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NORPLANT® IMPLANTS GUIDELINES *for* FAMILY PLANNING SERVICE PROGRAMS

Second Edition

A PROBLEM-SOLVING REFERENCE MANUAL

editors

Noel McIntosh

Ann Blouse

Lois Schaefer

JHPIEGO
CORPORATION

AVSC International

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GUIDELINES
for **FAMILY PLANNING**
SERVICE PROGRAMS

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This manual was developed to meet the growing need of family planning trainers and service providers for concise, up-to-date information on levonorgestrel (NORPLANT®) implants. The first edition of these guidelines was adapted from educational materials developed by the Population Council and by a collaborative group of international organizations including AVSC International, Family Health International (FHI), International Planned Parenthood Federation (IPPF), the Johns Hopkins Center for Communication Programs, Leiras Oy Pharmaceuticals, the Program for Appropriate Technology (PATH), and the World Health Organization (WHO). Specific publications which were most helpful in preparing the second edition were: *Norplant Levonorgestrel Implants: A Summary of Scientific Data* by The Population Council; *Recommendations for Updating Selected Practices in Contraceptive Use: Results of a Technical Meeting*, vol.1, by the Technical Guidance Working Group; *Improving Access to Quality Care in Family Planning: Eligibility Criteria for Initiating Use of Selected Methods of Contraception* by WHO; *Norplant Contraceptive Subdermal Implants: Managerial and Technical Guidelines* by WHO; *Infection Prevention for Family Planning Service Programs*, 2nd ed. by Tietjen et al; and *PocketGuide for Family Planning Service Providers* by Blumenthal and McIntosh. Throughout this manual, references to these and other documents are **specifically cited** within the text or **acknowledged** at the end of each chapter.

COMMENTS ON THE SECOND EDITION

The need for a second edition reflects, in part, the unexpectedly large request from our international colleagues for the first edition and the need to incorporate the many excellent suggestions and comments received from them. In addition, there is new information on:

- the effectiveness, safety and acceptability of Norplant implants (**Chapter 1**);
- the importance of thorough counseling to improve client satisfaction and continuation (**Chapter 2**);
- a simpler process for client assessment (**Chapter 4**);
- the management of the most common side effect—changes in the menstrual bleeding pattern (**Chapter 8**); and
- a removal method that is easier to learn than the standard method (**Chapter 9**).

Finally, a new chapter, **Providing Quality Services**, has been added. This chapter reflects the need for up-to-date information on how to practically assess the quality of Norplant implants services, seek solutions to problem areas and gradually introduce changes that will improve all areas of service delivery. Moreover, it documents the importance of having well thought-out service delivery and training standards—standards which can be tailored to the clients' needs by the service delivery team and clinic manager.

Although the text of several chapters has been altered, our **goal** as described in the **Preface** of the first edition remains the same: **to provide a practical, inexpensive problem-solving reference manual for family planning service providers, clinic managers and clinical trainers**. Furthermore, in a continuing effort to make these guidelines as up-to-date as possible, we have attempted to harmonize them with the most recent documents available. We concur that it must be the mission of "...donor organizations and technical assistance agencies to work together to offer developing countries a **consistent** set of service guidelines that reflect not only current epidemiologic insight, but also respect for individual women's choices."¹

The editors gratefully acknowledge the valuable assistance of our international colleagues, consultant trainers and JHPIEGO staff for their suggestions, comments and most importantly, for their time and effort in reading the drafts of the manual. Special thanks go to Mark Perloe (USA), Linda Tietjen (USA), Tikaman Vaidya (Nepal), Gilberte Vansintejan (USA), as well as Jeff Spieler and his staff in the Research Division, Office of Population, United States Agency for International Development, and Sally Girven and Cynthia Steele Verme of AVSC International.

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¹ Angle MA, LA Brown and P Buekens. 1993. IUD protocols for international training. *Studies in Family Planning* 24(2): 125-131.

(May 1995)

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PREFACE

The purpose of this manual is to provide clinicians (physicians, nurses and midwives) with essential information on how to use Norplant implants safely. The material is arranged sequentially according to the usual way in which clients are cared for—starting with general counseling and ending with management of common side effects and other problems. Moreover, the information is provided in concise modules for ease in learning and recall, and key points are repeated in several sections to emphasize their importance. Finally, the last two chapters provide up-to-date guidelines for both improving the quality of services and organizing and managing service delivery programs where provision of Norplant implants is a significant component.

Specific objectives are to:

- Describe the basic process of counseling clients about using Norplant implants.
- Explain the indications and precautions for implants use.
- Define the items necessary to include in the assessment of a potential client.
- 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 implants.
- Describe the important elements in the followup of implants users.
- Provide a guide to the management of possible side effects and complications of implants use.
- Describe a step-by-step procedure for removal of Norplant implants.
- Describe the management skills needed to organize and provide quality services.

Successful programs are those in which the staff exhibit:

- good clinical judgment in selecting acceptors;
- care, sensitivity and thoroughness in informing the client about Norplant implants and common side effects;
- skill in inserting (and removing) the implants;
- knowledge and the ability to recognize real or potential problems; and
- capability to take appropriate clinical action in response to these problems, including knowing when (and where) to refer clients with serious complications.

ONE

INTRODUCTION

BACKGROUND

The Norplant contraceptive implants system is an effective, reversible contraceptive method that provides protection from pregnancy for up to 5 years. It was developed by the Population Council, an international organization established in 1952 to improve contraceptive technology.

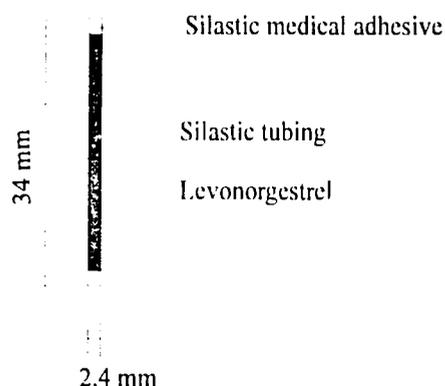
The history of contraceptive implants may be thought of in four stages:

- **research** on the concept of an implantable contraceptive which began in **1966**;
- **development** of the Norplant implants system by **1974**;
- **initiation** of long-term clinical trials in six countries (Brazil, Chile, Denmark, the Dominican Republic, Finland and Jamaica) starting in **1975**; and
- **introduction** of the method into family planning programs worldwide beginning in **1983**.

