.5% chlorine solution for 10 minutes before allowing staff and cleaning personnel to handle or clean them. Before immersing needles and syringes, fill with chlorine solution. (This pre-wash soak kills most microorganisms, including HBV and HIV.) Surgical drapes also may be decontaminated by soaking in chlorine solution.

**STEP 3:** All surfaces (such as the procedure table or instrument stand) that could have been contaminated by blood and mucus also should be decontaminated by wiping down with chlorine solution.

**STEP 4:** If single-use (disposable) gloves were used, carefully remove them by inverting, and place in the leak-proof waste container. However, if the gloves are reusable, first briefly immerse both gloved hands in the bucket containing the chlorine solution and then carefully remove by inverting. Deposit the gloves in the chlorine solution.

### CLEANING AND RINSING

After decontamination, thoroughly clean instruments with water, detergent and soft brush, taking care to brush all teeth, joints and surfaces. Next, rinse well after cleaning to remove all detergent (some detergents can render chemical disinfectants inert). Dry instruments before further processing. Surgical drapes should be washed with detergent and water and air or machine dried.

### STERILIZATION

Instruments, reusable gloves, needles and syringes, and surgical drapes used for Norplant insertion or removal should be sterilized by autoclaving. Metal instruments, needles and glass syringes also can be sterilized by dry heat.

#### Standard Conditions for Heat Sterilization

- **Steam sterilization:** 121°C (250°F) at 106 kPa (15 lb/in²) pressure for 20 minutes for unwrapped items; 30 minutes for wrapped items. Allow all items to dry thoroughly before removing.

- **Dry heat:** 170°C (340°F) for 60 minutes (total cycle time - placing instruments in oven, heating to 170°C, timing for one hour and then cooling - is from two to two and a half hours) or 160°C (320°F) for two hours (total cycle time is from three to three and a half hours). Note: Dry heat sterilization (170°C for 60 minutes) can be used only for metal or glass instruments.

- **Storage:** Unwrapped instruments must be used immediately. Wrapped instruments, gloves and drapes can be stored for up to one week if the package remains dry and intact; one month if sealed in a plastic bag.

### HIGH-LEVEL DISINFECTION

High-level disinfection through boiling or the use of chemicals is recommended if sterilization is not possible. Surgical (metal) instruments, reusable gloves, needles and syringes, and surgical drapes should be boiled for 20 minutes and allowed to dry. Air-dried surgical drapes should be ironed before use. Alternatively, instruments can be soaked for 20 minutes in a glutaraldehyde or 8% formaldehyde solution, thoroughly rinsed in boiled water and air dried. Use immediately or store for up to one week in a clean, dry, HLD container with a tight-fitting lid or cover.
<table>
<thead>
<tr>
<th>Process</th>
<th>Decontamination is the first step in handling dirty instruments; reduces risk of hepatitis B and AIDS.</th>
<th>Cleaning removes particulate matter and improves the quality of subsequent sterilization or high-level disinfection.</th>
<th>Sterilization destroys all microorganisms, including endospores.</th>
<th>High-Level Disinfection destroys all viruses, bacteria, parasites, fungi and some endospores.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Instruments / Equipment</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Examination table top, or other large surface areas</td>
<td>Wipe off with 0.5% chlorine solution.</td>
<td>Wash with detergent and water if organic material remains after decontamination procedure.</td>
<td>Not necessary</td>
<td>Not necessary</td>
</tr>
<tr>
<td>Linens (caps, gowns, masks and surgical drapes)</td>
<td>Soak in 0.5% chlorine solution for 10 minutes if contaminated with blood or body fluids prior to cleaning. (Rinse and wash immediately.²)</td>
<td>Wash with detergent and water, removing all particles. Rinse with clean water, air or machine dry.</td>
<td>Not necessary for caps, gowns and masks, if used. Surgical drapes: • Autoclave at 121°C (250°F) and 106 kPa (15 lb/in²) for 30 minutes.</td>
<td>Not necessary for caps, gowns and masks, if used. Surgical drapes: • Boil or chemically HLD.³</td>
</tr>
<tr>
<td>Gloves (rubber or plastic)</td>
<td>Soak in 0.5% chlorine solution for 10 minutes prior to cleaning. (Rinse or wash immediately.²)</td>
<td>Wash with detergent and water, removing all particles. Rinse with clean water and check for holes. If to be sterilized, dry inside and out (air or towel dry).</td>
<td>Preferable: • Autoclave at 121°C (250°F) and 106 kPa (15 lb/in²) for 20 minutes. • Do not use for 24-48 hours.</td>
<td>Acceptable³</td>
</tr>
</tbody>
</table>
Table 5-3: Infection Prevention for Norplant Services (continued)

<table>
<thead>
<tr>
<th>Instruments/Equipment</th>
<th>Decontamination</th>
<th>Cleaning</th>
<th>Sterilization¹</th>
<th>High-Level Disinfection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Instruments including</td>
<td>Soak in 0.5% chlorine solution for 10 minutes prior to cleaning. (Rinse or wash immediately.)</td>
<td>Using a brush, wash with detergent and water, removing all particles. Rinse with clean water. If to be sterilized, air or towel dry.</td>
<td>Preferable: • Dry heat for one hour after reaching 170°C (340°F), or • Autoclave at 121°C (250°F) and 106 kPa (15 lb/in²) for 20 minutes if unwrapped, 30 minutes if wrapped.</td>
<td>Acceptable³</td>
</tr>
<tr>
<td>Norplant trocars</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Needles and syringes</td>
<td>Fill assembled needle and syringe with 0.5% chlorine solution and then soak for 10 minutes prior to cleaning. Rinse by flushing (x3) with clean water.</td>
<td>Disassemble, then wash with detergent and water removing all particles. Rinse with clean water, air or towel dry syringes (only air dry needles).</td>
<td>Preferable: • Dry heat for two hours after reaching 160°C (320°F) (glass syringes only), or • Autoclave at 121°C (250°F) and 106 kPa (15 lb/in²) for 20 minutes if unwrapped, 30 minutes if wrapped.</td>
<td>Acceptable³</td>
</tr>
<tr>
<td>Storage containers for</td>
<td>Soak in 0.5% chlorine solution for 10 minutes prior to cleaning. (Rinse or wash immediately.)</td>
<td>Wash with detergent and water removing all particles. Rinse with clean water, air or towel dry.</td>
<td>Preferable: • Dry heat for one hour after reaching 170°C (340°F), or • Autoclave at 121°C (250°F) and 106 kPa (15 lb/in²) for 20 minutes if unwrapped, 30 minutes if wrapped. Re-sterilize weekly, when empty or contaminated.</td>
<td>Boil container and lid.³ If container is too large then: • Fill container with 0.5% chlorine solution and soak for 20 minutes. • Rinse with water which has been boiled for 20 minutes and air dry before use. Re-disinfect weekly, when empty or contaminated.</td>
</tr>
<tr>
<td>instruments</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Norplant Guidelines for Family Planning Service Programs
Table 5-3: Infection Prevention for Norplant Services (continued)

<table>
<thead>
<tr>
<th>Instruments/Equipment</th>
<th>Decontamination</th>
<th>Cleaning</th>
<th>Sterilization</th>
<th>High-Level Disinfection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Norplant capsules</td>
<td>Not necessary</td>
<td>Not necessary</td>
<td>Come in sterile packages. Discard if package seal broken.</td>
<td>Never acceptable</td>
</tr>
</tbody>
</table>

1. If unwrapped, use immediately; if wrapped, may be stored up to one week prior to use.
2. Avoid prolonged exposure to chlorine solution to minimize corrosion of instruments and deterioration of rubber or cloth products.
3. If sterilization (dry heat or autoclave) not available, these items can be HLD by boiling or soaking in chemical disinfectants as follows:

   **Boiling:**
   - Boil for 20 minutes in a pot with a lid (start timing when water begins to boil).
   - All items must be covered completely with water during boiling. (Place items that float in a weighted, porous bag.) See Appendix F.
   - Do not add anything to the pot after water begins to boil.
   - Air dry before use or storage. (Air dried surgical drapes should be ironed before use.) See Appendix F.

   **Chemical HLD with 8% formaldehyde or glutaraldehyde (should not be used for gloves):**
   - Cover all items with correct dilution of properly stored disinfectant.
   - Soak for 20 minutes or as per manufacturer's instructions.
   - Rinse well in water which has been boiled for 20 minutes and air dry before use or storage.

4. Instruments with cutting edges and needles should not be sterilized at temperatures above 160°C to avoid dulling them.

Infection Prevention

After completing either a Norplant insertion or removal, and while still wearing gloves, properly dispose of contaminated objects (gauze, cotton and other waste items) in a leak-proof container or plastic bag. Following this, surgical instruments and reusable gloves which were in contact with blood or body fluids should be decontaminated by soaking for 10 minutes in a disinfectant (0.5% chlorine solution) immediately after use. Surfaces such as procedure tables, instrument stands and lamps that may have been contaminated by blood also should be decontaminated before reuse. Next, instruments, needles and syringes and reusable gloves should be thoroughly cleaned with detergent and water and completely rinsed before further treatment. Finally, instruments, gloves and surgical drapes should be sterilized. If sterilization is not possible, high-level disinfection (HLD) is the only acceptable alternative (see Appendix E for details).

For a detailed description of the processes for instruments, needles and syringes, and other items, see Appendix E. For sterilization or HLD of instruments and other items, see Appendix F.

CLINIC SITE FOR NORPLANT INSERTION AND REMOVAL

Any outpatient clinic or minor surgery room is a suitable area for Norplant insertion or removal. If possible, the room should be located away from heavily used areas of the clinic or hospital. The room should:

- Have adequate lighting
- Have tile or concrete floors to facilitate cleaning
- Be kept free of dust and insects
- Be air-conditioned if possible. (If windows need to be open for ventilation, they should have tight-fitting screens.)

There should be adequate handwashing facilities including a supply of clean water (i.e., clear, not cloudy or with sediment) nearby and suitable containers, with tight-fitting lids, or plastic bags for disposal of contaminated waste items.

PREPARATION OF CLIENTS

Although skin cannot be sterilized, preoperative washing of the surgical site and antiseptic preparation minimizes the number of microorganisms on the client's skin. Both are important in reducing the risk of infection following insertion or removal of Norplant capsules.

When cleansing and antiseptic preparation are done correctly, the rate of infection following insertion and removal is low - less than 1%; therefore, use of prophylactic antibiotics is not recommended.

SURGICAL ATTIRE FOR CLIENTS AND STAFF

Because insertion and removal of Norplant are minor surgical procedures (i.e., minimal or no incision required and only superficial tissues are entered):
• Clients can wear their own clothing provided it is clean

• Staff do not have to wear a cap, mask or gown

INFECTION PREVENTION TIPS: NORPLANT INSERTION

To minimize the client’s risk of post-insertion infection, clinic staff should strive to maintain an infection-free environment. To do this:

• Have the client wash her entire arm and hand thoroughly with soap and water, and rinse thoroughly, being sure to remove all traces of soap. (Residual soap decreases the effectiveness of some antiseptics.) This step is particularly important when client hygiene is poor. (It may be easier to wash her arm before she enters the procedure area.)

• Wash hands thoroughly with soap and water.

• Put on sterile or HLD gloves. A separate pair of gloves must be worn for each client to avoid cross-contamination. Using new, single-use (disposable) gloves is preferable.

• When prepping the insertion site with an antiseptic solution, select from among the following chemicals (or those locally available):
  
  • 1 to 3% iodine, followed by 60 to 90% alcohol
  
  • Iodophor such as povidone iodine (PVI) or Betadine®
  
  • 60 to 90% isopropyl or ethyl alcohol
  
  • 4% chlorhexidine (e.g., Hibiclens®)
  
  • Savlon®

• It is preferable to use a sterile or high-level disinfected (HLD) sponge forceps to prep the insertion site with a cotton or gauze swab soaked with antiseptic. (If prepping is done with a gloved hand, care must be taken not to contaminate the glove by touching any unprepped skin.)

• Before removing gloves, gently place instruments into a bucket of 0.5% chlorine solution for decontamination. Before immersing the needle and syringe, fill with chlorine solution. Separate the plunger from trocar and immerse (dried blood makes them difficult to separate later). Soak for 10 minutes; then rinse immediately with clean water to avoid corrosion of the needle.

• While still wearing gloves, dispose of contaminated objects (gauze, cotton and other waste items) in a properly marked leak-proof container with a tight-fitting lid, or in a plastic bag. If single-use (disposable) gloves were used, after disposing of all other waste items, carefully remove gloves by inverting and place in the waste container.

• Before removing reusable gloves, immerse both hands briefly in the chlorine solution to decontaminate the outside and then remove by inverting. Place gloves in the chlorine solution and soak for 10 minutes.

• Wash hands with soap and water.
INFECTION PREVENTION TIPS: NORPLANT REMOVAL

Norplant removal should be performed with similar care. To minimize risk of infection to clients, service providers and their co-workers during Norplant removal:

- Have the client wash her entire arm and hand thoroughly with soap and water, and rinse thoroughly, being sure to remove all traces of soap. (Residual soap decreases the effectiveness of some antiseptics.) This step is particularly important when client hygiene is poor. (It may be easier to wash her arm before she enters the procedure area.)

- Wash hands thoroughly with soap and water.

- Put on sterile or HLD gloves. A separate pair of gloves must be worn for each client to avoid cross-contamination. Using new, single-use (disposable) gloves is preferable.

- Prep the removal site with an antiseptic solution. Select from among the following chemicals (or those locally available):
  - 1 to 3% iodine followed by 60 to 90% alcohol
  - Iodophor such as povidone iodine (PVI) or Betadine®
  - 60 to 90% isopropyl or ethyl alcohol
  - 4% chlorhexidine (e.g., Hibiclens®)
  - Savlon®

- It is preferable to use a sterile or high-level disinfected (HLD) sponge forceps to prep the removal site with a cotton or gauze swab soaked with antiseptic. (If prepping is done with a gloved hand, care must be taken not to contaminate the glove by touching any unprepped skin.)

- Before removing gloves, gently place instruments into a bucket of 0.5% chlorine solution for decontamination. Before immersing the needle and syringe, fill with chlorine solution. Soak for 10 minutes; then rinse immediately with clean water to avoid corrosion of the needle.

- While still wearing gloves, dispose of contaminated objects (Norplant capsules, gauze, cotton and other waste items) in a properly marked, leak-proof container with a tight-fitting lid, or in a plastic bag. If single-use (disposable) gloves were used, after disposing of all other waste items, carefully remove gloves by inverting and place in the waste container.

- Before removing reusable gloves, immerse both hands briefly in the chlorine solution to decontaminate the outside and then remove by inverting. Place gloves in the chlorine solution and soak for 10 minutes.

- Wash hands with soap and water.

MAINTENANCE OF A SAFE ENVIRONMENT

Maintaining a safe, infection-free environment for the delivery of Norplant services is an ongoing process which requires frequent retraining and close supervision of clinic staff. With diligent
Infection Prevention

application of recommended practices, infections following Norplant insertion and removal and transmission of diseases, such as hepatitis B and AIDS, can be avoided. However, the practices described in this chapter must be conscientiously applied before, during and after each procedure. Laxity at any point in the routine can have disastrous results for the safety level of the next procedure.

REFERENCES


BACKGROUND

Only specially trained clinicians should perform Norplant insertions and removals. A health care provider experienced with Norplant can perform an insertion in 10 to 15 minutes. Most problems associated with Norplant (e.g., infection and expulsion) are due to improper or careless insertion. To minimize post-insertion problems, all phases of the insertion process must be performed carefully and gently, using recommended infection prevention practices (see Chapter 5). Remember that proper insertions make removals relatively trouble-free; if capsules are inserted too deep, or otherwise improperly placed, removals may be much more difficult.

CLIENT ASSESSMENT

In many developing countries, Norplant is inserted at the first clinic visit. Under these circumstances, to minimize the risk of problems, particularly the possibility of a pre-insertion pregnancy, a brief assessment of the woman’s health must be conducted (see Chapter 4 and Appendix B).

Timing of Insertion

Norplant capsules may be inserted at any time during the menstrual cycle, provided it can be determined that the client is not pregnant or at risk of being pregnant (i.e., is currently using an effective contraceptive method or has not had intercourse after day seven of the menstrual cycle). Optimal times for inserting Norplant are:

- During menstruation (within seven days from onset)
- Postpartum (within three to four weeks) if not breastfeeding
- Postabortion (immediately or within the first seven days)
- While breastfeeding (if more than six weeks postpartum)

Note: If insertion is done after day seven of the menstrual cycle (when ovulation could occur) and the client is using no contraception, a back-up method, preferably a barrier method, should be used for at least the next seven days.

PREPARATION

It is important that the instruments be in excellent condition (e.g., forceps must have a very tight grasp and the scalpel must be sharp). The Norplant insertion/removal kit supplied by USAID contains all the instruments needed for Norplant insertion and removal (see Appendix G for contents).

Sterilize all instruments and other items in advance (see Chapter 5). Where possible, wrap these items in a sterile cloth so that they are ready when needed. (Check your sterilizer regularly to make sure it is working properly.) If sterilization equipment (autoclave or dry-heat sterilizer) is not available, high-level disinfection

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(HLD) of the instruments and other items by boiling for 20 minutes or soaking in an approved disinfectant is the only acceptable alternative (see Appendix F).

Note: Gloves should be free of talc in order to prevent transfer of talc to the Norplant capsules.

The capsules are packed in sterile, heat-sealed, paperbacked pouches. They will remain sterile for the duration of the labeled shelf life of five years, as long as they are stored away from moisture and excessive heat in a dry area and are not damaged.

The following equipment and instruments are recommended for each insertion (Figure 6-1):

- Examining table for the woman to lie on
- Support for arm (optional)
- Set of six capsules in sterile pouch
- Sterilized (or HLD) surgical cloths, and bowl to hold Norplant capsules
- Pair of sterile (or HLD) gloves
- Soap for washing the arm
- Antiseptic
- Local anesthetic (1% concentration without epinephrine)
- Syringe (5 or 10 ml) and 2.5 - 4 cm (1-1½ inches) long needle (22 gauge)
- #10 trocar with plunger
- Scalpel with #11 blade
- Ordinary bandaid or sterile gauze with surgical tape
- Sterile gauze and compresses
- Epinephrine for anaphylactic shock (readily available for emergency use)

Figure 6-1. Basic Materials for Insertion

GENERAL PROCEDURE

The capsules can be placed beneath an area of healthy skin on the inner aspect of the upper arm (Figure 6-2). (The arm that the woman uses less should be selected.)

First, wash the skin with soap and water, then swab with an antiseptic and apply a local anesthetic. Make a shallow incision which just penetrates the skin and which is 6-8 cm (2-3 inches) above the elbow fold. The capsules are introduced through the incision by a specially designed 10-gauge trocar. The capsules are fed through the trocar and placed just beneath the skin one at a time in a fan-shaped pattern, with the fan opening away from the elbow. Sutures are not required; a simple bandage suffices.

It is important that the capsules be placed superficially just beneath the skin (dermis). Deep placement will make removal much more difficult. The ends of the capsules nearest the incision should be placed close together, and the opposite ends fanned out so that the two outermost capsules form an angle of about 75° (Figure 6-2).
STEP-BY-STEP INSTRUCTIONS FOR INSERTION

Before starting the procedure, determine if the client has ever had a local anesthetic before, or if she is allergic to this type of drug.

Getting Ready

STEP 1: Have client wash her entire arm and hand with soap and water, and rinse, being sure to remove all traces of soap (residual soap decreases the effectiveness of some antiseptics). This step is particularly important when client hygiene is poor.

STEP 2: Cover procedure table (and arm support or side table, if available) with a clean cloth.

STEP 3: Ask the client to lie down on the table so that her non-dominant arm (the one she uses less) is comfortably extended straight or slightly bent and is well supported.

STEP 4: Place a clean, dry cloth under the client's arm.

STEP 5: Determine optimal insertion area 6-8 cm (2-3 inches) above the elbow fold and, if desired, use a template (pattern) and a pen to indicate where the incision will be made and the six capsules placed. (If an antiseptic containing alcohol will be used to prep the arm, a pen with permanent ink must be used.)

STEP 6: Prepare an instrument tray and open the sterile instrument pack without touching the instruments and other items.