DESCRIPTION

The Norplant implants system consists of six small flexible capsules made of Silastic® tubing and filled with a synthetic progestin, levonorgestrel (LNG) (**Figure 1-1**).

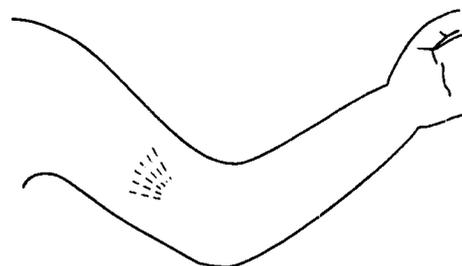
Figure 1-1. Norplant Capsule, Actual Size



Source: Population Council 1990.

The capsules are inserted just under the skin (subdermally) on the inner side of a woman's upper arm (**Figure 1-2**) using a minor surgical procedure. They provide highly effective contraception for up to 5 years. Moreover, after the Norplant implants are removed, normal fertility promptly returns.

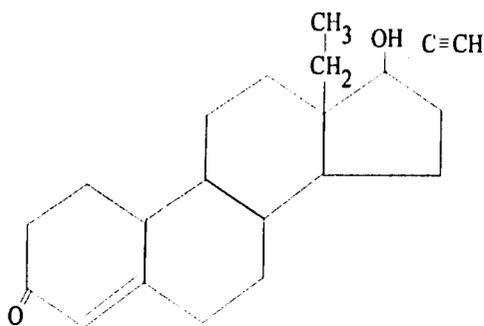
Figure 1-2. Norplant Implants Insertion Site



Introduction

The active contraceptive hormone in Norplant implants is the progestin, levonorgestrel (LNG). It is a steroid hormone with potent progesterone-like activity and weak androgenic properties. It is a synthetic derivative of testosterone. Its chemical structure is depicted in **Figure 1-3**.

Figure 1-3. Structure of Levonorgestrel



The implants are made from medical grade Silastic tubing which is a co-polymer of dimethylsiloxane and methylvinylsiloxane. Each capsule is 34 millimeters (mm) long, with a diameter of 2.4 mm and contains 36 milligrams (mg) of levonorgestrel in a dry crystalline (powder) form. The capsules are sealed at each end with Silastic (polydimethylsiloxane) Medical Grade Adhesive A.

The materials used in the production of Norplant implants are not new to medicine. Levonorgestrel has been used for more than 30 years in combined (estrogen and progestin) oral contraceptives (COCs) and in progestin-only minipills (POPs). The Silastic tubing used to make the capsules has been used in humans (prosthetic valves and other surgical devices) since the 1950s, and the Silastic Medical Adhesive (Silicone Type A) has been used extensively in surgical implants such as cardiac pacemakers for many years (Croxatto 1993).

What is **new** about Norplant implants is the way they deliver the contraceptive drug into the body: the levonorgestrel continuously passes through the capsule walls into the bloodstream at a relatively constant rate for up to 5 years. Thus, this method makes it possible for a single act of contraceptive acceptance to replace more than 1,800 days of pill taking.

Packaging

The contraceptive is prescribed as a set. One sealed, sterile plastic pouch contains six subdermal capsules, each filled with 36 mg of levonorgestrel, for use in **one woman**.

Storage and Shelf Life

The sterile packs of Norplant implants should be stored away from excessive heat (temperature range: 20-50° C) and moisture. An unopened, undamaged sterile pack of Norplant capsules, if properly stored, has a **shelf life** of 5 years (currently 3 years in the United Kingdom and the United States). The last date for insertion (expiration date) is stamped on each box.

Effective Life

If inserted anytime **before** the expiration date (shelf life), Norplant implants are effective for up to 5 years. The implants should be removed by the end of the 5th year (**effective life**). If desired, a new set of implants may be inserted immediately after removal.

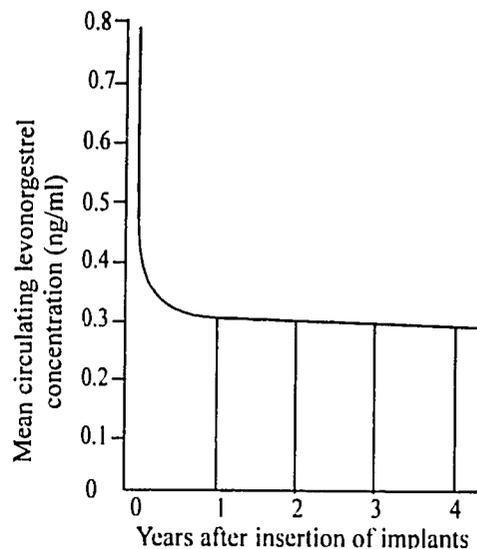
PHARMACOKINETICS

A blood level of levonorgestrel sufficient to prevent pregnancy is reached within 8 to 24 hours after insertion of Norplant implants and is maintained at an effective level for at least 5 years (Croxatto 1993; Sivin 1993). Initially, the six-capsule system has a relatively high release rate, about 85 micrograms per day ($\mu\text{g}/\text{day}$) during the first few weeks of use. This decreases to about 50 $\mu\text{g}/\text{day}$ by 9 months, to 35 $\mu\text{g}/\text{day}$ by 18 months, and finally to a steady level of 30 $\mu\text{g}/\text{day}$ for the rest of the 5-year period (Population Council 1990).

Within 24 hours after inserting a set of Norplant implants under the skin in the upper arm, a mean LNG serum level of between 1.0 and 2.0 nanograms per milliliter (ng/ml) is reached and maintained for several days. This compares to initial blood levels of 3 to 5 ng/ml of progesterone for low-dose oral contraceptives (Nash 1990). The concentration of LNG declines relatively rapidly during the first weeks of use to a mean level between 0.25 and 0.4 ng/ml by 6 months (**Figure 1-4**). This level is sufficient to prevent pregnancy and decreases only slightly during the remaining 4.5 years (Population Council 1990).

Circulating levels of LNG among individual users differ by a factor of several fold and many values fall outside the mean ranges stated above. Several factors account for this variation among subjects. **One factor** is the subject-to-subject variation in the rate of LNG metabolism. **Another** is variation in the weight of individuals and fat-to-muscle ratios. A **third factor** is variability in the levels of the sex hormone binding globulin

Figure 1-4. Mean Levels of Levonorgestrel



Source: Nash 1990.