STEP 7: Carefully open the sterile pouch containing the Norplant capsules by pulling apart the sheets of the pouch and allowing the six capsules to fall into a sterile cup or bowl.

Remember: Contact with cotton or other cloth makes the capsules more reactive (i.e., more apt to cause adhesions or scarring because minute particles of the cotton adhere to the Silastic capsules).

Note: If sterile cup or bowl is not available, the capsules can be dropped into an HLD bowl or onto the HLD tray containing the instruments. Alternatively, partially open the pouch and remove the capsules one at a time, as needed, using HLD forceps. (To avoid dropping the capsules, practice using the tweezers or forceps to pick up and insert them in the trocar.) Do not touch the inside of the package or its contents except with an HLD instrument.
Note: If a capsule falls on the floor, leave it for later disposal. It is contaminated. Open a new package and continue with the procedure. (Never attempt to re-sterilize contaminated capsules. They should be handled as contaminated waste and destroyed by burning or burying.)

Pre-Insertion Tasks

**STEP 1:** Wash hands thoroughly with soap and water, and dry them with a clean cloth.

**STEP 2:** Put sterile or HLD gloves on both hands. (A separate pair of gloves must be worn for each client to avoid cross-contamination.) Using new, single-use (disposable) gloves is preferable. Do not use powder with gloves. The tiny powder (talc) granules may fall into the insertion site and cause a fibrous reaction (scarring). If gloves are powdered, wipe off fingers with sterile gauze soaked with sterile or boiled water.

**STEP 3:** Arrange instruments and supplies, count to make sure there are six capsules.

**STEP 4:** Select from among the following antiseptics (or those locally available) for preparation of the insertion site:

- 1-3% iodine, followed by 60-90% alcohol
- Iodophor such as povidone iodine (PVI) or Betadine®
- 60-90% isopropyl or ethyl alcohol
- 4% chlorhexidine (e.g., Hibiclens®)
- Savlon®

**STEP 5:** It is preferable to use a sterile or HLD sponge forceps to prep the insertion site with a cotton or gauze swab soaked with antiseptic. (If prepping is done with a gloved hand, care must be taken not to contaminate the glove by touching any unprepped skin.) Begin by wiping at the insertion site and move outward in a circular motion for 8-13 cm (3-5 inches) and allow to air dry before proceeding. Wipe off excess antiseptic only if necessary to see the template marks.

**STEP 6:** If a sterile surgical drape with a hole in it is available, it should be used to cover the arm (Figure 6-3). The hole

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**Figure 6-3. Surgical Draping**
should be large enough to expose the area where the capsules will be inserted. A second option is to cover the arm below the insertion area with a sterile cloth. Alternatively a decontaminated, cleaned and machine- or air-dried cloth can be used. (If air dried, iron before using.)

**STEP 7:** After determining the absence of known allergies to the anesthetic agent or related drugs, fill a syringe with about 3 ml of local anesthetic (1% without epinephrine). This is enough to numb the area while inserting the six capsules.

**STEP 8:** Insert the needle just under the skin at the incision site (point closest to the elbow) and release a very small amount of anesthetic to raise a small wheal (raised area) under the skin. Then, without removing the needle, gently advance it under the skin (subdermally) for about 4 cm (1½ inches) (Figure 6-4). This will raise the dermis up from the underlying soft tissue. Then slowly withdraw the needle, "laying a track" of anesthetic. Experience has shown that three equally spaced tracks which mimic the fan-shaped pattern of the capsules (e.g., injecting anesthetic just between where capsules 1 and 2, 3 and 4, and 5 and 6 will be inserted) provide adequate numbing and reduce the amount of local anesthetic needed. **One ml is sufficient in each of the tracks.** Finally, to ensure uniform distribution of the anesthetic, gently massage it into the arm; this will improve the anesthetic’s effectiveness.

**Note:** To prevent local anesthetic toxicity the total dose should not exceed 10 ml of a 10 grams/liter (g/l) (1% without epinephrine) local anesthetic.

**Figure 6-4. Injecting the Anesthetic**

![Injecting the Anesthetic](image)

**Procedure to Insert Capsules**

Before making the incision, gently touch the incision site with a scalpel to ensure the anesthetic is working.

**STEP 1:** Holding the scalpel at about a 45° angle, make a shallow incision which just penetrates the skin. **Do not make a long or deep incision.**

**Note:** Based on a recent study by Diaz et al (1991), if the trocar is new or resharpened, it can be used in place of the scalpel to make the skin incision. These authors found no significant differences in pain, tenderness, edema (swelling), discoloration due to blood infiltration or scarring between an incision made by a scalpel or the trocar. Added advantages of using a trocar are:

- Eliminates need for scalpel
- Prevents making an incision larger than required
STEP 2: Refresh your memory about the purpose of the two marks on the trocar. The trocar should be held so that the bevel on the tip faces upward (Figure 6-5). There are two marks on the trocar; the mark (1) close to the hub indicates how far the trocar should be introduced before loading each capsule. The mark (2) close to the tip indicates how much of the trocar should be left under the skin following the insertion of each capsule.

Figure 6-5. Markings on the Trocar.

Figure 6-6. Inserting the Trocar at a Shallow Angle

Figure 6-7. Advancing the Trocar

STEP 3: With the bevel of the tip of the trocar facing up and the plunger in place, insert the tip of the trocar through the incision at a shallow angle (Figure 6-6). Starting at either the right or the left side of the fan-like pattern, move the trocar forward, stopping as soon as the point is completely beneath the skin (2-3 mm past the end of the bevel). Never force the trocar. If resistance is met, try another angle.

STEP 4: To keep the capsules on a superficial plane, tilt the trocar upward, tenting the skin (Figure 6-6, lower). Advance the trocar slowly and smoothly toward mark (1) near the hub (Figure 6-7). The trocar should be shallow enough so that it can be readily followed with a finger. It should visibly raise the skin at all times. Passage of the trocar will be smooth if it is in a proper, shallow plane.
STEP 5: When the trocar has been advanced as far as mark (1), remove the plunger from the trocar.

STEP 6: Load the first capsule into the trocar, using the thumb and forefinger. Push the capsule down to the top of the hub and reinsert the plunger (Figure 6-8). If the capsules are picked up by hand, be sure the sterile gloves are free of powder or other particles. If all items are only HLD, the preferred technique is to use forceps to remove the capsule from the partially opened sterile pouch and to load it in the trocar (see Note in STEP 7, under previous section Getting Ready).

Note: Using either fingers or forceps, it is best to keep one hand below the capsule in order to catch it if it falls.

STEP 7: Use the plunger to gently advance the capsule toward the tip of the trocar until you feel resistance - but never force the plunger. (Resistance should be felt when the plunger is about half-way inserted into the trocar.)

STEP 8: Hold the plunger firmly in place with one hand. Slide the barrel of the trocar back out of the incision until the lower mark (2) just clears the incision, and the hub touches the handle of the plunger (Figure 6-9). It is important to keep the plunger steady and not to push the capsule into the tissue.

STEP 9: When the hub of the trocar touches the handle of the plunger, the capsule should now be lying beneath the skin, free of the trocar. Feel the capsule with a finger to make sure it is free of the tip of the trocar.
**Important:** Make sure the capsule is free of the point of the trocar to avoid cutting it as the trocar is moved forward to insert the next capsule. The capsule should be released under the skin when the mark (2), close to the tip of the trocar, is visible in the incision.

**Note:** Repeated sharpening shortens the trocar, lessening the distance to mark (2). Therefore, when using sharpened trocars, be careful not to pull the trocar too far back or it will come out of the incision.

**STEP 10:** Without completely removing the trocar, slide it over about 15°, following the fan-like placement pattern marked on the arm. Fix the position of the first capsule with a forefinger and advance the trocar along the side of this finger (Figure 6-10). This will ensure a suitable distance between capsules and will keep the trocar from puncturing any of the previously inserted capsules.

**Note:** To avoid contaminating the trocar when inserting and pulling back on it, try not to touch it, especially the part of the barrel that goes under the skin.

**Figure 6-10. Fixing the First Capsule and Moving to Position Two**

When mark (1) is reached, load the next capsule into the trocar and proceed as before (STEPS 5 - 9). Remember that the capsules should fan out, about 15° apart, so that the angle between the outer capsules (1 & 6) forms a total angle of about 75°.

**STEP 11:** As you proceed, in order to minimize the risk of infection and/or expulsion, make sure that the ends of the capsules nearest you are not less than 5 mm from the incision. Also make sure the ends of each of the capsules closest to the incision (small end of the fan-like pattern) are no farther apart than the width of one capsule.

**STEP 12:** As you insert the six capsules, one by one, try not to remove the trocar from the incision (see STEP 10). Preventing the trocar from coming out minimizes tissue trauma, decreases the chance of infection and shortens insertion time.

**STEP 13:** After the last capsule is in place, withdraw the trocar and plunger. **Palpate capsules to make sure all six have been inserted.**

**STEP 14:** Check that the tips of all capsules are well clear of the incision (about 5 mm). If a capsule tip protrudes from or is too close to the incision, it should be carefully removed and reinserted in the proper position. Finally, press down on the incision with a gauzed finger for a minute or so to stop any bleeding, and then clean the area around the insertion site with a small amount of antiseptic solution applied to a cotton or gauze swab.
STEP 15: Bring the edges of the incision together and use a bandaid or surgical tape with sterile cotton to cover the incision (Figure 6-11). Sutures are not necessary and may increase scarring. Check for any bleeding. Cover the insertion area with a dry compress (pressure dressing) and wrap gauze snugly around the arm to ensure hemostasis (Figure 6-12) and minimize the bruising (subcutaneous bleeding).

Figure 6-11. Covering the Incision

Figure 6-12. Applying the Pressure Dressing

PROCEDURE TO FOLLOW AFTER INSERTION OF CAPSULES

STEP 1: Before removing gloves, gently place instruments into a bucket of 0.5% chlorine solution for decontamination (see Appendix F for how to make solution from household bleach). Before immersing the needle and syringe, fill with chlorine solution. Separate the plunger from trocar and immerse (dried blood makes it difficult to separate them later). Soak for 10 minutes; then rinse immediately with clean water to avoid corrosion of metal items.

STEP 2: While still wearing gloves, dispose of contaminated objects (gauze, cotton and other waste items) in a properly marked, leak-proof container with a tight-fitting lid, or in a plastic bag. If single-use (disposable) gloves were used, after disposing of all other waste items, carefully remove gloves by inverting and place in the waste container.

STEP 3: Before removing reusable gloves, immerse both gloved hands briefly in the chlorine solution to decontaminate the outside, then remove by inverting. Place the gloves in the chlorine solution and soak for 10 minutes.

STEP 4: Wash hands with soap and water.

STEP 5: Immediately place a notation in the client's file indicating location of the capsules and specifying any unusual events that may have occurred during insertion. A simple drawing showing the approximate location of the six capsules in the client's arm may be helpful.
STEP 6: Observe the client for at least five minutes for bleeding from the incision or adverse effects before sending her home. She also should be given post-insertion care instructions.

CLIENT INSTRUCTIONS FOR WOUND CARE AT HOME

- Keep the area dry and clean for at least 48 hours. The incision could become infected if the area gets wet while bathing or washing clothes.

- There may be bruising, swelling or tenderness at the insertion site for a few days. This is normal.

- Routine work can be done immediately. Avoid bumping or straining the area or applying unusual pressure to the site.

- Leave the gauze pressure bandage in place for 48 hours and the bandaid or surgical tape in place until the incision heals (i.e., normally three to five days).

- After healing, the area can be touched and washed with normal pressure.

- If signs of infection occur, such as fever, inflammation (redness plus heat) at the site, or if there is persistent pain for several days, return to the clinic.

If Infection Occurs

- Treat infections with appropriate therapy for local wound infections (see Chapter 8).

- If there is an abscess (with or without beginning expulsion of any capsules), remove all capsules.

KEY POINTS FOR SUCCESSFUL INSERTIONS

- Select the arm the client uses less for the first set of capsules.

- Use recommended infection prevention practices to avoid infections.

- Make sure that the capsules are placed at least 6-8 cm (2-3 inches) above the elbow fold, in the medial aspect of the arm.

- The insertion incision should be small, just penetrating the skin. Use a scalpel or a sharp trocar to make the incision.

- The six capsules are placed, one at a time, just under the skin in a fan-like position using a trocar.

- Insert the trocar through the incision at a shallow angle, superficially, just beneath the skin. Never force the trocar. To ensure superficial placement, the trocar should visibly raise the skin at all times.

- Make sure one capsule is completely free of the trocar before the next one is inserted. To avoid damaging the previous capsule, hold it with your thumb and middle fingers and advance the trocar alongside the tips of the fingers. The first and sixth capsules should form an angle of about 75°.

- Do not remove the tip of the trocar from the incision until all the capsules have been inserted. This will help ensure that all six capsules are inserted on the same superficial plane.
• After insertion, palpate the capsules to check that all six have been inserted. If a capsule tip protrudes from or is too close to the incision, it should be carefully removed and reinserted in the proper position.

• Draw location of capsules in the client’s file, and write a notation if anything unusual has happened.

TIPS FOR KEEPING A TROCAR SHARP

Stress proper care of trocars in training and in the clinic.

• Repeated use will cause it to become blunt. The trocar should be examined carefully after every ten insertions.

• After use, separate plunger from trocar to help keep it sharp.

• If it appears that the trocar is becoming blunt, it may be sharpened in the same way that a knife or pair of scissors is sharpened, using a smooth grindstone.

• When sharpening a trocar, avoid excessive grinding that could change the angle of the point, thereby making the trocar unusable. Excessive grinding will shorten the trocar, lessening the distance to mark (2) near the tip of the trocar (Figure 6-5).

• Another problem due to excessive grinding is that the blunt end of the plunger, when fully inserted, may protrude beyond the point of the trocar. This makes insertion of the trocar under the skin more difficult. If this happens, pull back slightly on the plunger until it no longer protrudes beyond the trocar’s point.

• After approximately 100 insertions, the trocar should be replaced, not resharpened.
REFERENCES


SEVEN

POST-INSERTION AND FOLLOW-UP CARE

BACKGROUND

Long-term success, as defined by satisfied clients and high continuation rates, will occur only if clinic staff recognize the importance of providing follow-up care (including counseling) and prompt management of side effects as well as other problems should they occur.

Most clients will not experience problems following Norplant insertion. When they do occur, however, immediate problems may include:

- Pain at the insertion site that may require a mild analgesic (e.g., aspirin or ibuprofen)
- Bleeding from the incision

Because of these potential problems, it is recommended that all clients remain at the clinic for at least five minutes before being discharged.

CARE OF INSERTION SITE

Clients should be told, and if possible be given written instructions on, how to care for the insertion site. This should be done before the client leaves the health care facility.

- Tell the client to expect some tenderness for a day or two at the insertion site when the anesthetic wears off. There may be some discoloration, bruising and swelling in the area for the first few days; however, this should not interfere with her usual activities.

- The client should try not to bump the insertion site or get it wet for at least three days. The protective gauze pressure bandage should be left in place for 48 hours and the small adhesive bandage for at least three to five days until the incision is healed. (The incision could become infected if the area gets wet while bathing or washing clothes.)

- The client can resume her normal activities immediately - household chores, child care, employment - as long as she keeps the area around the insertion site dry.

- After the site has healed, she does not have to worry about bumping the area or putting pressure on it. The area can be touched and washed. The capsules will remain where they are placed.

- If signs of infection occur, such as fever, inflammation (redness and heat) at the site, or there is persistent pain for several days, she should return to the clinic.
ANSWERS TO COMMON QUESTIONS

Telling a client about the common side effects associated with Norplant, as well as what to do if certain problems occur, promotes effective and continued use. In particular she should know the answers to these common questions:

Are the capsules visible?

Since the incision is tiny, Norplant does not leave a noticeable scar in most women. The capsules usually are not visible. When they are, the outline of the capsules resembles veins underneath the skin. In some women the scar may be darker (hyperpigmentation). This usually disappears following removal of the capsules.

Will the capsules move or migrate to some other place in the body?

Absolutely impossible. The capsules remain where they are inserted until they are removed. They are flexible and cannot break inside the woman's arm. The user does not have to be concerned if the capsules are bumped or if pressure is put on the area, such as when a child is carried. After the incision has healed, the skin over the capsules can be touched at any time.

How effective is Norplant?

No contraceptive is 100% effective; however, Norplant is one of the most effective contraceptives available. For every 100 women who use Norplant for a year, fewer than 1 will become pregnant. That is a lower failure rate than for the pill or most IUDs and is comparable to voluntary sterilization. There is a correlation between effectiveness and a woman's weight.

Women who weigh more than 70 kg, or 154 lb, have a somewhat higher risk of becoming pregnant than lighter women.

How quickly does Norplant become effective?

Norplant becomes effective within 24 hours after insertion.

How long will the capsules be effective?

They protect for five years, but can be removed earlier. All six capsules are needed for protection, even if the method is used for less than five years.

Can a woman who is breastfeeding use Norplant?

A hormonal contraceptive is not considered the method of first choice for breastfeeding women; however, studies have shown no significant effects on the growth or health of infants whose mothers used levonorgestrel implants beginning six weeks after childbirth. There is no reported experience with the use of Norplant earlier than six weeks after childbirth.

Do other drugs interact with Norplant?

Certain drugs increase the ability of the liver to break down the hormone delivered by Norplant thereby making the capsules less effective in preventing pregnancy. Such drugs include rifampin, used to treat tuberculosis; drugs used for epilepsy (seizure disorders) such as barbiturates (e.g., phenobarbital), phenytoin (e.g., Dilantin®) and carbamazepine (e.g., Tegretol®) but not valproic acid; and phenylbutazone (e.g., Butazolidin®), a drug used for arthritis.
Is there any danger if the capsules get bumped or if pressure is put on the area?

No. The capsules are very flexible and soft. They cannot break inside the woman's body. Once the incision is healed she should not be concerned about putting pressure on the area such as when carrying a child.

Is it all right to touch the skin over the capsules?

Yes. After the incision has healed, the woman can touch the skin over the capsules any time she likes. In fact, some women feel reassured by touching and counting the capsules.

Will there be pain after the insertion?

When the anesthetic wears off, there may be some tenderness in the area of the capsules for a day or two. Some discoloration, bruising and swelling also may be felt for a few days after the procedure. This is not serious and should not interfere with the woman's activities.

How should the client care for the insertion site?

She should be careful not to bump the insertion site for a few days. She should also keep the area dry and leave the protective gauze bandage in place for 48 hours. She should keep the small adhesive bandage on for three to five days, until the incision is healed.

How soon after insertion can a couple resume sexual relations?

Couples should wait at least 24 hours before resuming sexual relations unless a back-up method (e.g., condoms or spermicidal agent) is used.

When should the client return to the clinic?

The follow-up schedule depends on the clinic or program from which the woman receives Norplant. Some clinics may ask the woman to return for periodic health checkups or to report on her experience with the capsules. She should be encouraged to return to the clinic if she:

- Wants the capsules removed for any reason
- Has any problems with the method that worry her
- Thinks that there is an infection at the insertion site
- Wants to have a child
- Is moving away and needs the address of a clinic in her new area that provides Norplant services
- Thinks she might be pregnant

Can the client work immediately after the insertion?

Yes. She can resume her normal work and domestic activities as soon as she leaves the clinic as long as they do not include bumping the site. She can continue to do household chores, as long as she does not get the incision area wet for at least three days.

What is the most common side effect of Norplant?

It is very important to tell clients about common side effects, so they can be fully
informed when making a decision about whether to choose or continue to use Norplant. This way, if they have any side effects, such as irregular bleeding or a missed menstrual period, they will not be surprised and will know how to deal with the situation. Experience shows that providing such information increases the length of use as well as acceptability of the method.

The most frequently reported side effect is a change in the menstrual bleeding pattern, such as:

- Untimely bleeding or spotting between periods
- Prolonged (greater than eight days) menstrual bleeding during the first months of use
- No bleeding at all for several months (amenorrhea) or, for a few women, for a year or longer
- A combination of these changes

What kind of bleeding pattern a woman will have cannot be predicted. Many women can expect an altered bleeding pattern to become more regular after 9 to 12 months. Despite the increased frequency of bleeding in some women, the monthly blood loss is usually less than normal menses. In fact, in some studies, hemoglobin levels have been shown to rise in Norplant users. A follow-up visit to the clinic is recommended if a client experiences prolonged heavy bleeding.