(SHBG), a large molecule that circulates in the blood stream. Unlike other progestins, levonorgestrel binds tightly to SHBG which tends to maintain higher LNG levels in the blood (Weiner and Johansson 1976). **In addition**, there is evidence that **two local factors** may affect LNG release from the implants:

- the thickness of the fibrous sheath that forms around each capsule, and
- the vascular (blood vessel) pattern and amount of fat tissue surrounding the capsules (Population Council 1990).

Finally, the time required for one half the LNG to be cleared from the body after removal of all six capsules is about 40 hours. Therefore, following removal of the implants, plasma LNG becomes unmeasurable within a few days (Croxatto et al 1988).

Introduction

MECHANISM OF ACTION

Pregnancy is prevented through a combination of mechanisms. The two **primary** means are:

- production of thick, scanty cervical mucus which prevents sperm penetration, and
- inhibition of ovulation in about 50% of menstrual cycles.

Other, **secondary** actions which may add to these contraceptive effects include:

- suppression of endometrial growth (hypoplasia), and
- decreased natural progesterone production by the ovary during the postovulatory (luteal) phase in those cycles in which ovulation occurs.

Effect on Cervical Mucus

Perhaps the most important contraceptive effect of the LNG in the implants is the change in the composition of the cervical mucus it causes—even in those women menstruating regularly. Research has shown that within 24 to 48 hours after insertion, the cervical mucus becomes thick, is decreased in amount and does not permit sperm to pass through it. For example, in postcoital tests with women using Norplant implants, few sperm were able to reach the endocervical canal and those that did had decreased motion (Brache et al 1985; Croxatto et al 1987). This effect is similar

to that seen with other progestin-only contraceptives (POCs) and combined oral contraceptive pills. In addition, this action has been confirmed in laboratory tests which showed markedly reduced movement of sperm through cervical mucus obtained from implants users compared with women **not** using a hormonal contraceptive during the **pre-ovulatory phase** of their cycles.

Effect on Ovulation

In studies conducted to determine how often ovulation occurred in implants users, serial blood samples were drawn twice weekly and natural progesterone measured. As shown in **Table 1-1**, during the 1st year only about 11% of cycles were considered ovulatory while by year 5, more than 50% were ovulatory (Population Council 1990).¹ Research using ultrasonography and measurements of circulating natural progesterone have demonstrated that blocking ovulation is an important contraceptive action in preventing pregnancy (Brache et al 1990).

How Ovulation is Prevented

The small amount of LNG which is continuously released from the capsules acts on special areas of the brain (hypothalamus and anterior pituitary gland) to:

- decrease the secretion of follicle-stimulating hormone (FSH) and luteinizing hormone (LH), and
- block (or significantly reduce) the LH surge at mid-cycle (**Figure 1-5**).

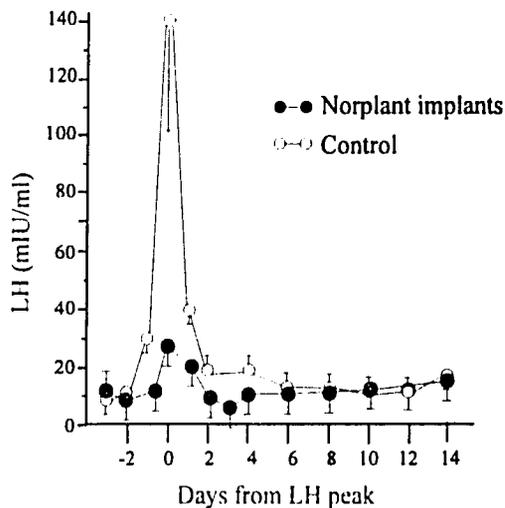
¹ To be classified as "compatible with ovulation," a progesterone level above 9.5 nanamoles per liter (nM/l) in at least one sample was required as well as values above 6.4 nM/l in the sample immediately following or preceding it.

Table 1-1. Frequency of Ovulation in Women Using Norplant Implants

Years of Norplant Implants Use	Number of Women	Ovulatory (%)	Anovulatory (%)	Uncertain (%)
1	27	11	82	7
2	21	62	29	10
3	36	28	64	8
4	23	44	52	4
5	48	52	46	2
6	19	74	26	0
7	15	60	33	7
Average (1-7 years)	189	44	50	5

Source: Population Council 1990.

Figure 1-5. Mean LH Levels of Norplant Implants Users

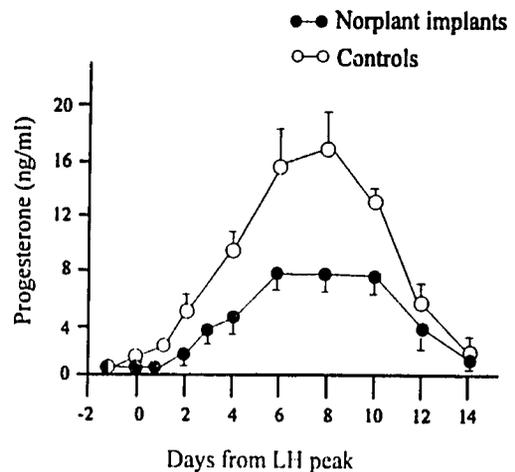


Source: Alvarez et al 1986.

Thus, in implants users ovulation is either prevented (no LH surge) or, if ovulation does occur, progesterone levels are reduced (Davies and Newton 1992). As depicted in Figure 1-6, mean natural progesterone levels even in "ovulatory" cycles are significantly less than those in women not

using a hormonal contraceptive (Population Council 1990).

Figure 1-6. Mean Progesterone Levels in Norplant Implants Users



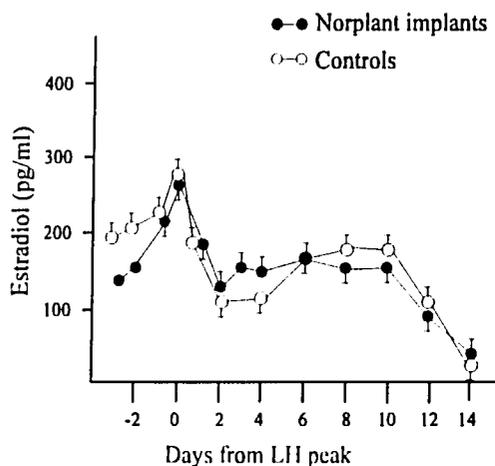
Source: Alvarez et al 1986.