Sometimes a woman is concerned about amenorrhea, (i.e., when she does not have any menstrual bleeding or spotting at all). There is no harm to the woman’s health if she doesn’t get her period (i.e., there is no “build up” of blood in the uterus). If a woman’s menses have not returned after one year, she probably will remain amenorrheic for as long as she has the capsules. Also, not having menses has no harmful effect on her future fertility.

Remember: The more thoroughly you counsel a prospective Norplant user about bleeding irregularities, the less likely it is that this side effect will lead to dissatisfaction and discontinuation.

Should the Norplant user be given any drugs to control irregular bleeding or spotting?

At the present time the answer is "no." Research is being conducted to test the effectiveness of a few treatments, but it is still too early to tell if any will be successful (see Chapter 1 for details). Thorough counseling to reassure the client that the bleeding is not serious is the most helpful thing to do in this case.

Should a woman with very heavy and/or prolonged bleeding (with or without anemia) be taken off Norplant for medical reasons?

No. If the woman wants to continue using Norplant, she should be checked to be sure there are no other causes for the bleeding. Following this, the first approach should be reassurance. Short-term (7-21 days) use of a combination contraceptive pill also can be tried. Other conditions then may need to be ruled out. Do not perform a D&C unless indicated for another medical condition. Use oral iron treatment (one tablet daily for one to three months) if anemic.
What are other common reactions?

A small number of women using Norplant have complained about the following conditions, which may be method-related:

- Headache (the most frequent complaint after menstrual irregularities)
- Nervousness/anxiety
- Lower abdominal pain
- Dizziness
- Dermatitis (inflammation of the skin)
- Acne (pimples and/or oily skin)
- Change of appetite
- Weight gain
- Mastalgia (breast tenderness)
- Hirsutism (excessive facial hair growth) or hair loss
- Leukorrhea (whitish vaginal discharge)

Pre-existing conditions of acne or excessive growth of body or facial hair also could be worsened. Occasionally, an infection may occur at the implant site, or there may be a brief period of pain or itching.

Functional ovarian (follicular) cysts, detectable only during a physical examination, sometimes occur in Norplant users. They usually disappear spontaneously within a few months without need for medical or surgical treatment.

There are a number of other complaints reported by Norplant users or discovered by physicians that may or may not be associated with the method:

- Breast discharge
- Cervicitis (inflammation of the cervix, detected by physician)
- Mood change
- Depression
- General malaise
- Weight loss
- Pruritus (itching)
- Hypertension

What are the warning signs of possible problems?

The Norplant user should return to the clinic if she has any of the following problems:

- Active thrombophlebitis or thromboembolic disease (blood clots in lungs, legs or eyes)
- Severe lower abdominal pain
- Heavy vaginal bleeding
- Pus or bleeding at the insertion site (this may indicate infection)
- Expulsion of a capsule (this rarely occurs with proper placement)
- Episodes of migraine, repeated bad headaches, or blurred vision
- Delayed menstrual period after a long interval of regular cycles

Failure to have a period after regular cycles may be a sign of pregnancy. If the client is not bleeding at her expected time and has lower abdominal pain or symptoms of pregnancy, she should visit the clinic.

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without delay. Although pregnancy is rare, there is a chance it could be ectopic (developing outside the uterus). To date, the occurrence of ectopic pregnancy has been very low for Norplant acceptors - about 1 for every 1,000 women users per year.

When must Norplant be removed?

Norplant should be removed at the end of five years. Before that time, however, the capsules can be removed if the user desires to discontinue the method, either for a personal or medical reason. The capsules should be removed by a health worker trained in removal. If the client wants to continue using Norplant, she may receive a new set of capsules at the same time the old set is removed.

Where should the client go to have the capsules removed?

The client should return to the same clinic where the capsules were inserted, or to another clinic where the method is provided. The counselor should be sure that the client knows she has access to removal. If removals are not done every day, the clinic should post a schedule of the regular days of the week when the removals are performed.

What happens if Norplant capsules are left in after five years?

The effectiveness of Norplant decreases after five years so the chance of becoming pregnant increases. If left in place, Norplant capsules will continue to release the hormone for many years (some calculations indicate as long as 20 years). Given the reduced effectiveness, however, Norplant capsules should be removed after five years and replaced with a new set if continued contraception with Norplant is desired.

How long does removal take?

The removal process usually takes from 15 to 30 minutes, but may take longer if some of the capsules were not inserted correctly and are more difficult to locate.

How soon after removal can a woman become pregnant?

Once the capsules are removed, the contraceptive effect ceases almost immediately. Return to previous fertility is usually prompt. In a recent study of women who had Norplant removed and wished to become pregnant, 40% conceived within 3 months of removal, 63% within 6 months, 76% by 1 year and 90% within 24 months. These rates are similar to those for women using no contraception.

In conclusion

To help a client understand and remember the most important points, be sure to explain them to her clearly and simply, and have her repeat them back to you so you are sure she clearly understands the method. It is also useful to give the client printed materials if available and a reminder card listing the date of insertion, follow-up and removal (see Figure 7-1).
Figure 7-1. SAMPLE CLIENT CARD

ABOUT YOUR NORPLANT

Name: ____________________________

Your capsules were inserted by: ____________________________
at: ____________________________

Date of insertion: ________________

Follow-up visit: ________________

Period of use: Five years

Return for removal of the capsules on: ____________________________

FOLLOW-UP CARE

When to Return to the Clinic

- Unless there is a problem or she has questions, the client does not need to return until she has the capsules removed. Annual preventive health care visits, at which time the Norplant capsules can be checked, are recommended.

- When possible, the client should return to the same clinic where the capsules were inserted if she has any worries or questions about the method, if she is concerned that she might be pregnant, or if she decides she wants the capsules removed.

- The client should return to the same clinic if she has any of the following medical problems:
  - Delayed menstrual cycle after a long interval of regular cycles, particularly if accompanied by lower abdominal pain
  - Heavy vaginal bleeding
  - Arm pain
  - Pus or bleeding at the insertion site
  - Expulsion of a capsule
  - Episodes of migraine, severe headaches or blurred vision

As mentioned earlier, successful Norplant programs require well-trained staff who exhibit:

- Good clinical judgment in selecting acceptors

- Care, sensitivity and thoroughness in informing the user about Norplant and its common side effects

- Skill in inserting and removing Norplant
Post-Insertion and Follow-up Care

- Knowledge and ability to recognize real or potential problems
- Capability to take appropriate clinical action in response to these problems, including knowing when (and where) to refer clients with serious complications

REFERENCES


MANAGEMENT OF SIDE EFFECTS AND OTHER HEALTH PROBLEMS

BACKGROUND

Most side effects and other health problems associated with the use of Norplant are not serious. As mentioned previously, changes in menstrual bleeding patterns are the most common adverse effects. In addition to menstrual bleeding problems, women using Norplant occasionally develop enlarged ovarian follicles which rarely cause symptoms and usually are discovered only incidentally at pelvic examinations. They generally regress spontaneously and rarely require surgical treatment. Ectopic pregnancies also have occurred among Norplant users although clinical studies have shown no increase in the rate of ectopic pregnancies per year among Norplant users compared with users of no contraceptive method. Finally, several other conditions that may or may not be associated with Norplant use have been reported. They include headache, breast tenderness and/or discharge, weight gain, increased body or facial hair (hirsutism) and vaginal infection (vaginitis). In this section, additional information regarding the most important of these side effects and other health problems is provided.

IRREGULAR MENSTRUAL BLEEDING

The most frequently reported side effect is a change in the menstrual bleeding pattern. Because the irregularities vary widely, it cannot be predicted what kind of change a particular client may experience. If increased frequency of bleeding occurs, the quantity of blood lost is rarely enough to cause anemia, but there have been a few cases which required treatment with iron tablets. Fortunately, these bleeding irregularities gradually diminish over time (i.e., after 6-12 months).

Despite the fact that medical treatment for prolonged and/or heavy bleeding is not recommended, many clinicians feel obligated to give some medication in an attempt to correct the bleeding pattern and to improve continuation. The rationale of why not to treat menstrual irregularities, especially with estrogens, is covered in Chapter 1.

DELAYED DISINTEGRATION OR DISAPPEARANCE OF FOLLICLES

If follicles (eggs and their surrounding cells) in the ovary develop while using Norplant, disintegration or disappearance of the follicles is sometimes delayed and the follicles may continue to grow beyond the size they normally would reach. These enlarged follicles may produce discomfort in some women, although most users are not aware of them unless they are found incidentally on a physical (pelvic) exam. In the majority of women, these enlarged follicles will disappear on their own and should not require treatment. Rarely, they may twist or rupture so that surgery is required.

ECTOPIC PREGNANCIES

Ectopic pregnancies (implantation of the fertilized egg outside the uterus) have occurred among Norplant users. To date, clinical studies have shown no increase in
the rate of ectopic pregnancies per year among Norplant users as compared with users of no contraceptive method. For example, the incidence among Norplant users was 1.3 per 1,000 woman-years as compared to 1.4 among non-contraceptive users.

Symptoms of ectopic pregnancy include spotting and cramping pain, which usually begin shortly after the missed period. Therefore, clinicians should be alert to the possibility of an ectopic pregnancy among any woman using Norplant who becomes pregnant.

Any client who presents with lower abdominal pain must be evaluated to rule out ectopic pregnancy.

RISKS BASED ON EXPERIENCE WITH COMBINED ORAL CONTRACEPTIVES (COCs)

Combination pills contain a progestin such as levonorgestrel and an estrogen, another type of hormone. Some rare but serious problems have been associated with the use of combination pills. It is unknown whether the risks associated with COC use also are the same for a progestin-only contraceptive like Norplant. Because levonorgestrel is released at a low rate, it is not expected that Norplant users will be at risk for most of the side effects of COCs, which not only have higher progestin doses but also contain estrogen.

Remember: If a woman desires removal of the Norplant capsules because of a side effect (or for any reason) she should not be required to keep them.

The steps in evaluating and managing the reported side effects and other health problems associated with Norplant use are outlined in Table 8-1.
### Table 8-1: Management of Side Effects and Other Health Problems

<table>
<thead>
<tr>
<th>SIDE EFFECT OR PROBLEM</th>
<th>ASSESSMENT</th>
<th>MANAGEMENT</th>
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</table>
| Amenorrhea (absence of vaginal bleeding or spotting) | Rule out pregnancy by checking symptoms, perform a pelvic exam (speculum and bimanual) and a pregnancy test if available. | Periods of amenorrhea are common in Norplant users. However, amenorrhea for six weeks or more after a pattern of regular menses may signal pregnancy.  
If intrauterine pregnancy is confirmed, counsel client regarding options and refer for appropriate care. If the client elects to continue the pregnancy, remove Norplant and assure her that the small dose of levonorgestrel to which she was exposed will have no harmful effect on the fetus.  
If pregnancy is ruled out, no treatment is required except counseling and reassurance. Explain that blood does not build up inside the uterus. The continued action of small amounts of a progestin, such as levonorgestrel, shrinks the endometrium leading to decreased bleeding and in some women no bleeding at all. Advise the client to return to the clinic if amenorrhea remains a concern.  
Normal periods usually return within one to three months after the capsules are removed. In rare instances, amenorrhea may persist for a longer interval. |
<table>
<thead>
<tr>
<th>SIDE EFFECT OR PROBLEM</th>
<th>ASSESSMENT</th>
<th>MANAGEMENT</th>
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<tbody>
<tr>
<td>Bleeding/Spotting (prolonged and/or heavy)</td>
<td>Perform pelvic exam (speculum and bimanual) to be sure bleeding is not due to genital tract lesions such as vaginitis, cervicitis, cervical polyp or uterine fibroids.</td>
<td>If an abnormality of the genital tract is found, treat the problem and counsel or refer for further evaluation. Do not remove Norplant. Advise client to return for additional counseling after management of problem(s).</td>
</tr>
<tr>
<td></td>
<td>If pregnancy (intrauterine or ectopic) or spontaneous abortion is suspected, examine and perform pregnancy test if indicated and available.</td>
<td>If pregnant, counsel as above for Amenorrhea and remove Norplant if client elects to continue pregnancy.</td>
</tr>
<tr>
<td></td>
<td>If no abnormality noted, check for severe anemia (pale conjunctiva or nail beds, low hematocrit or hemoglobin).</td>
<td>If negative pregnancy test, but enlarged uterus, counsel client to return in two weeks for repeat pelvic exam and pregnancy test.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>If ectopic pregnancy is suspected, refer for complete evaluation.</td>
</tr>
<tr>
<td></td>
<td>No abnormality noted and client is not anemic.</td>
<td>For hematocrit &lt; 30 or hemoglobin &lt; 9 g/dl give iron (FeSO4, one tablet daily for one to three months) and nutritional counseling. If anemia persists or client requests, remove Norplant and help client choose another method.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Note: Despite the increased frequency of bleeding in some women, the monthly blood loss in Norplant users usually is less than with normal menses. In some users hemoglobin levels increase over time. (More women have increases than decreases in hemoglobin.)</td>
</tr>
<tr>
<td>Bleeding/Spotting (intermenstrual and/or irregular)</td>
<td>No abnormality noted and client is not anemic.</td>
<td>Reassure her that light intermenstrual bleeding or spotting occurs in a large percentage of women using Norplant (15-20% of women during the first few cycles of use). It is not serious and usually does not require treatment. Most women can expect the altered bleeding pattern to become more regular after 9-12 months.</td>
</tr>
<tr>
<td>SIDE EFFECT OR PROBLEM</td>
<td>ASSESSMENT</td>
<td>MANAGEMENT</td>
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<tr>
<td>Capsule Expulsion</td>
<td>Check for partial or complete expulsion of capsules. Remove partially expelled capsules. Check to determine if: • Remaining capsules are in place, and • Area of insertion is not infected (no pain, heat and redness)</td>
<td>If not infected and remaining capsules in place, open a new package of capsules and insert a new one(s) through separate incision. If infected and/or remaining capsules not in place, remove remaining capsules and insert a new set in the other arm or help client choose another method.</td>
</tr>
<tr>
<td>Headache (especially with blurred vision)</td>
<td>Ask if there has been a change in pattern or severity of headaches since Norplant. Perform physical examination, measure blood pressure. Examine as appropriate: • Eyes (fundoscopic) • Neurologic</td>
<td>If headaches are severe and/or recurrent or blood pressure is elevated since starting Norplant, refer and/or remove Norplant. If blurred vision persists, refer and/or remove Norplant. If headaches are mild, treat with analgesics and reassure. Re-evaluate after one month if mild headaches persist.</td>
</tr>
<tr>
<td>Infection</td>
<td>Check area of insertion for infection (pain, heat and redness), pus or abscess.</td>
<td>If infection (not abscess): • Cleanse area (soap and water or antiseptic) • Give appropriate oral antibiotic for seven days. Do not remove Norplant. Ask client to return after one week. If no improvement, remove Norplant and insert a new set in the other arm or help client choose another method. If an abscess: • Prep with antiseptic • Incise and drain • Remove Norplant capsules • Perform wound care • Give oral antibiotics (as above)</td>
</tr>
</tbody>
</table>
# Management of Side Effects and Other Health Problems

## Side Effect Assessment

### Lower Abdominal/Pelvic Pain

- Take careful history, perform abdominal and pelvic (speculum and bimanual) examinations.
- Check vital signs: 
  - Pulse
  - Blood Pressure
  - Temperature
- Examine to rule out:
  - Ectopic pregnancy
  - PID
  - Appendicitis
  - Ovarian cysts

- Do lab tests for Hb/Hct and a pregnancy test if indicated and available.

### "Missing" Norplant Capsules

- Usually due to capsules being inserted too deep (subcutaneously) or, rarely, to less than six inserted.

### Management

- Refer immediately if the client has any of the following:
  - Lower abdominal tenderness
  - Elevated resting pulse
  - Decreased blood pressure
  - Elevated temperature
  - Suspected/confirmed pregnancy and acute anemia (e.g., <9 g/dl hemoglobin or <30% hematocrit)

- In some women with Norplant, ovarian follicles develop and their atresia (shrinkage) is sometimes delayed. In these instances, the follicle may continue to grow beyond the size it would attain in a normal cycle. These enlarged follicles cannot be distinguished from ovarian cysts. They usually occur during the first six months of use, generally are asymptomatic and often are palpable. In most cases these enlarged follicles disappear spontaneously and should not require treatment or removal of Norplant. Rarely, they may twist or rupture, sometimes causing abdominal pain, and surgical intervention may be required.

- Can be detected by x-ray (see Chapter 9) or sonography. If regular sonography used, need to increase focal length to about 15 cm. Capsules best seen in cross-section (transverse) as a shadow (echo-free area) under each capsule.
<table>
<thead>
<tr>
<th>SIDE EFFECT OR PROBLEM</th>
<th>ASSESSMENT</th>
<th>MANAGEMENT</th>
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</thead>
<tbody>
<tr>
<td>Other Problems (may or may not be method-related)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Breast Tenderness (Mastalgia)</td>
<td>Check breasts for:</td>
<td>Refer for evaluation if abnormality present. If no abnormality, reassure.</td>
</tr>
<tr>
<td></td>
<td>• Lumps or cysts</td>
<td>Do not remove Norplant unless client requests it, after counseling.</td>
</tr>
<tr>
<td></td>
<td>• Discharge or galactorrhea (leakage of milk-like fluid)</td>
<td></td>
</tr>
<tr>
<td>Chest Pain, (especially if it occurs with exercise)</td>
<td>Assess for possible cardiovascular (CV) disease. Check:</td>
<td>If strong evidence for CV disease, refer for evaluation and possible Norplant removal.</td>
</tr>
<tr>
<td></td>
<td>• Blood pressure</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Heart for irregular beats (arrhythmias)</td>
<td></td>
</tr>
<tr>
<td>Excess Hair Growth (hirsutism), Acne/Dermatitis or Hair Loss</td>
<td>Review history, pre- and post-insertion.</td>
<td>Pre-existing conditions such as increased facial or body hair might be worsened. Changes usually are not excessive, may improve over time, and do not require Norplant removal unless client requests it after counseling.</td>
</tr>
<tr>
<td>Jaundice</td>
<td>Acute jaundice occurring after insertion is not method-related. Rule out:</td>
<td>Norplant should not be used if the client has active liver or gall bladder disease. Refer for further evaluation and possible removal of Norplant.</td>
</tr>
<tr>
<td></td>
<td>• Active liver disease (hepatitis)</td>
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<tr>
<td></td>
<td>• Active gall bladder disease</td>
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</tbody>
</table>
### Management of Side Effects and Other Health Problems

#### SIDE EFFECT OR PROBLEM

<table>
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<th>ASSESSMENT</th>
<th>MANAGEMENT</th>
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<tbody>
<tr>
<td>Nausea/ Dizziness/ Nervousness</td>
<td>Rule out pregnancy by checking symptoms, perform a pelvic exam (speculum and bimanual) and a pregnancy test if available.</td>
<td>If pregnant, refer as above for Amenorrhea.</td>
</tr>
<tr>
<td>Thrombo- phlebitis or Thrombo- embolic Disease (legs, lungs, or eyes)</td>
<td>Assess for active thromboembolic disease.</td>
<td>Norplant should not be used in the presence of active thromboembolic disease. Refer for further evaluation and possible removal of Norplant.</td>
</tr>
<tr>
<td>Weight Gain or Loss (change in appetite)</td>
<td>Compare pre-insertion weight (if known) and current weight. Rule out pregnancy. Check that the client is eating and exercising properly.</td>
<td>Counsel client that normal fluctuations (increase or decrease of 2 kg) may occur. Review diet if weight change is excessive. Counsel that women over 70 kg may have an increased risk of pregnancy.</td>
</tr>
</tbody>
</table>

#### REFERENCES


NINE

NORPLANT REMOVAL

BACKGROUND

Unlike insertion, the removal of Norplant capsules does not have to be timed to the menses and can be done at any time. Norplant removal takes more time than insertion and is somewhat more difficult to perform. As has been stressed throughout other sections of this reference manual, a correct insertion - with capsule placement just beneath the skin - will make the removal procedure much easier. The material that follows is intended to reinforce practical training and to serve as a ready reference for questions. It cannot substitute for actual practice, which is absolutely necessary.

While all types of health workers can be trained to insert and remove Norplant capsules, a clinician skilled in removal must be consulted in cases of difficult removal. If a more skilled clinician is not available immediately, the removal attempt should be halted. The client should be told to return to complete removal of the remaining capsules after the incision site is healed, or be referred to a physician who is more experienced and skilled in Norplant removal. In addition, if any capsules have been removed, she should be told she is no longer protected from pregnancy and should be offered an alternative method of contraception.

Clinicians need to work gently, carefully, and patiently. As with insertion, using recommended infection prevention practices (e.g., aseptic technique) throughout the removal procedure is essential to minimize infection and the risk of disease transmission.

PREPARATION

It is important that the instruments be in excellent condition (e.g., scalpel must be sharp and forceps should have a very tight grasp). The Norplant insertion/removal kit supplied by USAID contains all the instruments needed for Norplant insertion and removal (see Appendix G for contents).

Check that all instruments and other items have been sterilized (see Chapter 5). Where possible, wrap the instruments in a sterile cloth so that they are ready in advance. (Check your sterilizer to make sure it is working properly.) If sterilizing equipment (autoclave or dry-heat sterilizer) is not available, high-level disinfection (HLD) of instruments and other items by boiling for 20 minutes or soaking in an approved disinfectant is the only acceptable alternative (see Appendix F).

The following equipment is needed for each removal (Figure 9-1):

---

Removal

* Examining table for the woman to lie on
* Support for arm (optional)
* Sterilized (or high-level disinfected) surgical cloths and bowl
* Pair of sterile (or HLD) gloves
* Soap for washing arm
* Antiseptic
* Local anesthetic (1% concentration without epinephrine)
* Syringe (5 or 10 ml) and 2.5 - 4 cm (1-1½ inches) long needle (22 gauge)
* Scalpel with #11 blade
* Two forceps (mosquito and Crile)
* Tweezers (optional)
* Ordinary bandaid or sterile gauze with surgical tape
* Sterile gauze and compresses
* Epinephrine for anaphylactic shock (readily available for emergency use)

Figure 9-1. Basic Materials for Removal

GENERAL PROCEDURE

An easy removal depends on correct insertion. Routine removals take longer than insertions - usually from 15 to 30 minutes. If the capsules were placed properly they will be easier to remove; if they were placed too deep, problems can occur.

It is helpful to locate the capsules first with ungloved fingers. Some clinicians choose to mark the positions of the capsules with a ballpoint pen. The area is washed with soap and then swabbed with an antiseptic before the local anesthetic is applied to the incision site. The clinician should apply the anesthetic under the ends of the capsules nearest the incision site; anesthetic applied over the capsules may obscure them.

Only one small incision should be made, through which all six capsules will be removed. The incision should be no longer than 4 mm. It should be located at a site as equidistant as possible from the ends of all the capsules. The first capsules to be removed should be those that are easiest to reach (i.e., those closest to the surface and/or nearest to the incision).

If the last one or two capsules prove difficult to remove, heroic measures should not be taken to remove them. (Total time for removal should not exceed 45-60 minutes.) In this situation, the woman should be asked to return when the area is fully healed (in about four to six weeks), and a second attempt made. Hard-to-find capsules can be located through x-rays or by ultrasound. Finally, the clinician should work gently and carefully to avoid injuring the client's arm.
STEP-BY-STEP INSTRUCTIONS FOR REMOVAL

Getting Ready

STEP 1: Have client wash her entire arm and hand with soap and water, and rinse, being sure to remove all traces of soap. (Residual soap decreases the effectiveness of some antiseptics.) This step is particularly important when client hygiene is poor.

STEP 2: Cover procedure table (and arm support or side table, if available) with a clean cloth.

STEP 3: Ask the client to lie down on the table so that the arm with the capsules rests on the table or arm support (Figure 9-2). Her arm can be extended straight or can be slightly bent, as the clinician prefers.

STEP 4: Place a clean, dry cloth under the client’s arm.

Figure 9-2. Positioning the Arm

STEP 5: Locate the six capsules by palpation (Figure 9-3). To gauge where to make the incision, palpate the ends of the capsules with bare (ungloved) fingers. (If it is difficult to find the capsules, refer to the client’s file where a diagram should be found noting the original capsule placement.)

TIP: To make locating the capsules easier, moisten fingertips with a small amount of antiseptic solution. Doing this decreases friction between the clinician’s fingertips and the client’s skin, and allows the capsules to be more easily palpated.

Figure 9-3. Palpating the Capsules

STEP 6: Prepare an instrument tray and open the sterile instrument pack without touching the instruments and other items.

Pre-Removal Tasks

STEP 1: Wash hands thoroughly with soap and water.

STEP 2: Put on sterile or HLD gloves and arrange supplies and instruments so that they are readily accessible.

STEP 3: Select from among the following antiseptics (or those locally available) for preparation of the removal area:

- 1-3% iodine, followed by 60-90% alcohol
- Iodophor such as povidone iodine (PVI) or Betadine®
- 60-90% isopropyl or ethyl alcohol
Removal

- 4% chlorhexidine (e.g., Hibiclens®)
- Savlon®

**STEP 4:** Using a sterile or HLD sponge forceps, prep the area with a cotton or gauze swab soaked with antiseptic. (If prepping is done with a gloved hand, care must be taken not to contaminate the glove by touching any unprepped skin.) Begin wiping at the incision site and move outward in a circular motion for 8-13 cm (3-5 inches) and allow to air dry before proceeding.

**STEP 5:** If a sterile surgical drape is available, it should be used to cover the arm and should have a sufficiently large opening to expose the area where the capsules are located. A second option is to cover the arm below where the capsules have been inserted with a sterile cloth. Alternatively, a decontaminated, cleaned and machine- or air-dried cloth can be used. (If air dried, iron before using.)

Again, locate the six capsules by palpation.

**STEP 6:** The procedure for injecting the local anesthetic is critical to an easy and rapid removal. After determining the absence of known allergies to the anesthetic agent or related drugs, fill the syringe with about 3 ml of a local anesthetic (1% without epinephrine). Insert the needle under the ends of the capsules nearest the elbow (distal) (Figure 9-4). Then gently advance the needle about one-third the length of the first capsule (1 cm) and "lay a track" of anesthetic (about 0.5 ml) to raise the end of the capsule as you withdraw the needle. Without removing the needle, slide the tip over and insert under the next capsule. Repeat this process until the ends of all six capsules are raised. Never put anesthetic over the capsules or the fluid may obscure them. If necessary, additional small amounts can be added as the removal process continues.

**Remember:** Always check that the anesthetic is working before proceeding.

![Figure 9-4. Injecting the Anesthetic Under the Capsules](image)

**Note:** To prevent local anesthetic toxicity the total dose should not exceed 10 ml of a 10 g/l (1% without epinephrine) local anesthetic.

**Procedure to Remove Capsules (Standard Method)**

**STEP 1:** Choose a point for the incision that is equidistant from the ends of all the capsules (Figure 9-5). If it seems appropriate, the removal incision may be made at the point of the insertion incision. Before selecting this site, however, make sure that none of the capsule ends are under the old incision. (This avoids the possibility of cutting through the capsules.) If another set of capsules is to be inserted, you may be able to use the same incision site for both removal of the first set and insertion of the second.
STEP 2: At the site chosen, make a small incision of about 4 mm or less with a scalpel. Do not make a large incision (Figure 9-6).

Figure 9-6. Making the Incision

STEP 3: Begin by removing the capsule that is closest to the surface and/or nearest the incision.

STEP 4: Push the capsule gently toward the incision with the gloved fingers of one hand until the capsule tip becomes visible at the incision.

Figure 9-5. Incision Point for Removal

STEP 5: When the tip is visible in the incision, insert the open tips of the mosquito forceps under the end of the capsule so as not to push it farther away from the incision (Figure 9-7). Then grasp the end of the capsule with the forceps.

Figure 9-7. Pushing the Capsule Toward the Incision

STEP 6: A fibrous tissue envelope will probably surround the capsules. Rub the end of this sheath with a piece of sterile gauze to expose the end of the capsule. If the tissue envelope does not open with rubbing, carefully use the scalpel to open the sheath and free up the capsule (Figure 9-8).

Figure 9-8. Opening the Fibrous Sheath
STEP 7: Grasp the freed end of the capsule with the second pair of forceps (Figure 9-9). Release the first pair (closest to the tip) and remove the capsule with the second forceps. Since tissue does not adhere to silicone rubber, the capsule should slide out very easily (Figure 9-10). If for some reason the capsule does not come out easily, gently scrape away any adherent tissue from the capsule with the scalpel blade.

Figure 9-9. Grasping the Freed Capsule with the Second Forceps

STEP 8: Select for removal the next capsule that appears easiest to retrieve. Add incremental amounts of anesthetic if required. Follow the same procedure for the remaining capsules.

Remember: Apply the anesthetic under the capsule, so as not to obscure it.

Note: For capsules that are difficult to remove using the standard method, see Removing Hard-to-Retrieve Capsules, in this chapter.

Count to be sure all six capsules have been removed. It is important to show the client all six capsules to assure her. If the client wishes to continue using Norplant, see the subsequent section on Second Insertions.

Comments: There is usually more bleeding during removal than insertion. Bleeding can be controlled by applying pressure.

Figure 9-10. Capsule Removal

Occasionally all the capsules cannot be removed readily at the first visit. Do not take heroic measures to remove the last one or two. As a general rule, if all capsules have not been removed within about 45-60 minutes, or the client is experiencing significant discomfort, it is best to stop the procedure, send the woman home, and ask her to return when the area is fully healed (in about four to six weeks). Usually the remaining capsules will be readily located and removed at a second visit. If the woman does not want to run the risk of pregnancy, she should be given a back-up method to use, such as condoms or oral contraceptives, until all the capsules are removed.

STEP 9: If the client does not want another set of Norplant capsules, clean the area around the incision site with a small amount of antiseptic solution applied to a cotton or gauze swab. Then proceed with bandaging the incision area.
**Removal**

**STEP 10:** Bring the edges of the incision together and close with a bandaid or surgical tape with sterile cotton to cover the incision (Figure 9-11). *Sutures are not necessary and may increase scarring.* Check for any bleeding. Cover the removal area with a dry compress (pressure dressing) and wrap gauze snugly around the arm to ensure hemostasis (Figure 9-12) and minimize the bruising (subcutaneous bleeding).

![Figure 9-11. Covering the Incision](image)

![Figure 9-12. Applying the Pressure Dressing](image)

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**PROCEDURE TO FOLLOW AFTER REMOVAL OF CAPSULES**

**STEP 1:** Before removing gloves, gently place instruments into a bucket of 0.5% chlorine solution for decontamination (see Appendix F for how to make solution from household bleach). Before immersing the needle and syringe, fill with chlorine solution. Soak for 10 minutes; then rinse immediately with clean water to avoid corrosion of metal items.

**STEP 2:** While still wearing gloves, dispose of contaminated objects (Norplant capsules, gauze, cotton and other waste items) in a properly marked, leak-proof container with a tight-fitting lid, or in a plastic bag. If single-use (disposable) gloves were used, after disposing of all other waste items, carefully remove gloves by inverting and place in the waste container.

**STEP 3:** Before removing reusable gloves, immerse both gloved hands briefly in the chlorine solution to decontaminate the outside, and then remove by inverting. Place gloves in the chlorine solution and soak for 10 minutes.

**STEP 4:** Wash hands thoroughly with soap and water.

**STEP 5:** Observe the client for at least five minutes before sending her home. Tell her that when the anesthetic wears off, there will be some tenderness for a day or two. As with insertion, there may be some...
Removal
discoloration, bruising, and swelling for a few days in the area where the capsules were removed.

Note: Clients should be reminded that the fibrous sheaths in the arm (tracks where the capsules were located) may be felt for some time. This sensation will disappear over the next few months.

ALTERNATIVE REMOVAL METHOD: THE "POP-OUT" TECHNIQUE

Recently, Damey et al (1990) reported a simpler method for removing some or all of the Norplant capsules. This method, called the "pop-out" technique does not involve the use of forceps. As a result the capsules can be removed with less discomfort and bleeding and usually through a smaller incision. Also, the amount of trauma and bruising is less and the scar smaller and less visible. Finally, using this approach, the risk of breaking the capsules during removal is reduced. The sole disadvantage of the "pop-out" method is that it may not work if the capsules were poorly positioned (aligned) when inserted or if inserted too deep.

To use this method, carefully palpate the area to locate the capsules. Wash hands and put on sterile or HLD gloves. Clean and prep the skin and inject the local anesthetic in the client’s arm as previously described.

STEP 1: Palpate the tips of the capsules closest to the elbow to confirm the location of the one most centrally positioned and equidistant from the tips of the others. Push on the proximal end of the selected capsule (end closest to the client’s shoulder) with a finger. When the distal tip (the one nearest the elbow) is clearly visible (i.e., pushes up under the skin) make a small incision (2-3 mm) over the tip with the scalpel (Figure 9-13).

Figure 9-13. Making the Incision

STEP 2: Now apply pressure with thumb and finger to the distal tip of the capsule in order to bring the tip into better position under the incision (Figure 9-14).

Figure 9-14. Positioning the Distal Tip Under the Incision

STEP 3: Insert the pointed tip of the scalpel blade into the incision until you feel it touch the end of the capsule. If necessary, cut the fibrous sheath surrounding the tip of the capsule while still holding the capsule with the thumb and index finger (Figure 9-15). (Many times it is not necessary to cut the fibrous sheath because it is so thin the tip of the capsule is easily exposed.)
**Note:** If the scalpel is required to open the fibrous sheath covering the distal end of the capsule (Figure 9-15), care must be taken to avoid accidently cutting the Silastic capsule.

**Figure 9-15. Opening the Fibrous Sheath**

**STEP 4:** With the sheath opened, the distal end of the capsule will now come into view when the tissue surrounding it is gently squeezed with both thumbs (Figure 9-16).

**Figure 9-16. Exposing the Distal Tip of the Capsule**

**STEP 5:** With gentle pressure on the proximal end of the capsule (nearest the shoulder), it will "pop out" of the incision (Figure 9-17) and can be grasped easily and gently removed (Figure 9-18).

Once the first capsule is removed, the remaining ones are "popped out" using the same approach. It may not be possible to remove all six capsules using this technique. If difficulty is encountered, remove the remaining capsules using the standard (forceps) method. After all six capsules have been removed and counted, the incision is closed with a bandaid or surgical tape. A pressure dressing usually is not required because this removal method causes little or no trauma to the underlying (subcutaneous) tissue. Dispose of contaminated waste items and decontaminate the instruments and reusable gloves by soaking in 0.5% chlorine solution as previously described.

**Remember:** Removal of the capsules is more difficult if they are broken during attempts to get them out. Once the Silastic capsule is damaged, it may break again with each attempt to grasp it with the forceps.

**Figure 9-17. "Popping Out" the Capsule**

**Figure 9-18. Grasping the Capsule**
Removal

To reduce the risk of breaking the capsules, push on them gently. Use as little pressure (squeezing) as possible to "pop" them out. Also, be very careful when grasping the capsules after they have been "popped out" of the incision. Rarely, removal of a broken capsule may require an additional cut at the proximal end of the capsule (i.e., end nearest the shoulder) so that the remaining piece can be removed.

Remember: If a capsule cannot be palpated under the skin or located with forceps through the incision, it is best to stop the procedure and attempt to find and remove it at a later time after the incision area has fully healed.

REMOVING HARD-TO-RETRIEVE CAPSULES

Occasionally, one or more capsules may be difficult to remove. For example, sometimes the tip of the capsule cannot be pushed to the incision site. Follow these steps to remove such capsules.

STEP 1: Feel the ends of the capsule with the left fore and middle fingers. (Reverse hands if you are left-handed). Keeping the middle finger on the end of the capsule nearest the client's shoulder, and the forefinger on the end nearest you, push the capsule toward the incision (Figure 9-19).

Figure 9-19. Pushing the Capsule Toward the Incision

STEP 2: Introduce the mosquito forceps into the incision below the capsule. At the same time, keep pressing the end of the capsule with your finger.

STEP 3: Grasp the capsule from below with the curved tips of the mosquito forceps pointing up toward the surface of the skin and pushing against the finger (Figure 9-20). Approximately 1 cm of the forceps will now be inside the incision and under the skin.

Figure 9-20. Grasping the Capsule from Below

STEP 4: Do not try to pull the capsule out. Instead, while continuing to push the distal end of the capsule toward the incision, flip the handle of the forceps 180° toward the client's shoulder and grasp the handle with the opposite hand (Figure 9-21).

Figure 9-21. Flipping the Forceps
STEP 5: Clean the soft tissue surrounding the capsule with gauze until the capsule becomes visible.

Note: If the capsule does not become visible after flipping (STEPS 3 and 4): Twist the forceps 180° around its main axis (Figure 9-22). The tip of the capsule will then become visible on the opposite side of the forceps.

Figure 9-22. Twisting the Forceps to Show the Capsule

STEP 6: Open the fibrous tissue envelope with the scalpel. Then, use the second (Crile) forceps to grasp the part of the capsule that becomes visible (Figure 9-23), release the first forceps and remove the capsule.

Figure 9-23. Grasping the Capsule with the Crile Forceps

STEP 7: The remaining capsules can be removed using the same technique as necessary: flipping the forceps 180° over the capsule and rotating it around the main axis of the forceps. Additional small amounts of local anesthetic can be injected for the removal of the remaining capsules.

STEP 8: After removing the capsules, check for any bleeding and that all six capsules have been removed. Bring the edges of the incision together and use a bandaid or surgical tape to close the incision.

STEP 9: Dispose of waste items and decontaminate instruments and gloves as described previously.

CAPSULES THAT CANNOT BE PALPATED

There are two ways to locate Norplant capsules that have been inserted too deep to feel with the fingers: x-ray and ultrasound. By using a radiopaque object to mark the original incision site, the capsules, which also are radiopaque, usually can be detected by x-ray (set at 50-55 kilovolts and 4-5 milliamperes, exposure time 0.03 seconds). Their depth cannot be determined by x-ray, however, and further examination would be required to establish their exact location. With ultrasound, the image caused by the capsules also can be detected (i.e., a shadow, echo-free area, will be present under each capsule).

CLIENT INSTRUCTIONS

• Remind client to keep the area around the incision clean and dry, keep the gauze pressure bandage in place for 48
Removal

hours, and the bandaid or surgical tape in place until the incision has healed (usually three to five days) to prevent infection.

- After healing, the area can be touched and washed with normal pressure.

- If signs of infection occur, such as fever, inflammation (redness plus heat) at the site, or persistent pain for several days, return to the clinic.

- Because the contraceptive effect is lost immediately after the capsules are removed, make sure the client is provided with an alternative contraceptive method if she does not want to become pregnant.

SECOND INSERTIONS

If the client wants to continue using Norplant, the second set of capsules should be inserted at the time the first set is removed.

- The capsules may be placed through the incision in the same direction as that of the first set.

- Alternatively, the capsules can be inserted in the opposite direction. (When inserted in the opposite direction, be sure the capsules do not lie so close to the elbow crease as to interfere with its movement.)

- A new incision should be necessary only if there is not enough room between the incision and the elbow crease or if the area of the original insertion is bruised.

- If the site of the first insertion is unsuitable (e.g., capsules were encased in thick fibrous tissue), the second set should be inserted in the other arm.

KEY POINTS FOR SUCCESSFUL REMOVALS

- An easy removal depends on correct insertion. If the capsules were placed properly, they will be easier to remove. If they were placed too deep, problems can occur.

- Routine removals take only slightly longer than insertions - usually from 15 to 30 minutes.

- Palpate the area to identify the location of each capsule. You can mark the position of each capsule with a pen.

- Inject small amounts (usually not more than 3 ml total) of the local anesthetic under the capsule ends nearest the original incision sites. If anesthetic is applied over the capsules, it will obscure them and make removal more difficult or impossible.

- Only one small incision should be made, through which the six capsules will be removed. Make the incision no longer than 4 mm, in a site as equidistant as possible from the ends of all the capsules.

- First remove those capsules that are easiest to reach because they are closest to the surface and nearest the point of the incision.
Removal

- If a capsule cannot be worked toward the incision easily with the thumb and a finger of one hand, introduce closed forceps into the incision and gently dissect the tissue while pushing the capsule toward the incision.