This is due to the action of LNG and similar other 19-nortestosterone steroids in limiting secretion of progesterone, but not estrogen, from the corpus luteum which forms in the ovary following ovulation (Figure 1-7). As

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a consequence, even in ovulatory cycles, natural progesterone levels may be too low for the fertilized egg (zygote) to successfully implant in the cells lining the uterine cavity (endometrium).

Figure 1-7. Mean Estrogen Levels in Norplant Implants Users



Source: Alvarez et al 1986.

Whether ovulation is prevented (or just impaired due to decreased function of the corpus luteum) varies from cycle to cycle. It depends on several factors, such as the duration of implants use as shown in **Table 1-1**.

Effect on Endometrium

Levonorgestrel and other synthetic progestins block progesterone receptors (specific proteins located inside the uterine endometrial cells that bind progesterone). This action causes the endometrial cells which line the uterine cavity to have fewer, smaller glands which function poorly (i.e., they do not have much secretory activity). This added effect of LNG is thought to further reduce the likelihood of successful implantation and is an important **secondary effect** in implants users.

CLINICAL EXPERIENCE

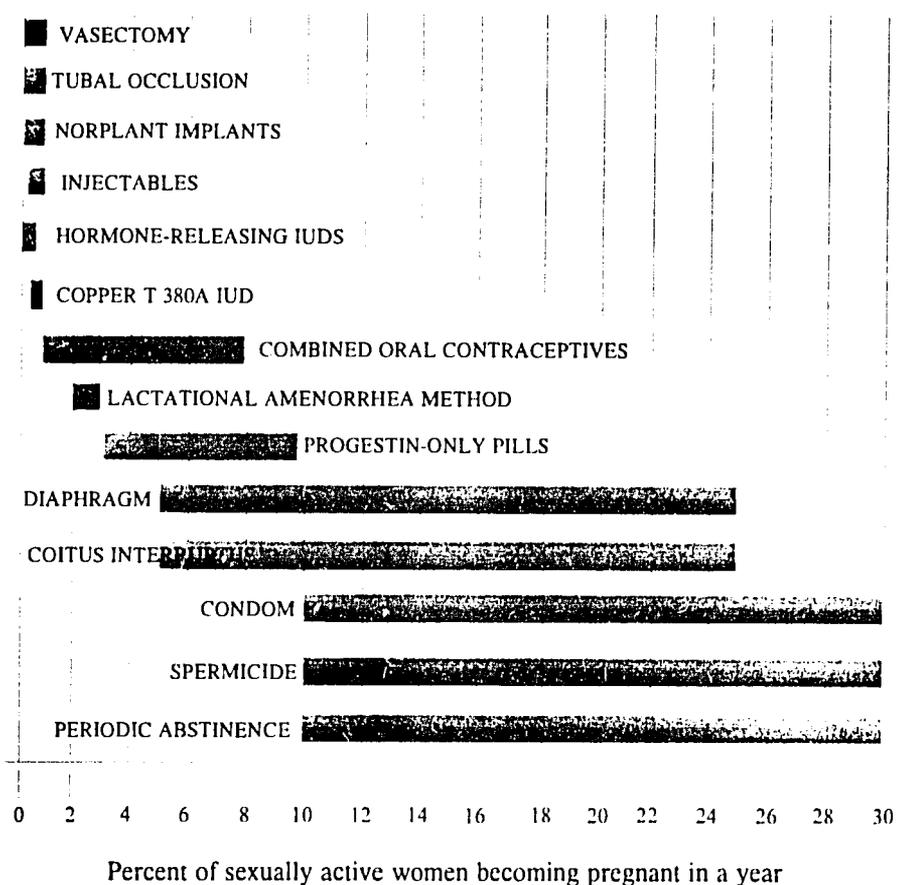
The **effectiveness** of a contraceptive method usually is the most important factor, both for the individual (or couple) trying to choose a method and for the health worker. For valid comparisons of effectiveness to be made among the most commonly used methods, failure rates must be presented not only for individuals using the method **consistently and correctly**, but also for **typical users**. Data presented in this way, showing the range of failure rates for the first year of use for most contraceptive methods, are illustrated in **Figure 1-8**.

Effectiveness of Norplant Implants

The Norplant system is one of the most effective contraceptive methods ever developed. The 1st year pregnancy rate is only 0.2 per 100 woman-years, and the 5-year cumulative rate is just 1.6 (Sivin 1988). With the exception of voluntary sterilization, the Copper T 380A IUD and progestin-only injectables, no other contraceptive method is so effective.

Clinical experience with Norplant implants has been gained from many years of research and clinical evaluation worldwide. By 1990, more than 55,000 women from 46 countries, including the USA, had participated in these clinical trials. Based on results from all countries, the Pearl index (i.e., number of pregnancies times 1200 divided by total months of use) is 0.2 for the 1st 2 years and 0.9, 0.5 and 1.1 per 100 woman-years for the 3rd through 5th years (Darney et al 1990b.) The 1st and 2nd year failure rates compare favorably with the lowest expected failure rates for male and female voluntary sterilization (Trussell et al 1990).

Figure 1-8. Estimated Range of Failure Rates for Contraceptives Used Worldwide



Adapted from: Population Action International 1991.

Effectiveness and Body Weight

Early studies demonstrated an increased **gross cumulative pregnancy rate** in women weighing more than 70 kg (9.3 versus 4.5 in users weighing 60 to 69 kg). These studies, however, were carried out using capsules made from a harder, more dense type of tubing.

Subsequent studies using a softer, less dense tubing have shown much lower pregnancy

rates (Table 1-2). With the less dense tubing, the 5-year cumulative pregnancy rate in women weighing more than 70 kg is only slightly higher (2.4 versus 1.5) than for lighter women (Sivin 1988). Because the softer, less dense tubing is the product now used worldwide, service providers no longer need to be concerned about recommending Norplant implants to heavier women (> 70 kg).

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Table 1-2. Comparison of Cumulative Pregnancy Rates: Less Versus More Dense Tubing

Weight of Women	Cumulative Pregnancy Rates	
	Tubing Density	
	Less Dense ^a	More Dense
< 50 kg	0	0.3
50-59 kg	2.0	4.3
60-69 kg	1.5	4.5
> 70 kg	2.4	9.3

^a This is the product now marketed worldwide.

Source: Sivin 1988.

Pregnancy may be more likely in Norplant implants users who take medications which increase the production of the liver enzymes that metabolize (break down) the levonorgestrel released from the implants. (These drugs decrease the effectiveness of combination and progestin-only contraceptive pills as well.) Drugs which fall into this category include:

- **anti-epilepsy (seizure disorder) drugs** such as barbiturates (phenobarbital), phenytoin (Dilantin[®]) and carbamazepine (Tegretol[®]) but **not** valproic acid, and
- **antibiotics** (only rifampin and griseofulvin²).

Contrary to earlier reports, antibiotics other than rifampin (for tuberculosis) and griseofulvin (antifungal) now are **not** thought to reduce the effectiveness of Norplant implants and combined (estrogen and progestin) oral contraceptives (COCs) or progestin-only pills (POPs) (Angle, Huff and Lea 1991).

Compliance

As mentioned above, a major stumbling block to the effective use of most modern contraceptive methods is the problem of "user" versus "method" failure. For example, most pregnancies in women taking oral contraceptives are due to their forgetting to take the pill on one or more days. A key advantage of Norplant implants is that one act of contraceptive acceptance by a woman will provide up to 5 years of continuous pregnancy protection without the need to remember to take a pill every day or check that a device is still in place (Angle, Huff and Lea 1991). Because Norplant implants do not protect women from hepatitis B, AIDS and other sexually transmitted diseases, women may wish to use a barrier contraceptive method in addition to the implants to protect themselves.

Continuation

Continuation rates reported in several well-monitored multicenter studies have ranged from 76-95% in the first year, decreasing to 25-78% by year 5 (Table 1-3). The average duration of use in these studies was 3.5 years (Sivin 1988).

² Because griseofulvin usually is used only for a short period of time (2 to 4 weeks), women taking it for fungal infections can continue to use Norplant implants. They should use a backup method while taking griseofulvin and until the start of the next menstrual period after stopping the antibiotic.

Table 1-3. Cumulative Continuation Rates per 100 Woman-Years

	Total Number of Women	Years of Use				
		1	2	3	4	5
ICCR STUDIES						
Chile	491	90%	82%	72%	63%	55%
Dominican Republic	1009	79	60	44	33	25
Scandinavia	377	76	60	53	37	33
USA	396	82	65	50	44	N/A
NON-ICCR STUDIES						
Columbia	389	92	76	68	N/A	N/A
Egypt	250	90	69	63	59	58
Indonesia	437	95	92	88	82	78

Source: Sivin 1988.

Changes in the menstrual bleeding patterns of Norplant implants users were the main reason for stopping the method. Based on pooled data from the International Committee for Contraception Research (ICCR) studies, approximately 9% of women stopped using implants during the 1st year due to menstrual changes, but this decreased to 3% in the 5th year.

As shown in **Table 1-4**, 1st-year continuation rates for Norplant implants compare favorably with those found for other contraceptives (Trussell et al 1990).

Table 1-4. First-Year Continuation Rates of Selected Contraceptive Methods

Method	Continuation Rate at One Year (%)
Norplant implants	90
Oral contraceptive pills	73
IUD	73
Condom	64
Cervical cap	63
Vaginal sponge	
Nulliparous	60
Parous	53
Diaphragm	57
Spermicide	43

Source: Trussell et al 1990.

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OUTCOME OF PREGNANCY

The use of Norplant implants does not appear to increase the frequency of **ectopic pregnancy**. In pooled studies of implants users, the incidence of ectopic pregnancies was only 1.3 per 1000 woman-years. This rate is comparable to the ectopic pregnancy rate of 1.4 per 1000 woman-years reported in the 1980s for US women aged 15 to 44 who were **noncontraceptive users** (Sivin 1990).

If a woman **does** become pregnant with Norplant implants in place, however, she is more likely to have an ectopic pregnancy (20-30%). Furthermore, because the risk of ectopic pregnancy increases slightly with duration of Norplant implants use, it should be ruled out in any woman suspected of being pregnant (Croxatto 1993). Therefore, all women with Norplant implants who present with symptoms of pregnancy should be carefully evaluated.

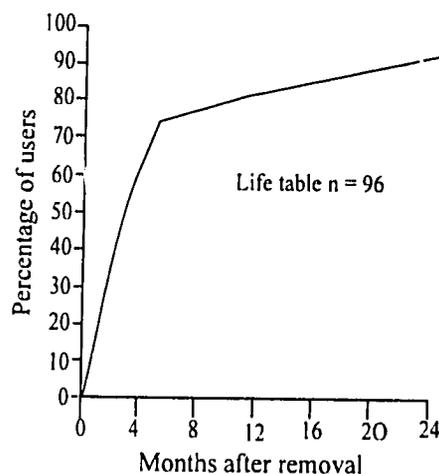
Norplant implants use has not been associated with other pregnancy-related problems. To date, there has been only one known instance of a **birth defect** among women using implants. This case involved delivery of a male infant who was born with ambiguous genitalia (underdeveloped penis, rudimentary scrotum and one testis absent). It is highly unlikely that these defects were due to use of implants (Croxatto 1993).

RETURN OF FERTILITY

One of the most important characteristics of Norplant implants is that their contraceptive effect is totally reversible. Once the implants are removed, serum levels of LNG become undetectable within a few days. This results in a prompt return to the woman's previous

level of fertility. Several studies have reported no long-term effects on future fertility, regardless of age or parity (i.e., young women with no previous pregnancies can safely use this method). In fact, pregnancy rates for women who have used Norplant implants compare favorably with those not using any contraception previously (Sivin 1988). For example, as shown in **Figure 1-9**, over 20% of women wanting to become pregnant did so within 1 month after removal, more than 50% within 3 months, 86% within 12 months and 93% within 24 months.

Figure 1-9. Pregnancy after Removal of Norplant Implants



Source: Sivin 1988.