- Add incremental amounts of anesthetic if needed. Control bleeding by applying pressure.

- Do not take extraordinary measures to remove the last one or two capsules if they are difficult to reach. (Total time for removal should not exceed 45-60 minutes.) In this situation, ask the client to return when the incision site is fully healed (in about four to six weeks), and try again.

- Finally, and most importantly, the physician or health worker should work gently and carefully to avoid injuring the client’s arm.

Remember: If even one capsule is removed, the client is no longer protected from pregnancy. She should be offered an alternative contraceptive method if she does not want to become pregnant.

REFERENCES


Norplant services, although not as easy to provide as other types of reversible contraceptives such as pills and injectables, often can be introduced into family planning programs using existing personnel, facilities, and referral and service delivery channels.

BACKGROUND

In order to make contraceptive methods readily available to as many people as possible, most family planning program managers employ a combination of service delivery strategies within the health care system. Some methods, such as oral contraceptives and condoms, can be provided through both clinic-based and community-based services. Because Norplant insertion and removal are minor surgical procedures, this service should be delivered only through clinic-based services.

Clinic-based services. There are two main types of clinic-based services: those that provide family planning as part of an integrated MCH/FP primary health care service and those that provide only family planning services. In integrated service clinics, family planning is provided as part of the maternal and child health and other primary health care services. Such clinics may be part of a national health service or may be paid for and run by nongovernmental organizations, women’s groups, etc. In addition, private medical practitioners provide clinic-based family planning services as part of their family health care. In many settings, they form an important group of health care providers who can supply Norplant services. Ideally, Norplant should be available whenever and wherever other types of surgical contraceptive methods are offered.

Clinics are used largely by people living in cities, suburban areas and towns. Potentially, the standard of care can be high (e.g., side effects can be treated on the premises and, if the facilities are available, laboratory studies can be done.) Also, the cost per user-year tends to be low for all methods because of the large number of people served. In most countries, however, 40 to 90% of the population live in rural areas and urban slums and have only limited access to clinics. Such people often are not willing to travel long distances for preventive, as opposed to curative, care. One solution to this problem is to provide services in rural areas through mobile facilities, usually operated out of large clinics or hospitals. The advantage of this approach is that it takes the service to the community. Operating costs, however, can be very high per client served. Moreover, assuring quality services, especially follow-up care and voluntary removal on demand may be more difficult.
FACILITIES

Norplant can be offered in a number of different permanent and temporary locations. Although most clinics providing primary health care services will be able to incorporate Norplant services within their existing facilities, there are certain space requirements that should be met to provide high-quality, comprehensive services. Space needs are as follows:

- A comfortable waiting room
- Toilet and washing facilities for clients and staff
- Space for counseling, preferably private
- An examination/procedure room which is private, with adequate lighting and a sink, and where clients can be examined and Norplant inserted and removed
- Cleaning area/utility room where instruments and reusable gloves can be cleaned and linen washed
- Area for sterilization (or high-level disinfection) of Norplant instruments and other items and space for their storage
- Storage area for medical supplies; it should be cool, dry, secure and well-ventilated
- Area for office work, maintenance and storage of records, and the storage of informational materials

Several of these functions may share a common space, especially in health facilities that are not very busy. As the caseload increases, a separate area may need to be assigned to each function.

CLIENT FLOW

The design of the facility should permit an orderly flow of clients in order to ensure comprehensive, cost-effective services and client satisfaction.

Figure 10-1 shows how a potential Norplant user might enter and proceed through a well-arranged health facility offering family planning services. It is important to note that a certain number of clients entering the Norplant service site may not be suitable candidates on medical grounds or may decide not to use Norplant after receiving additional information and counseling. Consequently, the program must be able either to provide alternative contraceptive methods or to refer clients for these services. Also, if a checklist is used for screening clients (see Appendix B) only a limited or no physical examination may be needed for the majority of clients.

If a new health facility is being established, its location should be assessed in relation to potential client accessibility. Can enough clients get to the clinic easily? Are the clinic hours convenient for working people? Providing services after normal working hours or on weekends may increase accessibility for the clients. If the service point is too distant, a client may not return for follow-up visits - both because of the distance involved and the possible expense (fares, loss of pay for time off, child care fees). Moreover, acceptability studies have shown that educating men about contraceptives makes an important contribution to ensuring overall acceptability of a particular method. A man could be more involved in...
Figure 10-1. Client Flow for Norplant Services

family planning activities if a clinic were open some evenings. Evening hours also would enable employed women to visit without taking time off from work, which is often difficult and costly.

**FOLLOW-UP AND REFERRAL**

The manager should be aware of the service and referral network in his or her community and employ it appropriately. Figure 10-2 illustrates the potential links between the client, the service delivery channels and the referral facilities. The various components of the system are defined below.

**Client:** A potential or continuing user of contraceptive services.

**Public sector (community-based):** A non-clinic facility, run by the community, dealing with health in general and especially with mother and child welfare, (e.g., a village community association or a mothers' association). Paramedical or volunteer health workers at this level must be trained to identify problems and to refer the client to the nearest health center when serious problems are encountered.

**Nurse/midwife:** A certified nurse/midwife who has been trained in family planning in general and specifically in Norplant. He or she should be backstopped by a physician and trained to recognize and manage most problems and refer serious ones early.

**Family planning clinic/health center:** A health facility providing basic health care to a community in a certain area.

**First-level hospital:** A district or regional hospital with approximately 50-100 beds, and facilities for dealing with moderately serious problems, but which has few, if any, medical specialists.

Figure 10-2. Potential Links Between the Client, Service Delivery Channels and Referral Facilities. For explanation, see text.
Second-level hospital: A larger or national hospital with approximately 300 beds and a larger number of specialized personnel.

Norplant services may be provided in any of the above facilities. Most simple complaints or side effects can be handled at all sites. A small percentage (five percent or less), however, may require referral to the nearest higher facility (first- or second-level hospital) for management of more serious problems (e.g., difficult removal or possible ectopic pregnancy). (For additional information on follow-up care and management of problems associated with Norplant use, see Chapters 7 and 8.)

PERSONNEL REQUIREMENTS

The number and type of staff needed in a clinic offering Norplant services will vary with the size of the clinic, the other services provided, service hours, and caseload. Consideration should be given to employing female staff to provide contraceptive services because they may be more culturally acceptable in certain circumstances than men - especially where intimate interviews or home visits and physical examinations, including pelvic examinations, may be necessary.

Staff Functions

Focusing on the tasks required to operate a family planning clinic will make staffing plans easier. Tasks should be delegated to staff with appropriate training, consistent with delivering medically safe services. The manager should specify the person in the clinic who will be responsible for carrying out a given function, taking into account the training and ability of each staff member. In some clinics several functions may be carried out by the same person. The functions that should be assigned to a specified person or persons are as follows:

- Managing clinic
- Supervising staff
- Cleaning the facility
- Ordering Norplant sets, insertion/removal kits and other supplies
- Storing and logging in Norplant and other supplies
- Bookkeeping
- Scheduling appointments for clients
- Providing informational materials to clients and ensuring continuing availability of these materials for clients and staff
- Counseling clients (at various times)
- Taking medical history of clients
- Screening clients for medical precautions
- Performing and recording general physical examination
- Processing used (soiled) instruments and other items (infection prevention)
- Preparing supplies needed for each insertion and removal
- Inserting and removing Norplant capsules
- Managing common side effects and other health problems, and making referrals for serious complications
• Scheduling follow-up visits
• Being responsible for any outreach activities initiated at the clinic to recruit new clients
• Following up clients who do not return for appointments
• Assessing user satisfaction with Norplant services
• Maintaining medical records
• Collecting and reporting data

STAFFING PATTERNS

Little practical information is available to guide program managers on the best staffing patterns for clinic-based family planning services, including additional staff needed (if any) for Norplant services. Some of the factors which influence decisions regarding staffing include:

• Type and mix of family planning services to be offered or added. The more effective methods of contraception (i.e., Norplant, IUDs and voluntary sterilization) tend to be more labor- and time-intensive than other methods; these require staff with specialized skills and additional logistical support and supervision.

• Volume of services. Low-volume, clinic-based facilities generally can operate with one person managing both the clinical and administrative aspects of service provision. High-volume facilities, which require five or more service providers, usually need a full-time manager as well as a clinical director.

• Mode of service provision. Whether services are to be offered only at the base facility or in conjunction with mobile units or temporary clinics will influence staffing patterns, generally by increasing the numbers of staff and costs.

• Allocation of responsibilities. In clinics with small caseloads, a nurse-midwife or a physician and an assistant usually can handle multiple functions and provide a complete range of services. In clinics with large caseloads, staff tend to be more specialized. As a consequence, while client flow may be more efficient, steps must be taken to ensure continuity in the way services are provided. In all types of facilities, however, functions should be allocated only to staff with appropriate training, and should be consistent with safe clinical practice. For example, a properly trained assistant might easily receive the client, take the preliminary medical history and provide initial counseling. Next, the nurse-midwife or physician can review the history, perform the physical/pelvic examination (if necessary), insert/remove the Norplant capsules and provide client instructions and exit counseling. The assistant also can oversee/perform instrument cleaning, sterilization or high-level disinfection and general cleaning services. As the caseload increases, more personnel, each responsible for one area or task, may be needed.

SUPERVISION

Supervisors are responsible for seeing that work which is being carried out by others for whom they are responsible, is being done efficiently and effectively. The task of a supervisor is a demanding one. The
supervisor’s function is that of supporting, guiding and directing the worker, and not giving orders or finding fault (criticizing). At the same time, supervisors must develop the ability to carry out their jobs despite dealing with and overcoming many obstacles placed in their way. Above all, they must be role models. They must be expert at problem-solving where resources are limited, trained staff in short supply and equipment and facilities often poorly maintained.

At all levels, supervision should be dynamic. Supervisors should maintain open lines of communication with their staff. Most importantly, to be effective, they must observe staff in their normal work environments to determine how services are being provided. Working side-by-side with staff to solve problems is a key element in providing quality Norplant services and maintaining high staff morale.

MATERIALS REQUIREMENTS

Before starting to provide Norplant, it is essential to arrange for supplies to ensure the continuous availability of the method. This includes all related materials, such as pregnancy test kits and the equipment and consumable items needed for Norplant services.

Introducing Norplant on a limited basis, in one center or district, may be a way to assess potential demand on a nationwide basis. There must be some degree of coordination between availability of Norplant and staff training. If many staff are trained for Norplant insertion and removal but few supplies (e.g., Norplant sets, insertion/removal kits and/or other medical kits) are available, few clients can be served. As a consequence, provider competency and proficiency in inserting and removing Norplant may diminish and the effectiveness and acceptability of the program may be lessened. See Appendix H for Forecasting Norplant Requirements.

RELATIVE COSTS OF DIFFERENT METHODS

It is not possible to compare accurately the costs of providing different contraceptive methods because they have markedly different unit costs, durations of use per unit, continuation rates, costs of distribution, and service delivery costs. The data in Table 10-1 provide an example of the way in which a partial comparison can be made. It must be stressed that the costs given are estimates based on large-scale purchases by public-sector donor agencies. Estimates do not include transport to the destination country, import fees, distribution costs, or service delivery costs.

As an example, consider a unit cost of $23 per Norplant at the point of manufacture. When used over the five-year duration, the annual cost of Norplant would be $4.60; however, not all women will use Norplant for a full five years. International experience with Norplant indicates that 80-90% of users continue use beyond the first year. Based on such continuation rates, the expected duration of use would be in the range 3.0-3.9 years, on average.

Discontinuation earlier than five years obviously increases the annual cost. Thus the adjusted annual cost might be expected to range from $5.90 to $7.70. Accurate first-year continuation rates for most of the
Table 10-1: Cost Estimates for Contraceptives

<table>
<thead>
<tr>
<th>METHOD</th>
<th>UNIT COST* (US$)</th>
<th>DURATION PER UNIT</th>
<th>ANNUAL COST (US$)</th>
<th>AVERAGE USE IN PRACTICE</th>
<th>ADJUSTED ANNUAL COST (US$)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Norplant</td>
<td>23.00</td>
<td>5 years</td>
<td>4.60</td>
<td>3-3.9 years</td>
<td>5.20-7.70</td>
</tr>
<tr>
<td>iUD (Copper)</td>
<td>0.95</td>
<td>8 years</td>
<td>0.12</td>
<td>2-2.7 years</td>
<td>0.25-0.30</td>
</tr>
<tr>
<td>Oral Contraceptive</td>
<td>0.17</td>
<td>1 month</td>
<td>2.21</td>
<td>-</td>
<td>2.40-2.80</td>
</tr>
<tr>
<td>Injectable</td>
<td>0.80</td>
<td>3 months</td>
<td>3.26</td>
<td>-</td>
<td>3.50-4.00</td>
</tr>
<tr>
<td>Diaphragm</td>
<td>3.30</td>
<td>1 year</td>
<td>3.30</td>
<td>-</td>
<td>3.50-4.00</td>
</tr>
<tr>
<td>Spermicide</td>
<td>1.52</td>
<td>20 uses</td>
<td>7.30</td>
<td>-</td>
<td>8.00-9.00</td>
</tr>
<tr>
<td>Condom</td>
<td>0.03</td>
<td>1 use</td>
<td>2.98</td>
<td>-</td>
<td>3.25-3.75</td>
</tr>
</tbody>
</table>


Other methods are not available; although for IUDs the rate is estimated at 70-80%, and for oral contraceptives, 40-50%. Annual costs for single-use methods, for example condoms, are based on eight episodes of intercourse per month. (A certain amount of waste, estimated at 10-25%, must be considered in adjusting the expected annual costs for methods like oral contraceptives, injectables, spermicides, and condoms.) As shown in this table, the adjusted annual cost for IUDs is significantly less than for all other reversible methods. This conclusion, however, is somewhat misleading. It does not take into account service delivery costs, which for IUDs are much higher than for other methods because of the required infection prevention practices, the need for sterile or HLD instruments and other supplies and specially trained providers. Service delivery costs for Norplant, however, are similar to those for IUD for the same reasons.

**EQUIPMENT AND INSTRUMENTS**

Norplant insertion or removal does not require an operating room, but sterile or high-level disinfected instruments and clean conditions are absolutely necessary. Items needed can be divided into three categories:

- **Basic instruments and equipment normally found in a comprehensive family planning clinic**
- **Items specific to Norplant (e.g., insertion/removal kit, see Appendix G)**
- **Materials and equipment needed to prevent infections and minimize transmission of serious diseases such as hepatitis B and AIDS**
The quantities needed in a particular clinic will be based on the predicted demand for Norplant insertions and expected removals. The basic needs are:

- An examining/procedure table (preferably with stirrups for pelvic examinations)
- Good light, artificial or natural

It cannot be overemphasized that equipment for sterilizing or high-level disinfecting instruments, and personnel trained to use it, must be available before any Norplant program can begin to function.

The quantity of materials needed "on hand" for Norplant insertions and removals is partly dependent on the availability of equipment for sterilization or high-level disinfection. Enough instruments must be available to continue doing insertions/removals, while other instruments are being decontaminated, cleaned and sterilized or high-level disinfected. Shortening the time allowed to process instruments is never an acceptable solution (see Chapter 5).

**ORDERING AND STORING NORPLANT**

All contraceptive delivery systems require adequate supply systems and staff to manage those systems. Norplant supplies should be ordered in time to ensure that services are not slowed by lack of them and that they are never in such excess that they cannot be used before their shelf life has expired (five years from the date of manufacture for Norplant).

**Supplies**

Maintaining a consistently adequate supply of Norplant capsules and trocars is extremely important. Ordering supplies requires knowledge of local usage rates, frequency of ordering and receiving supplies, anticipated delays, and available storage space. The guidelines for projecting Norplant requirements are detailed in Appendix H. The following guidelines are commonly used in ordering and storing supplies for established programs and are based on recommendations of the Family Planning Logistics Management Project.

- Supplies can be more precisely estimated based on the projected number of person-months of use during the interval for which orders are placed.
- The number of person-months of use can be estimated based on average numbers of regular or continuing users and numbers of new users over a specified time interval (e.g., 12 months).
- Modifications will need to be made for rapidly changing programs. For example, planning for supplies for new users is based on the assumption that new users enroll in the program with nearly equal frequency during each month of the year.

**Ordering**

To calculate the supplies needed for one year:

- Only one Norplant set is required for each new user, but in planning for replacements, programs should order three Norplant sets for every two acceptors expected.
Calculating Reserve Stocks

Reserve stocks are the supplies on hand to ensure adequate services in the face of higher than expected usage or if previous orders do not arrive when expected. Ordering adequate reserve stocks based on projected usage rates is one of the simplest techniques to ensure adequate supplies. Each clinic should have an estimated maximum and minimum number of Norplant sets needed. A clinic which is resupplied every quarter may have a maximum of six months and a minimum of three months (e.g., if 200 Norplant sets are inserted per month, the maximum stock would be 1,200 and the minimum stock would be 600).

Storing

Each Norplant set contains six levonorgestrel capsules sealed in a sterile plastic pouch. This pouch is in a labeled cardboard box. Clinic packs of ten pouches per box are available. The conditions needed for storing Norplant are identical on a national and local (clinic) level, although the amount of space required will differ. Each clinic should allocate space to store the packages of Norplant.

Because the capsules have a shelf life of five years from the date of manufacture, not from the date the product is delivered to a particular clinic, a careful system of inventory/quality control must be established to ensure the first capsules to expire are the first used - first expired/first out (FEFO). The products which were manufactured first should be the first products to leave the warehouse.

The capsules should be stored in a dry cupboard at room temperature (range: 20 - 50° C). It has been shown that the sealed packages of Norplant can be stored at room temperature and uncontrolled humidity for years without change in the steroid because levonorgestrel is very stable.

The packages also must be protected from dirt and any harsh handling that could tear or perforate the sterile pouches. Any capsule packages with damaged pouches should be discarded since the contents will no longer be sterile. There is no way to re-sterilize Norplant.

It is critical to emphasize proper handling and storage of Norplant and all contraceptives. The consequences of contraceptive spoilage and damage are serious:

- Unwanted pregnancies may occur
- Infections may occur
- User confidence in the family planning program may be undermined
- Scarce financial resources may be wasted

The primary factors involved in Norplant spoilage include:

- Time: non-observation of shelf life/expiration date
- Temperature: excessive heat
- Water and moisture: package damage, possible growth of microorganisms
- Light: especially direct, intense sunlight
- Living organisms: package damage from microorganisms, insects and small animals
- Shock and stress: package damage
Remember: Norplant must be kept in a safe storage area which is protected from excessive heat, direct sunlight and excessive moisture.

RECORD KEEPING

Keeping specific and up-to-date records on each Norplant user can improve follow-up and provide documentation for service statistics and program evaluation and help ensure that the clinic knows where the client is when it's time for Norplant removal (i.e., after five years). It is not easy to maintain complete follow-up. Clients may forget to return for visits, they may give vague or inaccurate addresses, they may lose interest in follow-up. The larger the number of clients and the longer the method is used by an individual client, the more difficult it is to maintain good follow-up.

There should be no difficulty in adapting client health records to include important information relevant to the use of Norplant.

The personal and clinical data that should be recorded for each client are indicated in Chapter 4 and Appendices B and C. The existing recording and reporting system should be reviewed in order to incorporate the use of Norplant in the program.

CHARACTERISTICS OF SUCCESSFUL PROGRAMS

Criteria for "success" vary from one program to another. In general, "successful" programs are characterized by:

- Setting realistic goals and achieving them
- Emphasis on quality and client satisfaction
- Provision of services in a manner convenient to the client
- An efficient and effective system of leadership, supervision and monitoring
- Efficient logistics
- A good referral system
ADDITIONAL INFORMATION

Centers for Disease Control: *Logistics Guidelines for Family Planning Programs.* Atlanta, Georgia, Centers for Disease Control, Center for Health Promotion and Education, Division of Reproductive Health, 1987, (72 pp).

This manual is written for family planning program managers in developing countries. It contains guidelines for those individuals who are responsible for procuring family planning supplies and ensuring that they reach their ultimate destination. Divided into five sections, the manual addresses the following topics: the definition of logistics, logistics systems management, evaluation of the logistics system, supply data analysis, and forecasting. The manual also contains sample forms and checklists for use in logistics management.