SIDE EFFECTS

Extensive clinical use in over 4 million women in 30 countries, including more than 1 million in the USA, has shown that Norplant implants are well tolerated by most women. A **major advantage** of implants is that they do not contain any estrogen, which causes many of the side effects associated with the use of COCs. **The most common**

side effect in Norplant implants users is a **change in the menstrual bleeding pattern** (Darney et al 1990b). Unlike COCs, which provide a predictable and adequate amount of estrogen, estrogen levels in implants users vary from day to day. As a consequence, the excellent cycle control (i.e., lack of breakthrough bleeding and spotting) typical for COC users does not occur with Norplant implants users. Instead, breakthrough bleeding and spotting are common, especially during the 1st 6 to 9 months of use.

This problem, as well as the other minor side effects seen with Norplant implants, is similar to those known to occur with progestin-only pills and injectables.

Although nearly all users will experience one or more side effects during the 5 years of use, serious problems are very rare (Darney et al 1990b). Unfortunately, despite the fact that most side effects are minor, they may prompt users to stop using implants. Therefore, careful explanation of the side effects **before** Norplant implants are inserted as well as **reassurance** that rarely do they represent a risk to the client's health helps in decreasing any concerns. As is the case with other contraceptive methods, thorough counseling of potential users **before** insertion has a major impact on user satisfaction and continuation rates.

Menstrual Bleeding Changes

A change in the menstrual bleeding pattern is experienced by **most** women using Norplant implants, especially during the 1st 90 days of use. It is the most frequently reported side effect and includes:

- prolonged bleeding during the first few months of use,

- bleeding or spotting between menstrual periods (intermenstrual),
- a decrease in the number of days of bleeding or spotting,
- no bleeding or spotting at all for several months (amenorrhea), and
- a combination of any of the above.

As shown in **Table 1-5**, increased bleeding during the 1st 90 days of use is common. (For comparison, 5 to 7 days of bleeding per cycle is considered normal.)

Table 1-5. Changes in the Menstrual Bleeding Pattern (1st 90 days)

Changes	% Users
Frequent bleeding (5+ episodes)	21%
Prolonged bleeding (8+ days per episode)	35%
Numerous bleeding days (21+)	27%
Numerous bleeding and spotting days (31+)	36%
Note: Some women had more than one type of increased bleeding.	

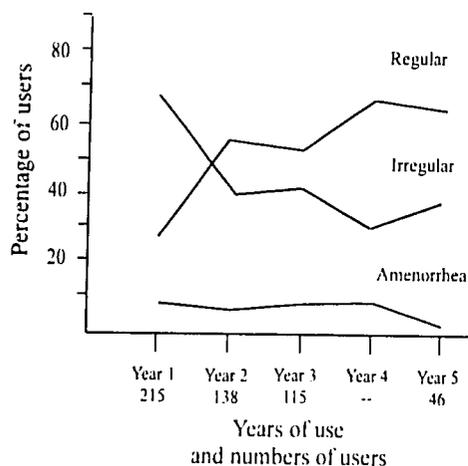
Adapted from: United States Food and Drug Administration 1990.

Typically, the frequency of these bleeding changes, especially irregular and prolonged bleeding, decreases with time and is less of a problem by the end of the 1st year. In one recently reported study, 234 women recorded their bleeding patterns after implants insertion (Shoupe et al 1991). In the 1st year of use, 66% had irregular

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cycles, 27% regular and 7% amenorrheic (Figure 1-10). By the 5th year of use, however, only 38% still had irregular cycles while 62% now had regular cycles, and none were without bleeding (amenorrhea).

Figure 1-10. Bleeding Patterns of Norplant Implants Users



Source: Shoupe et al 1991.

In addition, both the number of **bleeding and bleeding and spotting days** decreased with time (Table 1-6). As shown in this table, the mean number of bleeding and spotting days during the 1st year was 92.3 but decreased to 70.2 days in the 5th year (Sivin 1988).

Unfortunately, the pattern of bleeding is not predictable in any one woman. For example, in some women the average number of bleeding and spotting days was low in the 1st year but increased in years 2 to 5. For most women, however, the number of bleeding and spotting days decreased over time (Sivin 1988).

Although initially many women report an increase in the number of bleeding and spotting days while using Norplant implants,

research has shown that the average amount of blood loss usually is less compared with loss before using implants. For example, in several studies hemoglobin levels have increased with continued use of implants, and only rarely has heavy vaginal bleeding caused a significant decrease (Sivin 1988).

Women's Reaction to Menstrual Changes

Despite most women experiencing some change in their menstrual bleeding pattern, the majority do not seem concerned about it. As shown in one US clinical trial, 86% of implants users reported menstrual changes, but 69% were **not, or were only slightly**, bothered by them (Darney et al 1990a). Thorough pre-insertion counseling about possible changes in menstrual bleeding patterns can improve continuation. For example, in a study of two groups of Norplant implants users, the second group which received more counseling regarding this side effect had much higher continuation rates (Alvarez-Sanchez, Brache and Faundes 1988).

In addition, user satisfaction studies have found that staff attitudes and knowledge about the method, positive clinic management practices and the availability of "user friendly" client information are important in improving continuation of Norplant implants use (Darney 1990a).

Other Side Effects

In addition to menstrual pattern changes, several other side effects have been reported. Most of these are similar to those seen with other POCs and are **bothersome but not serious**. The most common include:

- headache (1.9%),

Table 1-6. Bleeding and Spotting Days per Year

Year	Bleeding Days	Bleeding and Spotting Days
	Mean	Mean
1	54.3	92.3
2	50.3	79.5
3	49.1	76.6
4	47.6	72.1
5	44.1	70.2

Source: Sivin 1988.

- weight change (usually increase) (1.7%),
- mood change (nervousness or anxiety) (1.1%),
- depression (0.9%), and
- other (nausea, change in appetite, breast tenderness, increase in body or facial hair and acne) (1.8%).

Some of these may **not** be linked **directly** to Norplant implants use. For example, when implants users were compared with users of IUDs at the end of the 1st year, there was a similar frequency of headache, nervousness and depression—symptoms usually associated only with hormonal contraceptive methods (Croxatto 1993). Of greater importance is that, to date, there has been no increased risk of serious cardiovascular (heart attack or stroke) or clotting problems, respiratory disorders or cancer (including breast or genital) reported in implants users (Population Council 1990).

Persistent Ovarian Follicles

Enlarged ovarian follicles sometimes have been reported in Norplant implants users as

well as in women using other POCs. These are thought to be caused by delay in the normal regression (shrinkage) of ovarian follicles which occasionally develop. In some women these persistent follicles may grow beyond the size they normally would reach, causing pelvic or lower abdominal discomfort. Most women, however, are not aware of them, and they are discovered only incidentally on pelvic examination. Because they disappear on their own in the vast majority of women, treatment is **not** required unless they twist or rupture (Population Council 1990).