This is a core training curriculum designed to improve technical logistics knowledge and skills of family planning personnel, to strengthen the commitment of family planning and AIDS control program managers to further improve their logistics systems, and to motivate and improve the self-image of the logistics worker. The core curriculum is targeted at mid-level family planning managers, but is tailored to address all levels and the needs of specific countries. The curriculum consists of the following ten modules: Introduction to Contraceptive Logistics Systems, Logistics System Assessment, Logistics Management Information Systems, The Contraceptive Logistics Pipeline, Assessing Supply Status, Maximum-Minimum Inventory Control, Forecasting Contraceptive Requirements, Contraceptive Storage, Quality Control of Contraceptives, and the Logistics Management Simulation Exercise.


Written in easily understandable English, this handbook presents the basics of management: planning, coordination, staffing, supervision, training, management information, financial management, contraceptive logistics, and program sustainability. In addition, the handbook contains case studies illustrating how these management principles can be applied. Filled with practical management tools, sample forms and worksheets, and country examples from around the world, the handbook describes how organizations can improve their managerial performance. Managers can use this contemporary reference at all levels within a family planning organization to learn how to be a better manager, to train managers to improve their managerial effectiveness, and as a reference when management problems need to be solved.
REFERENCES


APPENDIX A

FAMILY PLANNING COUNSELING GUIDELINES

Contents

Section One: Framework for Family Planning Counseling

The Counseling Process in the Family Planning Service Setting
Helping Clients Derive the Most from Counseling
Basic Principles
Essential Content of Family Planning Counseling
References

Section Two: How to Hold Group Discussions

Section Three: Summary of Steps in Family Planning Counseling

Initial Counseling
Method-Specific Counseling
Follow-up/Return Visit Counseling
References
SECTION ONE

FRAMEWORK FOR FAMILY PLANNING COUNSELING

THE COUNSELING PROCESS IN THE FAMILY PLANNING SERVICE SETTING

While family planning services may vary widely with regard to staffing patterns, staff roles and responsibilities, integration with other services, etc., there are certain elements common to the provision of all family planning services; counseling is one. The counseling process is the application of certain interactive techniques to facilitate presentation, explanation and discussion of technical information and of client questions, experiences and concerns. There are several counseling points during which there occurs an interactive exchange between service providers and the client. The counseling process is integral to each of these situations, but should be adapted for each as appropriate to individual client needs and program resources.

The elements in which the counseling process plays a central role, include:

- **Greet** the client by introducing yourself by name. Engage client to create a friendly atmosphere; express personal interest in her visit. Explain policies and regulations such as confidentiality. Assure client that the record system and staff commitment are designed to uphold promised confidentiality. Ask what the client's concerns are regarding family planning. Provide general education about family planning.

- **Ask** about information such as age, marital status, number of pregnancies, basic medical history and family planning history.

- **Tell** the client about information regarding family planning without losing sight of client's concerns. Explain all available methods, and their usage, benefits, side effects, disadvantages, effectiveness, etc. Use support materials such as pamphlets, brochures and samples to emphasize points. Let her handle samples of different methods.

- **Help** a client select a method by informing her of the characteristics, advantages and disadvantages of each method. Do not decide for her; let the client choose the method. Give more details about the selected method and let the client repeat it back to you for clarification. After a method is selected, the service provider will confirm the suitability of the method by conducting the appropriate medical assessment. Once this is completed, the chosen contraceptive method is then approved.

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• **Explain** to the client the instructions for use of the approved method. Ask the client to repeat all instructions. Encourage the client to ask questions or verbalize any remaining concerns.

• **Arrange a return visit** to follow up on the client. Specific return visit instructions should be provided.

**HELPING CLIENTS DERIVE THE MOST FROM COUNSELING**

Since information about how to use a method may be new and sometimes difficult to understand, providers need to make it easy to remember. This can be a major challenge. Six key points in helping clients remember are:

• **Brevity**

  Select the few most important matters to tell the client and emphasize which points need to be remembered. Asking clients what they already know is one way to find out what information they have and understand. This also allows the provider to ascertain if the client has misinformation about the method.

• **First things first**

  Give most important instructions first, that is, what the client has to do to use the method effectively.

• **Simplicity**

  Use short sentences and simple words that clients understand. Avoid technical terms and scientific explanations.

• **Repetition**

  Repeat the most important information and instructions. Ask the client to repeat instructions. Give clients printed material and remind them of instructions.

• **Organization**

  Organize information into categories and describe the system to the client. Use memory aids such as acronyms to remind users of the important information they need to remember. For instance: Norplant users need to remember the warning signs of potentially serious problems for which they should return to the clinic as soon as possible.

• **Specificity**

  Instructions should be specific and concrete rather than abstract and vague. For example: a vague instruction would be: "Norplant is effective for several years." The more helpful, specific instruction might be: "Norplant is effective for up to five years and should then be removed and either a new set inserted or another contraceptive method selected."

**BASIC PRINCIPLES**

An effective family planning counselor:

• Allows clients the maximum participation and involvement; helps the client to convince herself instead of trying to convince the client.

• Is an information giver, assistant and problem solver, suggests alternatives, helps clients to analyze and choose from...
**Family Planning Counseling Guidelines**

known options, doesn't prescribe solutions, and helps client feel she is making her own choice or decision.

- Helps the client reveal her personality and life situation rather than making assumptions.

- Not only provides information, but probes for client's fears, norms, concerns and other issues with emotional undertones which could serve as blockers or barriers to favorable decision-making.

**ESSENTIAL CONTENT OF FAMILY PLANNING COUNSELING**

In a practical sense, the elements of counseling fit into the three major phases of providing family planning services, namely; initial counseling at reception, method-specific counseling prior to service provision and post-insertion/follow-up counseling. Counseling skills are particularly important to client reception, client education, client assessment, actual provision of contraceptives, and during follow-up visits. Staffing patterns of any particular service as well as client load may dictate a shifting of counseling activities to alternate staff or location to meet varying needs.

**Initial Counseling**

At the time of client reception, initial counseling by a social worker, counselor or nurse is provided. Counseling in waiting areas with individuals or groups provides:

- A comfortable atmosphere for services through a warm and personalized welcome

- Explanation about what the client should expect during the clinic visit

- Education about all available contraceptive methods and what method may be best for her

- Education about the effectiveness of breastfeeding as a contraceptive method for postpartum clients

- Information that may help the client identify questions to ask the counselor on a one-to-one basis

Guidelines for conducting group sessions can be found in Appendix A.2.

**Method-Specific Counseling**

After moving from the waiting room to a private room, counseling area or an examination room in which counseling may be done, method-specific counseling is undertaken. Method-specific counseling is given prior to, and immediately after, the provision of a specific contraceptive. During this phase of counseling, the service provider:

- Asks the client which method interests her and what she knows about the method. This gives the service provider the opportunity to correct false rumors and misinformation, and to provide true information.

- Tells the client about and discusses how each method works, its effectiveness, advantages and disadvantages.

- Helps the client to begin to choose a method. Based on the client's needs and history, the service provider should advise the client on suitability of any
method in which the client may express an interest. This process leads to preliminary selection of a contraceptive.

- Advises the client on the need for further evaluation depending on the method selected.

Note: At this time the service provider conducts the appropriate physical and laboratory investigations in the examination room to confirm the suitability of the chosen contraceptive method. The client record is completed as appropriate.

After the preliminary selection of a contraceptive by the client and completion of the client assessment, a suitable method is identified and provided to the client. At this time the service provider:

- Explains simply and clearly how to use the method (or in the case of Norplant or IUDs, explains how it will be inserted) and its possible side effects.

- Allows the client to repeat instructions to ensure client comprehension.

- Discusses with the client the return visit. Emphasis can be placed on the continuing need for supplies and their availability, advice about side effects, detecting problems early, changing methods and removal services for Norplant.

It is important for the service provider and/or the client to recognize:

- Clients are less likely to stop family planning practice if they have frequent contact with providers. When appropriate reassurance is given, expected symptoms and minor side effects do not lead to discontinuation.

- Frequent contact builds trust.

- Regular return visits can allow providers to detect problems unnoticed by clients (e.g., early pregnancy, etc.).

Counseling and Follow-Up Visits

In general, the specific objectives of follow-up visits are to:

- Find out whether the client is satisfied and is still using the method

- Make sure that the client is using the method correctly and, if appropriate, to repeat instructions about use

- Provide supplies as appropriate

- Answer client's questions

- Reassure and possibly treat minor side effects

- Check for medical complications and refer for medical evaluation if necessary

- Help client change or stop a method when appropriate

Using this general framework, clients can be adequately counseled. Providers need to know what to do in each situation and how to adjust their counseling to each client. In particular, providers must be able to discriminate between serious problems that require referral and minor problems that are manageable.
REFERENCES


SECTION TWO

HOW TO HOLD GROUP DISCUSSIONS

Hold group discussions to:

• Give information about family planning methods to more than one person at once, which saves time
• Help people share their own experiences and support one another in their family planning decisions
• Answer questions some people may be too shy to ask

When to hold group discussions:

• While clients wait in clinics
• When community groups meet in schools, clubs, and other places

Suggestions about leading group discussions:

• Choose a quiet place with enough space. Avoid places where many people are coming and going.
• Limit groups to ten people or fewer if possible. It is desirable that someone look after the others' children.
• Seat group members in a circle and sit with them.

• Introduce yourself and explain the subject of the discussion.
• Help group members feel at ease. This may be done by playing a short game or by asking group members to introduce themselves.
• Start the discussion by presenting clear information. For example, if the purpose of the discussion is to talk about family planning methods, begin by briefly describing the methods.
• Use words that all in the group can understand.
• Show samples of family planning supplies when you talk about them. Let group members hold them and look at them.
• Use flip charts, diagrams or posters to help show important points.
• Ask many questions. Ask them in a gentle way. Encourage group members to talk with each other about the questions.
• Encourage group members to ask questions.
• Ask group members to tell about their own experiences with family planning.
• Summarize important points during the discussion and again at the end.
SECTION THREE

SUMMARY OF STEPS IN FAMILY PLANNING COUNSELING

Initial Counseling

- Greet client: Introduce yourself and welcome the client to clinic warmly.
- Provide general education about family planning.
- Explain what to expect during the clinic visit.
- Ask the client about her reproductive goals. Ask her if she wants to space or limit births. Be sure she understands the difference between reversible and permanent methods. Correct false rumors or misinformation about all methods.
- Explore any attitudes or religious beliefs that either favor or eliminate one or more methods.

Method-Specific Counseling

- Obtain biographic information (name, address, age, etc.).
- Give the woman information about all contraceptive choices available and the risks and benefits for each, including Norplant.
- Discuss the client’s needs, concerns, and fears in a thorough and sympathetic manner.
- Help the client begin to choose an appropriate method.

If she chooses Norplant:

- Screen the client carefully to make sure there is no medical condition that would be a problem.
- Clearly discuss the advantages of Norplant emphasizing the following points:
  - It is very effective.
  - It is easy to use.
  - It provides continuous protection for up to five years.
  - It is convenient, comfortable and reversible.
- Explain common side effects and be sure they are fully understood.
- Describe the insertion and the removal process and what the woman should expect afterwards.
• Review screening and client assessment (physical and pelvic exam) data to determine if the client is an appropriate candidate for Norplant or if she has any problems that should be monitored more frequently while Norplant is in place.

• Insert the six Norplant capsules.

• Give post-insertion counseling, including how she should care for the incision site and what to do if she experiences any side effects. Special emphasis should be given to bleeding irregularities. Provide follow-up visit instructions.

• Assure client she can return to the same clinic at any time to receive advice, medical attention, and, if desired, to have the capsules removed.

• Have client repeat the instructions.

• Answer client questions.

• Complete client record.

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**REFERENCES**


APPENDIX B

SAMPLE CLIENT SCREENING CHECKLIST

<table>
<thead>
<tr>
<th>Question</th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of last menstrual period:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Currently pregnant</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Weight over 70 kg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wish for another child in less than three years</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Breastfeeding, less than six weeks postpartum</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any drugs taken on a long-term basis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intermenstrual bleeding and/or bleeding after coitus (sex)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Amenorrhea (no menstrual bleeding for six weeks or more)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abnormal yellow skin or eyes (jaundice)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Severe headaches or visual disturbances</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Seizures</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Severe pain in calves, thighs or chest</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unusual shortness of breath after mild exercise</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Swollen legs or edema</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blood pressure above 160 mm (systolic) and/or 90 mm (diastolic)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mass or lump in the breast</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

If all of the above are negative (NO), and pregnancy is not suspected, the client may go directly for Norplant pre-insertion counseling and insertion. Any positive response means that she should be evaluated further before making a final decision.

Note: Clients do not always have exact information about or recall the answers to the items listed above. If necessary, health workers should be in a position to assess the accuracy of the information by restating the questions in several different ways. Also they should take into account any social, cultural or religious factors that might influence how the woman (and her partner) responds.

APPENDIX C

SAMPLE PHYSICAL EXAMINATION CHECKLIST
FOR CLIENTS SEEKING NORPLANT

<table>
<thead>
<tr>
<th>Service Provider's Observations</th>
<th>Service Provider's Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Look for abnormalities listed below.</td>
<td>If the responses fall in the &quot;YES&quot; column, follow the instructions below.</td>
</tr>
<tr>
<td>1. Is she pregnant?</td>
<td>1. If there is any chance the client is pregnant, do not insert Norplant. Do a urine pregnancy test (if available) if the pelvic exam is equivocal. Alternatively, have the client use a barrier method and return when she has her menses.</td>
</tr>
<tr>
<td>2. Is blood pressure greater than 160/90? Or is diastolic BP greater than 110?</td>
<td>2. Follow client more closely than one with normal BP. Although there have been no significant trends in Norplant users, increased BP has been reported in some users of combined oral contraceptives.</td>
</tr>
<tr>
<td>3. Is the urine positive for glucose?</td>
<td>3. Diabetic clients using Norplant may require more frequent follow-up to be sure diabetes is under control.</td>
</tr>
<tr>
<td>4. Is pulse irregular?</td>
<td>Questions 4-6: If answer yes to any one of these questions, client may have heart disease. Refer for medical evaluation if needed, before inserting Norplant. Alternatively, help client make informed choice of a non-hormonal method.</td>
</tr>
<tr>
<td>5. Is pallor or cyanosis observed?</td>
<td></td>
</tr>
<tr>
<td>6. Is extreme shortness of breath observed?</td>
<td></td>
</tr>
</tbody>
</table>
### Physical Examination Checklist

<table>
<thead>
<tr>
<th>Question</th>
<th>NO</th>
<th>YES</th>
</tr>
</thead>
<tbody>
<tr>
<td>7. Is she jaundiced?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. Does she have enlarged or tender liver?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. Does she have severe, tender varicose veins or a painful, swollen knot in leg?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10. Are her legs extremely swollen with fluid?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11. Does she have suspicious lumps in her breast?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Questions 7-8:**

If answer yes to either one of these, may be sign of active liver disease. Help client make informed choice of a non-hormonal method and refer for medical evaluation if needed.

9. May have active thrombophlebitis or indicate high risk of blood clot. Refer for evaluation and help client make informed choice of a non-hormonal method.


11. Lumps that are suspicious for cancer generally are: non-tender, unilateral, irregular in shape and may be fixed to the skin (above) or chest muscle (below). Refer to a specialist for evaluation before inserting Norplant.

Alternatively, lumps that are benign breast cysts or fibroadenomas usually are smooth, clearly defined in shape, often occur at the same place in both breasts, and are freely moveable. The lumps also may enlarge slightly each month just before menses.

If the lump(s) is not suspicious, give client Norplant.

**Source:** Adapted from Program for International Training in Health (INTRAH): *Guidelines for Clinical Procedures in Family Planning and Sexually Transmitted Disease: A Reference for Trainers.* Chapel Hill, North Carolina, INTRAH, 1989, p. 48.
APPENDIX D

PROCESSING REUSABLE GLOVES

HOW TO DECONTAMINATE AND CLEAN RUBBER GLOVES BEFORE STERILIZATION OR HIGH-LEVEL DISINFECTION

STEP 1: Before removing reusable gloves which may be soiled with blood, body fluids or semen, immerse hands briefly in a bucket of 0.5% chlorine solution or other locally available and approved disinfectant.

STEP 2: Remove gloves by inverting them, and soak the gloves in the chlorine solution for 10 minutes before handling in order to kill hepatitis B and AIDS viruses (even though cleaning staff wear gloves). This insures that both surfaces of the gloves are decontaminated.

STEP 3: Wash gloves in soapy water. Clean gloves inside and out.

STEP 4: Rinse gloves in clean water until no detergent (soap) remains. (Detergent can interfere with disinfection.)

STEP 5: Test gloves for holes by inflating them by hand and holding them under water. (Air bubbles will appear if holes are present.)

STEP 6: Gently dry gloves inside and out before proceeding with sterilization or high-level disinfection. (Gloves which remain wet for long periods of time will absorb water and become tacky.)

STEP 7: For gloves which are to be steam sterilized, package before further processing. For high-level disinfection, packaging is done after disinfection.

Note: Gloves should be discarded after processing three times because invisible tears may occur.

HOW TO STERILIZE GLOVES

After decontamination, cleaning and thorough drying, gloves need to be packaged prior to autoclaving: the cuffs should be rolled up, so that the gloves can be put on after sterilizing without contamination. If autoclaving, put gauze inside each glove and under the fold of the cuff (Figure D-1) and

Figure D-1. Gloves with Gauze Inside Glove and Under Fold.


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place them in a wire basket on their sides to allow optimum steam penetration. (If gloves are stacked in piles, penetration of steam under the cuffs may be poor.) (Do not tie tightly or wrap glove packs with rubber bands.) Autoclave at 121°C (250°F) for 20 minutes and at a pressure of 106 kPa (15 lb/in²). **Remember:** Higher temperatures and pressures are destructive to gloves. Immediately after autoclaving, gloves are extremely friable and tear easily. Gloves should not be used for 24 to 48 hours, to allow the elasticity to be restored and to prevent tackiness/stickiness (Figure D-2).

Figure D-2. Tips to Help Avoid Glove Problems

<table>
<thead>
<tr>
<th>PROBLEM: TACKY OR STICKY GLOVES</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Probable Cause</strong></td>
</tr>
<tr>
<td>---------------------</td>
</tr>
</tbody>
</table>
| Residual detergent (soap) | • Reduce amount of detergent used when washing gloves  
• Rinse gloves at least three times in clean water |
| Excessive exposure to high temperature | • Use 20 minutes sterilizing exposure at 121°C (250°F) and remove gloves from sterilizer as soon as cycle is completed |
| Gloves sterilized with other goods | • Sterilize gloves separately |
| Poor powdering | • Use absorbable glove powder and follow manufacturer’s instructions to insure a film of powder on all surfaces |
| Surfaces of gloves touching each other | • Paper or cloth wicks should be inserted between the palm and back of hand of each glove and between the hand of the glove and turned-back cuff. This allows steam to contact all surfaces during sterilization and prevents surfaces from adhering to each other |
| Deterioration of rubber/latex | • Rubber/latex gloves deteriorate while stored even though they have not been used. They become soft, sticky and unusable.  
• Do not overstack gloves  
• Store in a dry, cool area  
• Do not store in direct sunlight |

<table>
<thead>
<tr>
<th>PROBLEM: EXCESSIVE TEARING OR RUPTURING</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Probable Cause</strong></td>
</tr>
<tr>
<td>---------------------</td>
</tr>
<tr>
<td>Air testing too soon</td>
</tr>
<tr>
<td>Gloves used too soon following sterilization</td>
</tr>
</tbody>
</table>

**Source:** Southeast Asia Office (SEARO)/World Health Organization: *A Manual on Infection Control in Health Facilities*. New Delhi, SEARO Regional Health Papers (No.18), 1988, p. 29.
HOW TO HIGH-LEVEL DISINFECT GLOVES

After gloves have been decontaminated and thoroughly washed in detergent and water, they are then ready for high-level disinfection (HLD) by boiling for 20 minutes.

Instructions

STEP 1: Place gloves in a bag made of plastic or nylon netting. Cotton bags are less desirable because they dry slowly after use.

STEP 2: Place a weight in the bag so that all gloves and the bag are at least 1 inch below the surface of the water.

STEP 3: Close lid over pan and bring water to a full, rolling boil. (When water only simmers, very little steam is formed and the temperature at the water's surface may never get high enough to kill microorganisms.)