Reactions at the Insertion Site

If recommended infection prevention practices are followed, problems with healing at the insertion site are infrequent and usually occur only in the first few weeks of use. For example, in a study involving more than 2,000 women, the infection rate was 0.8% during the 1st year and the rate of pain or itching at the insertion site was only 4.7% (Population Council 1990). Therefore, with adequate attention to pre-insertion skin preparation, use of aseptic technique and correct placement of the capsules, the risk of infection should be very low (see **Chapter 5** for details).

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Expulsion of capsules also is uncommon. In a study involving 2,467 insertions, in only 7 women were one or more capsules completely or partially expelled (Population Council 1990). Not unexpectedly, this problem occurs most often when the capsules are inserted too shallow, the tips are too close to the incision or when infection is present (see **Chapter 6** for details).

Because the incision is small (about 2 mm long), insertion does not leave a noticeable scar in most women and the correct positioning of the capsules subdermally makes them barely visible. In some women, however, darkening of the skin over the insertion site occurs. This disappears when the capsules are removed.

Finally, once inserted, the capsules will **not** move around and **cannot** break inside the arm.

CLINICAL PHARMACOLOGY

A wide range of clinical studies have been conducted to determine the pharmacologic effects of Norplant implants. To date, no clinically important changes in carbohydrate metabolism; liver, kidney, adrenal or thyroid function; or blood clotting mechanisms have been demonstrated (Population Council 1990).

Carbohydrates

Use of Norplant implants has been associated with a slight, initial increase in glucose levels. Because these changes did not increase with time, they are not felt to be clinically important (Population Council 1990).

Lipoproteins

Studies investigating the effect of LNG on serum lipoproteins have produced variable results. For example, some studies demonstrated a decrease in total cholesterol, triglycerides and low-density lipoproteins in Norplant implants users while other studies have shown either transient effects or no changes. For example, in the six studies reported in **Table 1-7** the cholesterol to high-density lipoproteins (HDL) ratios either improved (i.e., decreased) or were unchanged (Darney et al 1990b).

Clotting Factors

Various effects on clotting factors have been reported in Norplant implants users. These include slight changes in levels of factor VII, factor X, antithrombin III activity, fibrinogen and platelets (Population Council 1990). The clinical importance of these changes has yet to be determined.

Iron Metabolism

Results from clinical trials have demonstrated a general improvement in iron concentration with Norplant implants use **despite** irregular menstrual bleeding being the most common side effect. Twice as many women have shown an increase in hemoglobin as opposed to a decrease. Furthermore, the overall increase in hemoglobin levels is about 2% in all users (Population Council 1990).

Endocrine Changes

Serum levels of **estradiol** have shown non-cyclic, irregular changes. Baseline values are normally 30 to 70 pg/ml, with occasional peaks to 200 to 400. Infrequently, peaks of up to 600 pg/ml have

been measured (Population Council 1990). Furthermore, in those women having ovulatory cycles, estradiol levels are similar to control values (Figure 1-7).

Significant decreases in circulating **androstenedione**, a weak androgen, and **total testosterone** have been reported in Norplant implants users. These findings are accompanied by slight decreases in sex hormone binding globulin (SHBG). Because testosterone is tightly bound to SHBG, it is only the **unbound (free) testosterone that is biologically active**. In the studies reported, the mean free testosterone levels were essentially unchanged; therefore, it is unlikely that the effect of levonorgestrel on androgen function is clinically important (Population Council 1990).

Endometrium

In several studies, the effect of levonorgestrel on the lining cells of the uterus (endometrium) has been examined. Samples of endometrium from 225 women who had used implants from 2 to 116 months were examined (Population Council 1990). Microscopically, the appearance was one of mixed proliferative and secretory activity, but a large number of biopsies showed considerable decrease in endometrial activity (hypoplasia or atrophy)—a pattern similar to that seen in women using COCs and POPs. In addition, no progressive changes were noted nor were there any clinically important pathologic changes. Based on these studies, it has been concluded that the long-term use of LNG is not associated with any hazardous effects on the endometrium.

Table 1-7. Effects of Levonorgestrel on Lipoprotein Levels

	Singh (1989)	Viegas (1988)	Affandi (1987)	Roy (1984)	Shaaban (1984)	Croxatto (1983)
Number of subjects	100	100	240	10	47	28
Cholesterol	↓	↓	↓	n/c	↓	↓
Triglycerides	↓	↓	n/c	n/c	↓	↓
HDL	n/c	↑	n/c	n/c	↑	n/c
LDL	↓		↓	n/c	↓	↓
Cholesterol/HDL ratio	n/c	↓	↓	n/c	↓	↓
↑ = increased; ↓ = decreased; n/c = no change						

Source: Darney et al 1990b.

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COUNSELING

BACKGROUND

Experience suggests good, thorough counseling improves user satisfaction and increases the successful use of any contraceptive method (Darney et al 1990). This is particularly important for Norplant implants where the woman depends entirely on the service provider for both insertion and removal.

Effective counseling also allows the woman (or couple) to arrive at an informed choice after having carefully considered the benefits and limitations of all methods available.

This chapter focuses on the following key components related to good counseling for Norplant implants use:

- client rights,
- the benefits of counseling,
- the counseling process, and
- the steps in counseling.

In addition, information is provided regarding rumors and facts about Norplant implants and counseling tips.

CLIENT RIGHTS¹

There are various reasons individuals and couples decide to start, continue or stop practicing family planning. Some people

may wish to delay the birth of their first child. Others may want to space the births of their children and some may want to ensure that only a desired number of children is 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.

Any member of the community who is of reproductive age should be considered a potential client of family planning services. Moreover, 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 beliefs. Finally, all persons 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 concept of acceptability and appropriateness changes with circumstances. Therefore, the client has the right to decide when to start, stop or switch methods.

¹ Adapted from: Huezco and Briggs 1987.

Counseling

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 person in 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 done. The client 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 services provided to a client should not be discontinued unless a decision to do so 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 followup

are two important aspects of a client's right to continuity of services.