STEP 4: Reduce heat so that water continues to boil at a rolling boil. (When water boils too violently, it evaporates quickly and wastes fuel.)

STEP 5: Start timer or note time on clock and record time rolling boil began on sterilization log. (No objects or water should be added after timing starts.)

STEP 6: Boil gloves for 20 minutes, starting from the time rolling boil begins.

STEP 7: After boiling for 20 minutes, remove netted bag using high-level disinfected, dry large forceps/pickups. Never leave boiled objects in water which has stopped boiling. (As the water cools and steam condenses, air and dust particles are drawn down into the container and may contaminate the gloves.)

STEP 8: Shake off excess water and hang the bag out to dry. (The netted bag will permit the gloves to dry quickly without being handled.) Avoid areas where dust or other particles may contaminate the contents of the bag.

STEP 9: Wearing previously HLD gloves, place bag in dry, HLD container. Open bag and remove gloves, reverse them and replace in bag. (This step permits the gloves to dry both inside and out.)

STEP 10: Shake off excess water and rehang the bag to dry.

STEP 11: Using previously HLD forceps or glove, open bag and place gloves in a covered, dry, high-level disinfected container.¹

STEP 12: Fold cuffs over and place together by pairs for easy donning later.

STEP 13: Gloves which have been HLD by boiling and have air dried do not need paper wrapping. They should be stored in an HLD container and removed as needed with HLD large forceps/pickups. Ideally, these

¹ To prepare an HLD container, boil (if small) or fill a plastic container with 0.5% chlorine solution and soak for 20 minutes. (The chlorine solution can then be transferred to another container and reused.) Rinse the inside thoroughly with boiled water. Air dry before use.
Processing Reusable Gloves

gloves will have the cuffs folded over. Use gloves immediately, or cover and store for later use (up to one week). Avoid recontamination of gloves before use.

Note: If supplies of gloves are limited and/or they will be used immediately after boiling (see STEP 6 above), they can be worn "wet."

Instructions

STEP 7: After boiling for 20 minutes, remove with HLD forceps/pickups.

STEP 8: Allow excess water to drip off gloves (shake gently) and place in an HLD container with a cover and allow to cool (about 5 minutes) before using.

ACCIDENTAL CONTAMINATION OF STERILE OR HLD GLOVES

There are several ways to contaminate sterile or HLD gloves:

- Tearing or puncturing the glove
- Touching any nonsterile object with the sterile glove
- Touching the outside of a sterile glove with an ungloved hand

(Service providers wearing sterile or HLD gloves should be careful not to contaminate gloved hands inadvertently by touching nonsterile objects, unprepped skin or mucous membranes.)

REGLOVING AFTER CONTAMINATION

There are two ways to reglove after contaminating a glove during a procedure:

- Remove contaminated glove by the cuff, and dispose of properly
- Have circulating nurse open a new sterile glove package, laying the glove package on a clean surface
- Put on replacement glove in the usual manner

Alternatively:

- Remove contaminated glove by the cuff and dispose of properly
- Have scrub nurse open another sterile glove package, remove a sterile glove, and hold the glove open by the cuff. Put your hand into the glove without touching the outside of the glove
- Adjust the glove after the scrub nurse lets go of the cuff
REFERENCES


APPENDIX E

DECONTAMINATING AND CLEANING INSTRUMENTS, NEEDLES, SYRINGES AND LINENS

HOW TO DECONTAMINATE AND CLEAN SURGICAL (METAL) INSTRUMENTS

STEP 1: After use, gently immerse all instruments used for pelvic examination, Norplant insertion or removal or any other surgical procedure in a plastic bucket of freshly prepared 0.5% chlorine solution or other locally available and approved disinfectant for at least 10 minutes before starting the cleaning process. This step is necessary to help prevent transmission of hepatitis B virus (HBV) or AIDS virus (HIV) to clinic staff.

STEP 2: After this pre-soak in chlorine solution, rinse the objects with water to remove any blood, body fluids and chlorine if instruments are not to be washed immediately. (Don’t use hot water as it can coagulate protein, making it hard to remove.)

STEP 3: Next, scrub instruments (hold under water to prevent infectious material becoming airborne through splashing) with a soft brush in detergent and water (be sure to clean the teeth, joints and screws - an old toothbrush works well for this).

STEP 4: Rinse again with clean water until no detergent remains. (Detergent can interfere with the action of some chemical disinfectants.)

STEP 5: Dry by air or with a clean towel. (Water from wet instruments will dilute chemicals used for high-level disinfection [HLD], making them ineffective.) Drying is not necessary for instruments which are to be boiled.

STEP 6: Proceed with sterilization (if available) or HLD by boiling or use of chemical disinfectants.

HOW TO DECONTAMINATE AND CLEAN NEEDLES AND SYRINGES

When available and affordable, single-use (disposable) syringes and needles are recommended for all client care and surgical procedures. If syringes are to be reused, needles and syringes should be sterilized either by autoclaving (steam) or by dry heat. When sterilization facilities are not available, needles and syringes may be high-level disinfected by boiling. Remember: boiling, even for several hours, will not reliably kill bacterial endospores. When single-use needles and syringes are used, it is important to:

- Maintain adequate supplies
- Ensure that the disposable items are not reused

Note: After use, dispose of used needles and syringes in special puncture-proof containers for sharp objects to avoid accidental injury and possible infection of workers during refuse removal.

When single-use syringes and needles are not available, the following steps should be taken to decontaminate and then clean needles and syringes:
Decontaminating and Cleaning

STEP 1: Leave needle attached to syringe.

STEP 2: Fill syringe with high-level disinfectant such as 0.5% chlorine solution by drawing up through the needle.

STEP 3: Cover syringe and attached needle with chlorine solution by laying them horizontally in a flat tray and leave immersed in decontamination solution for 10 minutes.

STEP 4: Expel disinfectant solution from syringe and needle.

STEP 5: Disassemble and clean with soapy water. (Be sure to clean hub area.) Insert stylet or needle wire through hub of needle to ensure that the cannula is not obstructed.

STEP 6: Reassemble and rinse syringe and needle with water at least three times (fill and expel through needle).

STEP 7: Detach needle from syringe and make sure hub area is clean.

STEP 8: Examine needle and syringe for bent needle tips or other damage, syringe seal condition (rubber ring), needle hub fit to syringe, readable syringe markers, etc. Dispose of damaged needles and syringes in a special puncture-proof container for sharp objects.

STEP 9: After cleaning as described above, it is critical that the syringe and needle be sterilized by either autoclaving or dry heat, or high-level disinfected by boiling prior to use.

HOW TO DECONTAMINATE AND CLEAN LINENS, SURGICAL DRAPES AND OTHER ITEMS

STEP 1: Pre-soak linens or clothing contaminated with blood or other body fluids in 0.5% chlorine solution or other locally available and approved disinfectant to kill HBV and HIV. This will minimize the risk to those staff responsible for washing these items.

STEP 2: After pre-soaking, wash linens and clothing with detergent and hot water.

STEP 3: Rinse thoroughly.

STEP 4: Dry linens and clothing in the sun or machine dry. To avoid recontamination, limit handling.

STEP 5: If air dried, iron surgical drapes when sterilization (autoclaving) is not available. (Other linens also can be ironed.) HBV and HIV are not transmitted by routine household objects. Routine washing of dishes, glasses and utensils in warm, soapy water is sufficient. Routine laundering of personal linens in hot water also is sufficient.

REFERENCES

APPENDIX F

INFECTION PREVENTION PROCESSES
FOR INSTRUMENTS AND OTHER ITEMS

DECONTAMINATION

Decontamination is the first step in handling used (soiled) surgical instruments and gloves. Decontamination is important for pre-treating instruments and objects that may have been in contact with blood or body fluids. Immediately after use, instruments should be placed for 10 minutes in a 0.5% chlorine solution, which rapidly inactivates hepatitis B and AIDS viruses. (Table F-1 describes how to make a 0.5% chlorine solution using commonly available bleaches.) Decontamination makes items safer to handle by personnel who clean them.

After decontamination, instruments should be rinsed immediately with cool water to prevent corrosion and to remove visible organic material before being thoroughly cleaned. Personnel should wear gloves while handling used instruments. Inexpensive rubber or vinyl household (utility) gloves work well for this.

Surfaces (especially examination tables) that may have come in contact with contaminated body fluids also should be decontaminated. Wiping with a suitable disinfectant such as a 0.5% chlorine solution before reuse, when visibly contaminated or at least daily, is an easy-to-do, inexpensive way to decontaminate large surfaces.

Table F-1: Preparing a 0.5% Chlorine Solution from Bleach (Sodium Hypochlorite Solutions)

<table>
<thead>
<tr>
<th>Type or Brand of Bleach (Country)</th>
<th>Chlorine % Available</th>
<th>How to Dilute to a 0.5% Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>JIK (Kenya)</td>
<td>3.5%</td>
<td>1 part bleach to 6 parts water</td>
</tr>
<tr>
<td>Household bleach (USA, Indonesia)</td>
<td>5%</td>
<td>1 part bleach to 9 parts water</td>
</tr>
<tr>
<td>Eau de Javel (France)</td>
<td>5%</td>
<td>1 part bleach to 9 parts water</td>
</tr>
<tr>
<td>15 °chlorum</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blanqueador, cloro (México)</td>
<td>6%</td>
<td>1 part bleach to 11 parts water</td>
</tr>
<tr>
<td>Lavindina (Bolivia)</td>
<td>8%</td>
<td>1 part bleach to 15 parts water</td>
</tr>
<tr>
<td>Chloros (UK), Lejia (Peru)</td>
<td>10%</td>
<td>1 part bleach to 19 parts water</td>
</tr>
<tr>
<td>Chloros (UK), Extrait de Javel (France)</td>
<td>15%</td>
<td>1 part bleach to 29 parts water</td>
</tr>
</tbody>
</table>

1 In some countries the concentration of sodium hypochlorite is expressed in chlorometric degrees (°chlorum); 1° chlorum is approximately equivalent to 0.3% available chlorine.

CLEANING

Cleaning is a crucial step in providing safe, infection-free equipment and instruments. A thorough cleaning with detergent and water physically removes organic material such as blood and secretions. Dried organic material can entrap microorganisms in a residue that protects them against sterilization or chemical disinfection. Organic matter also can partially inactivate disinfectants, rendering them less effective.

Gloves should be worn while cleaning instruments and equipment (thick household or industrial gloves work well). If torn or damaged, they should be discarded; otherwise, they should be cleaned and left to dry at the end of the day for use the following day. In addition to wearing gloves, extreme care must be taken to prevent needle sticks or cuts.

Instruments should be cleaned with a brush (old toothbrushes work well) in soapy water. Particular attention should be paid to instruments with teeth, joints or screws where organic material can collect. (Because chlorine breaks down protein, decontaminating by soaking in a chlorine solution makes cleaning easier.) After cleaning, instruments should be thoroughly rinsed with water to remove detergent residue which can interfere with chemical disinfection.

Reusable needles and syringes should be disassembled and cleaned with soapy water, paying special attention to the hub area. They then should be rinsed at least three times with clean water, expelling the water through the needle into another container so as not to contaminate the rinse water, and then dried. If possible, single-use (disposable) needles and syringes should be used, and never reused.

STERILIZATION

Whenever possible, instruments and other items that come in direct contact with the blood stream or tissues under the skin, such as needles, syringes and scalpels, should be sterilized after first being decontaminated and thoroughly cleaned, rinsed and dried. The sterilization process ensures that all microorganisms, including bacterial endospores, are destroyed. Bacterial endospores are particularly difficult to kill because of their tough coating.

Heat Sterilization. High-pressure saturated steam (autoclaving) or dry heat (by electric oven) are the most readily available methods of sterilization. Steam sterilization is generally the method of choice for sterilizing instruments and other items used in family planning and health care facilities. Where electricity is a problem, instruments can be sterilized in a non-electric steam autoclave using kerosene as a heat source. Under certain conditions solar panels can be utilized to reflect solar energy for heating purposes.

When instruments and equipment are steam-sterilized, it is essential that steam reach all surfaces; autoclaving closed containers will sterilize only the outside of the containers.

Dry heat sterilizers are good in humid climates but need a constant supply of electricity, making them impractical in many remote (rural) areas. Furthermore, dry heat sterilization can be used only with glass or metal objects - other substances will melt or
incinerate. (Needles and other instruments with cutting edges should be dry-heat sterilized at temperatures not higher than 162.8°C [325°F]; otherwise, the sharpness of the cutting edges can be destroyed.) The standard conditions for sterilization by steam or dry heat are shown in the box below.

**Standard Conditions for Heat Sterilization**

**Steam sterilization:** 121°C (250°F) at 106 kPa (15 lb/in²) for 26 minutes for unwrapped items; 30 minutes for wrapped items. Allow all items to dry before removing.

**Dry heat:** 170°C (340°F) for one hour (total cycle time - placing instruments in oven, heating to 170°C, timing for one hour and then cooling - is from two to two and a half hours) or 160°C (320°F) for two hours (total cycle time is from three to three and a half hours).

Sterile instruments generally should be used immediately unless they have been wrapped in a double layer of muslin, paper or other appropriate material during steam sterilization. The material must be porous enough to let steam through but tightly woven enough to protect against dust particles and microorganisms. **Wrapped sterile instruments have a shelf life of up to one week, but only if kept dry and intact.** Placing a wrapped pack in a sealed plastic bag will increase its shelf life to one month. All packs should be labeled with an expiration date.

**Chemical Sterilization**

An alternative to steam or dry heat sterilization is chemical sterilization (often called cold sterilization) by soaking for 8-10 hours in a glutaraldehyde or at least 24 hours in an 8% formaldehyde solution. Glutaraldehydes, such as Cidex®, often are in short supply and expensive, but they are the only practical sterilants usable for instruments (such as laparoscopes) which cannot be heated. Also, formaldehyde and glutaraldehydes require special handling and leave a residue on treated instruments; therefore, rinsing with sterile water after use is essential. (Using boiled water, since it does not reliably inactivate endospores, can recontaminate the sterile instruments.)

Although formaldehyde is less expensive than glutaraldehyde, it is more toxic. The vapors of both chemicals are irritating to the skin, eyes and respiratory tract (Table F-2). When using either formaldehyde or glutaraldehyde, gloves should be used, exposure time limited and both chemicals used only in a well-ventilated area.

**HIGH-LEVEL DISINFECTION**

Sterilization is the safest and most effective method for processing instruments which come in contact with the blood stream, tissue beneath the skin or tissues which are normally sterile. When sterilization equipment is either not available or not suitable, **high-level disinfection (HLD) is the only acceptable alternative.** HLD destroys all microorganisms, including viruses causing hepatitis B and AIDS, but does not reliably kill all bacterial endospores. For example, in family planning facilities, either sterilization or HLD are acceptable for processing instruments and gloves used for pelvic exams and IUD insertion and removal, since problems with endospores have not been reported with IUD use.
HLD can be achieved through boiling in water or soaking instruments in chemical disinfectants such as a glutaraldehyde (e.g., Cidex®) or 8% formaldehyde. Because boiling requires only inexpensive equipment, which usually is readily available, it is the preferred method for small clinics or those located in remote areas. Regardless of the method selected, however, HLD can be effective only when used (soiled) instruments and gloves are first decontaminated and thoroughly cleaned and rinsed before disinfection. The whole procedure should be monitored regularly.

**HLD by Boiling.** Boil instruments for 20 minutes. Timing should begin when the water is at a rolling ( bubbling) boil; all instruments should be totally submerged and nothing should be added to the container after boiling begins. Air dry disinfected items in a clean area of the room. Use instruments and other items immediately or place them in a covered, dry HLD container. Store for up to one week.

Moist heat at 80°C kills essentially all bacteria, viruses, parasites and fungi in 20 minutes. Therefore, unless the altitude of the health facility is over 18,000 feet (5,500 meters) it is not necessary to increase the boiling time.

**Chemical Disinfection.** A variety of chemical disinfectants are available worldwide which include:

- Ethyl or isopropyl alcohol
- Chlorine
- Formaldehyde (formalin)
- Glutaraldehyde
- Hydrogen peroxide
- Iodine and iodophors

Table F-2 provides guidelines for preparing and using a number of these disinfectants.

Although alcohols and iodophors are inexpensive and readily available, they are no longer classified as HLDs. (Alcohols do not kill some viruses and Pseudomonas species [Gram-negative bacteria] have been known to multiply in iodophors.) They should be used for disinfection only when the HLDs listed below are not available or appropriate.

**Note:** Chemical HLD of needles and syringes should be avoided because chemical residues, unless completely removed by rinsing, may interfere with the action of medications being injected.

The major advantages and disadvantages of each disinfectant are described below.
## Table F-2: Preparing and Using Chemical Disinfectants

<table>
<thead>
<tr>
<th>Disinfectant (common solution or brand)</th>
<th>Effective Concentration</th>
<th>How to dilute</th>
<th>Skin Irritant</th>
<th>Eye Irritant</th>
<th>Respiratory Irritant</th>
<th>Corrosive</th>
<th>Leaves Residue</th>
<th>Time Needed for HLD</th>
<th>Time Needed for Sterilization</th>
<th>Activated Shelf Life</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alcohol Ethyl Isopropyl &quot;Methylated spirit&quot;</td>
<td>60-90%</td>
<td>Use full strength</td>
<td>Yes (can dry skin)</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>20 minutes</td>
<td>Do not use</td>
<td>Change weekly; daily if heavily used; sooner if cloudy</td>
</tr>
<tr>
<td>Chlorine</td>
<td>0.5%</td>
<td>Dilution procedures vary&lt;sup&gt;3&lt;/sup&gt;</td>
<td>Yes (with prolonged contact)</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>20 minutes</td>
<td>Do not use</td>
<td>Change daily; sooner if cloudy</td>
</tr>
<tr>
<td>Formaldehyde (35-40%)</td>
<td>8%</td>
<td>1 part 35-40% solution to 4 parts boiled water</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>20 minutes</td>
<td>24 hours</td>
<td>Change every 14 days, sooner if cloudy</td>
</tr>
<tr>
<td>Glutaraldehyde Cidex&lt;sup&gt;®&lt;/sup&gt;</td>
<td>Varies</td>
<td>Varies: read instructions on container</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>20 minutes</td>
<td>10 hours for Cidex</td>
<td>Change every 14 days;&lt;sup&gt;4&lt;/sup&gt; sooner if cloudy</td>
</tr>
<tr>
<td>Hydrogen Peroxide (30%)</td>
<td>6%</td>
<td>1 part 30% solution to 4 parts boiled water</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>30 minutes</td>
<td>Do not use</td>
<td>Change daily; sooner if cloudy</td>
</tr>
<tr>
<td>Iodophors (10% povidone iodine-PVI)</td>
<td>Approximately 2.5%</td>
<td>1 part 10% PVI to 3 parts water</td>
<td>No&lt;sup&gt;5&lt;/sup&gt;</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Do not use</td>
<td>Do not use</td>
<td>Change daily</td>
</tr>
</tbody>
</table>

1 All chemical disinfectants are heat and light sensitive and must be stored appropriately.
2 Alcohols and iodophors are not HLDs; however, they can be used as intermediate-level disinfectants. For this purpose, soak for 20 minutes.
3 See Table F-1, for instructions on preparing chlorine solutions.
4 Different commercial preparations of Cidex<sup>®</sup> and other glutaraldehydes (e.g., Wavicide<sup>®</sup>) are effective at lower temperatures (20°C) and for longer activated shelf life. Always check manufacturer's instructions.
5 Except in people with allergies to iodophors.

High-Level Disinfectants

- **Chlorine Solutions.** Chlorine solutions are fast-acting, very effective against hepatitis B and AIDS viruses, inexpensive and readily available. They are extremely useful for decontaminating large surfaces such as examination tables.

A major disadvantage is that chlorine solutions can corrode metals; however, stainless steel instruments can be safely soaked in a 0.5% chlorine solution (using a plastic container) for up to 20 minutes. If they are then rinsed and dried promptly, corrosion is not a problem. Because chlorine solutions deteriorate rapidly, fresh solutions should be made at least daily or more often if the solution is visibly cloudy.

- **Formaldehyde.** Eight percent formaldehyde, which can be used as a chemical sterilant, also is an effective high-level disinfectant (HLD), but is highly toxic. Care must be taken to protect both staff and clients from the fumes when mixing and using formaldehyde solutions. Do not dilute with chlorinated water as a dangerous gas (bis-chloromethyl-ether) can be produced.

- **Glutaraldehydes** (e.g., Cidex®). Glutaraldehydes, which also can be used for chemical sterilization, are effective HLDs as well. Although less irritating than formaldehyde, they too should be used in well-ventilated areas. Avoid skin contact by using gloves and taking care not to splash the solution.

Because both formaldehyde (formalin) and glutaraldehydes leave a residue, instruments must be rinsed well with boiled water after disinfecting with these products to prevent skin irritation and remove residue.

- **Hydrogen Peroxide.** Hydrogen peroxide (H₂O₂), which must be diluted to a 6% solution, often is available locally and is less expensive than other chemical disinfectants. (The 3% H₂O₂ solutions used as antiseptics should not be used as disinfectants.) The major disadvantage of H₂O₂ is that it is corrosive and should not be used to disinfect copper, aluminum, zinc or brass. Also, it loses potency rapidly when exposed to heat and light, so needs to be stored carefully. WHO does not recommend using H₂O₂ in tropical environments because of its instability in the presence of heat and light.

Alternative Disinfectants

- **Alcohols** (ethyl or isopropyl). Alcohols are not corrosive to metal, can be used to disinfect rubber or latex as well as plastic items, and leave no chemical residue (therefore, rinsing is not required). The major disadvantages are that alcohols may be unable to penetrate organic material, evaporate rapidly, and do not kill some viruses.

- **Iodophors** (e.g., Betadine® or Wescodyne®). Iodophors (solutions of iodine mixed with a solubilizing agent) are usually readily available locally.
Povidone iodine (PVI) is a commonly available iodophor, usually sold as a 10% solution (1% iodine). Until recently iodophors and aqueous iodine solutions were classified as HLDs. Iodophors are good for disinfecting stainless steel equipment.

Storage of Disinfectants

- Disinfectants should be stored in a cool, dark area.
- Never store chemicals in direct sunlight or in excessive heat (e.g., upper shelves in a tin-roofed building).

### Key Steps in Chemical Disinfection

- Decontaminate instruments that have been contaminated with blood and body fluids; thoroughly clean and dry all equipment and instruments.
- Cover all items completely with correct dilution of properly stored disinfectant.
- Soak for 20 minutes.
- Rinse well with boiled water and air dry.
- Store for up to one week in a high-level disinfected (HLD), covered container or use promptly. To prepare HLD container, boil (if small) or fill a plastic container with 0.5% chlorine solution and soak for 20 minutes. (The chlorine solution can be transferred to a plastic container and reused.) Rinse the inside thoroughly with boiled water. Air dry before use.

Products That Should Not Be Used as Disinfectants. Many antiseptic solutions are used incorrectly as disinfectants. While antiseptics (sometimes called "skin disinfectants") are adequate for cleaning skin before an injection or surgical procedure, they are not appropriate for disinfecting surgical instruments and gloves. They do not reliably destroy bacteria and viruses and do not destroy bacterial endospores. For example, Savlon® (cetrimide with chlorhexidine gluconate), which is readily available worldwide, is a good antiseptic but is often mistakenly used as a disinfectant.

Antiseptics that should not be used as disinfectants are:

- Acridine derivatives (e.g., gentian or crystal violet)
- Benzalkonium chloride, a quaternary ammonium (e.g., Zephiran®)
- Cetrimide (e.g., Cetavlon®)
Infection Prevention Processes

- Cetrimide with chlorhexidine gluconate (e.g., Savlon®)
- Chlorinated lime and boric acid (e.g., Eusol®)
- Chlorhexidine gluconate (e.g., Hibiscrub®, Hibitane®)
- Hexachlorophene (e.g., Phisohex®),
- Chloroxylenol (e.g., Dettol®)
- Mercury compounds (toxic and not recommended as an antiseptic or a disinfectant)

Mercury solutions (such as mercury laurel), although low-level disinfectants, cause birth defects and are too toxic to use as either disinfectants or antiseptics.

Other products frequently used to disinfect equipment are 1-2% phenol (e.g., Phenol®), 5% carbolic acid (e.g., Lysol®) and benzalkonium chloride, a quaternary ammonium (Zephiran®). These are low-level disinfectants and should be used only to decontaminate environmental surfaces when chlorine compounds are not available.

REFERENCES


## APPENDIX G

### CONTENTS OF NORPLANT INSERTION/REMOVAL KIT PROVIDED BY USAID

<table>
<thead>
<tr>
<th>ITEM</th>
<th>QUANTITY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pan</td>
<td>1 each</td>
</tr>
<tr>
<td>Pan Cover</td>
<td>1 each</td>
</tr>
<tr>
<td>Trocar</td>
<td>5 each</td>
</tr>
<tr>
<td>Syringe, Control, 10 ml</td>
<td>3 each</td>
</tr>
<tr>
<td>Syringe, Hypodermic, 10 ml</td>
<td>3 each</td>
</tr>
<tr>
<td>Needle, Hypodermic, 22 Gauge x 1-1/2&quot;</td>
<td>12 (2 packages)</td>
</tr>
<tr>
<td>Handle, Surgical Knife, Size #3</td>
<td>3 each</td>
</tr>
<tr>
<td>Blade, Surgical, Size #11</td>
<td>24</td>
</tr>
<tr>
<td>Forceps, Crile, Curved, 5-1/2&quot;</td>
<td>1 each</td>
</tr>
<tr>
<td>Forceps, Mosquito, Halstead, Straight, 5&quot;</td>
<td>1 each</td>
</tr>
<tr>
<td>Forceps, Mosquito, Delicate, Curved, 5&quot;</td>
<td>1 each</td>
</tr>
</tbody>
</table>
There are three Norplant introductory stages for which the materials and services requirements will need to be forecast:

- Pre-introduction, when training and service delivery resources are being established
- Start-up, when Norplant is being incorporated into the program
- Mature program, when the Norplant introduction is fully launched

Prior to the start-up stage, the object of forecasting is to estimate initial and long-term requirements. The initial in-country experience and training program should start slowly to ensure that an adequate infrastructure is in place. Therefore, the pre-introduction stage requires few capsules (from several hundred to 1,000). Once the start-up stage has been launched, however, emphasis should be focused on monitoring demand to ensure that conditions of under-supply or over-supply are quickly corrected. In a mature program when there are approximately the same number of insertions and removals, the task of logistics management is to fine-tune the commodity supply system to minimize inventory and transport costs while maintaining maximum availability of capsules.

The following example (Table H-1) can be used to estimate Norplant requirements and the potential demand on service delivery requirements over time. This model assumes that 1,000 women per year choose to use Norplant. This is 20 insertions per week - it also assumes that the annual discontinuation rate is 20%. The table can be used to estimate any acceptance rate simply by using multiples of the numbers given.

Assuming 1,000 insertions per year (line 1 of the table) and an annual continuation rate of 80%, the number of women using the method increases with time (line 2). After the five-year effective life of the capsules has been completed, some women (line 3) will have to choose whether to have a second set of capsules inserted. In this example, 50% of the women choose to use Norplant again (line 4). The total insertions per year (shown in line 5) obviously dictates the capsule requirements shown in line 13. A certain loss of capsules during storage and distribution must be anticipated. Here, a 5% loss from inventory is assumed (line 14). The annual and cumulative capsule requirements are given in lines 15 and 16.

A small number of women who accept the method each year seek removal in the same year (line 6). Over time, an increasing demand for removal services for acceptors from earlier years will develop (lines 7 and 8). Later, women who have chosen a second set of capsules will begin to need removal services (line 9). The total removals per year is shown in line 10.

The caseload projection for clinical procedures (insertions plus removals) and related services is shown in line 11. With a constant rate of Norplant acceptors per year, the demand for procedures will double in about eight years. The number of women using Norplant at the end of each year, for whom follow-up clinical or counseling services may be needed, obviously increases with time, as shown in line 12. The service delivery requirements for Norplant are discussed in Chapter 10.

---

### Forecasting Norplant Requirements

#### Table H - 1

**ESTIMATING NORPLANT REQUIREMENTS**

<table>
<thead>
<tr>
<th>Years From Start of Program</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Insertions in current year</td>
<td>1000</td>
<td>1000</td>
<td>1000</td>
<td>1000</td>
<td>1000</td>
<td>1000</td>
<td>1000</td>
<td>1000</td>
<td>1000</td>
<td>1000</td>
</tr>
<tr>
<td>2. Users from previous years</td>
<td>0</td>
<td>898</td>
<td>1616</td>
<td>2191</td>
<td>2651</td>
<td>3019</td>
<td>3198</td>
<td>3341</td>
<td>3455</td>
<td>3547</td>
</tr>
<tr>
<td>3. Users remaining who entered 5 years ago</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>328</td>
<td>328</td>
<td>328</td>
<td>328</td>
<td>328</td>
</tr>
<tr>
<td>4. Second insertions</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>164</td>
<td>164</td>
<td>164</td>
<td>164</td>
<td>164</td>
</tr>
<tr>
<td>5. Total insertions - current year</td>
<td>1000</td>
<td>1000</td>
<td>1000</td>
<td>1000</td>
<td>1000</td>
<td>1164</td>
<td>1164</td>
<td>1164</td>
<td>1164</td>
<td>1164</td>
</tr>
<tr>
<td>6. Removals from current acceptors</td>
<td>102</td>
<td>102</td>
<td>102</td>
<td>102</td>
<td>102</td>
<td>102</td>
<td>102</td>
<td>102</td>
<td>102</td>
<td>102</td>
</tr>
<tr>
<td>7. Removals - acceptors 1-4 years earlier</td>
<td>0</td>
<td>180</td>
<td>323</td>
<td>438</td>
<td>530</td>
<td>538</td>
<td>574</td>
<td>603</td>
<td>625</td>
<td>644</td>
</tr>
<tr>
<td>8. Removals - women who entered 5 years ago</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>328</td>
<td>328</td>
<td>328</td>
<td>328</td>
<td>328</td>
</tr>
<tr>
<td>9. Removals - second set of implants</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>17</td>
<td>17</td>
<td>17</td>
<td>17</td>
<td>17</td>
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<tr>
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JHPIEGO EDUCATIONAL MATERIALS

JHPIEGO produces a variety of educational materials for use in reproductive health training programs. Materials listed below may be purchased from JHPIEGO; availability and prices are current as of March 1993 and are subject to change. Order forms are included for JHPIEGO-produced educational materials as well as the Zoe™ pelvic model.

IUD (Copper T 380A)

IUD Guidelines for Family Planning Service Programs. This reference manual provides clinicians (nurses, midwives and physicians) with essential information on how to safely use IUDs, specifically the Copper T 380A IUD. The material is arranged sequentially, according to the usual way in which clients are cared for—beginning with family planning counseling and ending with management of side effects and other health problems. (1992) Available in English ($6), French and Spanish ($7)

IUD Course Handbook. This handbook outlines a model two-week competency-based training course for clinicians (nurses, midwives and physicians) in insertion and removal of the Copper T 380A IUD. The learning objectives are keyed to the IUD Guidelines. Also included are pre- and post-course knowledge and skills assessments. Participants measure their progress using detailed counseling and clinical skills learning guides. There are two versions of the handbook: one for participants and one for trainers. The trainer’s handbook contains “Tips for Teaching the Course,” pre-course skills assessment, pre- and mid-course questionnaire answer keys and certification checklists in addition to all participant material. Handbooks are used in ratio of one trainer’s book for every five participant books. The handbook is designed to be adapted to local needs and conditions. (1993) Available in English ($5)

IUD Teaching Slide Set (Copper T 380A IUD Insertion and Removal). This annotated slide set is designed to supplement JHPIEGO’s IUD Course Handbook. The slides provide step-by-step instructions for performing the screening pelvic exam, loading the IUD in the sterile package, inserting the Copper T 380A IUD, removing the Copper T 380A IUD and managing problems. (1993) Available in English, French, Spanish and Portuguese ($28.50)

IUD Training Video (Insertion and Removal of the Copper T 380A IUD). This training video demonstrates a safe and gentle technique for IUD insertion and removal, including performing the screening pelvic examination, loading the Copper T 380A IUD in the sterile package, uterine sounding, use of the withdrawal technique in insertion, IUD removal and management of side effects and other health problems. (1990) Available in English, French and Spanish ($100/domestic; $125/international) (Use separate order form)

NORPLANT®

Norplant® Guidelines for Family Planning Service Programs. This reference manual provides clinicians (nurses, midwives and physicians) with essential information on how to safely insert and remove Norplant. The material is arranged sequentially, according to the usual way in which clients are cared for—beginning with family planning counseling and ending with management of side effects and other health problems. (1993) Available in English ($6), French and Spanish ($7)

Norplant® Course Handbook. This handbook outlines a model three-day competency-based training course in Norplant insertion and removal using a team approach. The learning objectives are keyed to the Norplant® Guidelines. Also included are pre- and post-course knowledge and skills assessments. Participants measure their progress using detailed counseling and clinical skills learning guides. There are two versions of the handbook: one for participants and one for trainers. The trainer’s handbook contains “Tips for Teaching the Course,” pre- and mid-course questionnaire answer keys and certification checklists in addition to all participant material. Handbooks are used in ratio of one trainer’s book for every five participant books. The handbook is designed to be adapted to local needs and conditions. (1993) Available in English ($5)
Norplant® Teaching Slide Set (Norplant® Insertion and Removal). This annotated slide set provides step-by-step instructions and trouble-shooting hints for Norplant insertion and removal, including removal by the "pop-out method" and difficult removals. (1993) Available in English, French and Spanish ($28.50)

INFECTION PREVENTION

Infection Prevention for Family Planning Service Programs. This reference manual is designed to enable clinic administrators, managers and health care professionals to develop uniform infection prevention (IP) standards for use in any type or size of family planning service program. The three sections of the manual cover basic IP principles and practices; practical and easy-to-do IP practices for each surgical contraceptive method; and "how to" instructions on using the recommended procedures. (1992) Available in English ($6), French and Spanish ($8)

Infection Prevention Course Handbook. This handbook outlines a model five-day training course in recommended IP practices for the safe delivery of all types of surgical contraceptive procedures. The learning objectives are keyed to the Infection Prevention manual. Included are pre- and post-course knowledge assessments. Participants measure their progress using detailed IP learning guides. An eight-hour refresher module is included for use in short, in-service surgical contraceptive courses. There are two versions of the handbook: one for participants and one for trainers. The trainer’s handbook contains "Tips for Teaching the Course," pre- and mid-course questionnaire answer keys and certification checklists in addition to all participant material. Handbooks are used in ratio of one trainer’s book for every five participant books. The handbook is designed to be adapted to local needs and conditions. (1993) Available in English ($8)

Infection Prevention Teaching Slide Set (Infection Prevention Overview and Processing Reusable Gloves). This annotated slide set is divided into two sections: the first provides an overview of recommended IP practices for use in family planning service programs; the second part provides step-by-step instructions on processing reusable gloves. (1992) Available in English, French and Spanish ($28.50)

TRAINING SKILLS

Training Skills for Reproductive Health Professionals. This reference manual is intended for use by medical and nursing school faculty and reproductive health trainers who are responsible for designing and teaching courses and workshops in reproductive health. It emphasizes a participatory training approach and use of competency-based knowledge and skill assessments. (1993) Available in English and French ($15)

Clinical Training Skills for Reproductive Health Professionals. This reference manual focuses on six essential areas of clinical skills training, including creating a positive training climate, coaching in the clinical setting, competency-based assessments, using audio-visuals, presenting illustrated lectures and designing a training course. (1993) Available in English and French ($7)

Clinical Training Skills Course Handbook. This handbook outlines a model six-day course to give expert reproductive health service providers the essential information they need to become clinical trainers. It is designed to be used with JHPIEGO's manual Clinical Training Skills for Reproductive Health Professionals. There are two versions of the handbook: one for participants and one for trainers. The trainer’s handbook contains "Tips for Teaching the Course," pre- and mid-course questionnaire answer keys and certification checklists in addition to all participant material. Handbooks are used in ratio of one trainer’s book for every five participant books. (1993) Available in English ($5)

Orders must be prepaid in U.S. dollars. For additional information or quantity orders, contact:

JHPIEGO Corporation
Materials Control Division
1615 Thames Street
Baltimore, Maryland 21231-3430 U.S.A.
Telephone (410) 614-0538 or Fax (410) 955-6199 or (410) 614-0586
## JHPIEGO EDUCATIONAL MATERIALS ORDER FORM

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**SHIPPING AND HANDLING** (See reverse for domestic and international rates)

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Availability and prices current as of March 1993
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#### INTERNATIONAL SHIPPING RATES

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Contact JHPIEGO for rates for larger quantities.

### INTERNATIONAL COURIER DELIVERY RATES

(Estimated delivery time 5-6 days, "Door-to-Door" service)

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*Delivery is not available to Rwanda at the present time. Country access subject to change.

Please mail or fax your order to JHPIEGO at the address listed below. All orders must be prepaid in U.S. dollars. Make check or money order payable to "JOHNS HOPKINS HOSPITAL". Please provide complete shipping information, including routing if applicable.

**NOTE:** We cannot ship to P.O. boxes.

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**FOR LARGE ORDERS OR ADDITIONAL INFORMATION, PLEASE CONTACT**

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____ Check payable to:  
Gaumard Scientific Co., Inc.  

Attention: ____________________  

Quantity  Catalog No.  Description  Unit Price  Total  

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Subtotal: _________  

Less Discount: _________  
(if applicable)  

Total: _________  

F.O.B. Miami.  
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and our customer service department will expedite your order. Overnight express service and  
2nd day service available at an additional charge.  

Quantity discounts are available. Please call our Customer Service Department.  

The Zoë™ Gynecologic Simulator was developed by JHPIEGO in collaboration with Gaumard Scientific Co.  

JHPIEGO Norplant Guidelines (3/93)
The **SIMA' ZOE** Gynecologic Simulator is a full size adult female lower torso for training in:

- Bimanual pelvic examination
- Palpation of normal and pregnant uteri
- Vaginal examination, including insertion of speculum
- Visual recognition of normal and abnormal cervices
- Uterine sounding
- IUD insertion and removal
- Diaphragm sizing and fitting
- Laparoscopic visualization and occlusion of fallopian tubes
- Minilaparotomy

The **ZOE** is supplied with the following:

- One anteverted and one retroverted parous uterus
- One ten week pregnant uterus
- One postpartum uterus
- Five (5) normal and four (4) abnormal cervices
- Ten (10) fallopian tubes
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**ZOE** interior and certain cervical replicas are individually hand-painted. Also available in black skin tone. All simulators are manufactured and assembled in the USA. Gaumard, SIMA, and SIMA Gyn/Aid are Registered Trademarks of Gaumard Scientific Co.

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Telephone (305) 666-8548  (800) 882-6655  
Fax (305) 667-6085

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JHPIEGO TEACHING VIDEO ORDER FORM

ALL LANGUAGES AND FORMATS (price includes shipping and handling):

$100 per video for domestic shipments
$125 per video for international shipments

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TOTAL ORDER

SHIPPING INFORMATION

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ORGANIZATION: __________________________________________________________

ADDRESS: _______________________________________________________________

TELEPHONE: ___________________________ FAX: _________________________________

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JHPIEGO Department
2125 Greenspring Drive
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Telephone (410) 252-1700 or Toll Free (800) 432-8433 or Fax (410) 252-6316

JHPIEGO Norplant Guidelines (3/93)
JHPIEGO produces a variety of educational materials for use in reproductive health training programs. Contact JHPIEGO at the address listed below for additional information or to place an order.

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**IUD Teaching Slide Set (Copper T 380A IUD Insertion and Removal).** The annotated slides provide step-by-step instructions for performing the screening pelvic exam, loading the IUD in the sterile package, inserting and removing the Copper T 380A IUD, and managing problems. (1993) English, French, Spanish, Portuguese ($28.50)

**IUD Training Video (Insertion and Removal of the Copper T 380A IUD).** This training video demonstrates a safe and gentle technique for IUD insertion and removal. (1990) English, French, Spanish ($100/domestic; $125/international)

**Norplant® Guidelines for Family Planning Service Programs.** This reference manual provides clinicians with essential information on how to safely insert and remove Norplant. (1993) English ($6); French and Spanish ($7)

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