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

BENEFITS OF COUNSELING

For the woman

- Counseling results in the woman arriving at a free and informed decision. She feels in control of her choice of Norplant implants and does not feel she has been pressured into accepting a method of contraception with which she does not feel happy.
- The woman knows exactly what to expect with the use of Norplant implants. She understands all the advantages they will offer and will also be prepared for any side effects that may develop.
- She knows whom to ask for advice if she feels concerned about anything at any time.
- She knows she can have the implants removed at any time she wishes.

For the clinician

- Although counseling may appear to be time consuming, it is cost-effective and saves time in the long run. Women who have received counseling are much more

likely to continue using Norplant implants and have fewer return visits (Darney et al 1990).

COUNSELING PROCESS

Good counseling focuses on the individual woman's needs and situation, and good counselors are willing to listen to the woman's questions and concerns. Counseling must be based on trust and respect between the client and the counselor.

Remember: All information exchanged in the counseling session should be treated confidentially.

Family planning counseling should enable a client to:

- consider her reproductive goals;
- make free, informed choices about family planning; and
- understand how to use her method of choice safely and effectively.

The elements of the counseling process have been organized into a system called **GATHER** (Gallen, Lettenmaier and Green 1987; Lettenmaier and Gallen 1987). This acronym is designed to help counselors remember important points in an effective counseling session. For additional information on the elements of the counseling process and the GATHER technique, see **Appendix A, Section One**.

STEPS IN COUNSELING

Several steps are needed in counseling clients considering Norplant implants.

Initial counseling (or education), prior to a decision on contraceptive use, is intended to familiarize the client with **all** contraceptive methods and other health care services provided by the clinic. **Education** about all methods can be done effectively in a group setting prior to individual counseling.

Group counseling provides the client with an opportunity to:

- ask questions about specific contraceptives in which she is interested, and
- be given more detailed information about available contraceptives in which she is interested.

Individual counseling is an important step because it may be the first time the client has had the opportunity to discuss her contraceptive options fully. At this time the client can:

- be helped to choose a suitable method;
- receive further explanation about how to use the method safely, effectively and with satisfaction; and
- discuss personal issues and needs.

If a client expresses an interest in knowing more about Norplant implants, let her examine the sterile package containing the capsules while providing general information about their use and insertion. Or, using a model training arm, demonstrate how the capsules are inserted. Tell her that they must

Counseling

be inserted and removed by a trained health care provider (physician, nurse or midwife).

Subsequent counseling about Norplant implants should cover the following points:

- basic health information to ensure there are no reasons the woman should not use implants;
- how the method prevents pregnancy;
- method characteristics (benefits and limitations) including the 5-year effective life of Norplant implants and their side effects, particularly those related to changes in the menstrual bleeding pattern;
- how the capsules are inserted and removed, how long each procedure takes and what discomfort, if any, to expect;
- the importance of having the capsules inserted during the correct time (day 1 to 7) of her menstrual cycle to ensure the woman is not pregnant, and which backup contraceptive method to use if insertion is delayed;
- freedom of the client to discontinue the method whenever desired; and
- no delay in return of fertility after removal.

In addition, basic information should be obtained to be sure there are no obvious reasons (e.g., suspected pregnancy) the client should **not** use Norplant implants.

Pre-insertion counseling is given at the time the capsules are inserted.

- Any questions the woman may have regarding the insertion procedure and what she can expect (e.g., postinsertion bruising of the arm, how long it will last, etc.) should be answered.
- The woman should be given clear instructions on how to care for the insertion area (incision) after insertion of the capsules.

Postinsertion counseling usually is provided immediately after insertion; however, some elements of this type of counseling should be given earlier and reinforced at this time (e.g., care of the insertion site). Post-insertion counseling should focus on those warning signs (continued pain, redness or bleeding at the insertion site, fever immediately after insertion, or expulsion of a capsule) which indicate the need for a quick return to the clinic. In addition, the client should be:

- told whom to contact if she develops any problems or has any concerns, and
- given written information (if appropriate) telling her the date, in 5 years time, by which she must have the capsules removed.

Followup counseling should reinforce information given postinsertion. Counselors need to listen attentively and be prepared to answer questions about any problems the client has had. Answering questions helps clients cope with any problems or side effects.

At each followup visit, the following points should be covered:

- The woman should be asked if she is happy with the method and if there have been any problems since her last visit.
- She should be given specific instructions for what to do if she wants to have the Norplant implants removed at anytime.

The key points and steps in providing counseling for implants are summarized in **Figure 2-1**.

RUMORS AND FACTS

Correcting false rumors and misinformation is an important job of family planning providers. When talking to the client about rumors and misinformation, do not just say that what she has 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 implants weaken the woman because they increase menstrual bleeding.

Response: No, the implants cannot weaken the woman in any way because the amount of hormone released is very small and, with time, the amount of menstrual bleeding actually decreases.

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. This is because each

capsule is surrounded by a small sheath of tissue which prevents it from moving.

False Rumor: The procedure of inserting the capsules is painful.

Response: No, 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: The capsules are implanted permanently.

Response: No, they can be removed at any time and must be replaced after 5 years if the client chooses to continue using Norplant implants.

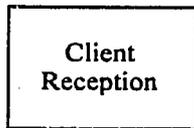
False Rumor: The capsules never need to be replaced.

Response: No, they need to be replaced every 5 years.

To help the client better understand and remember the most important facts about Norplant implants, be sure to explain them to her clearly and simply, and repeat them several times. Important facts about implants are summarized in **Table 2-1** and answers to additional questions can be found in **Chapter 7**.

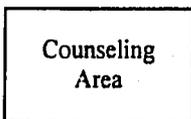
Figure 2-1. Steps in Counseling for Norplant Implants

Initial Counseling



- Greet the client by introducing yourself and warmly welcoming her to the clinic.
- Provide general education about family planning.
- Provide information about all contraceptive choices available and the risks and benefits of each. Explain the difference between reversible and permanent contraception. Correct false rumors or misinformation about all methods.
- Explain what to expect during the clinic visit.

Method-Specific Counseling



- Obtain basic information (name, address, age, etc.).
- Ask the client about her reproductive goals and need for protection against GTIs and other STDs, including HBV and HIV/AIDS. Ask her if she wants to space or limit births.
- Discuss the client's needs, concerns and fears in a thorough and sympathetic manner. Explore any attitudes or cultural or religious beliefs that either favor or eliminate one or more methods.
- Help the client begin to choose an appropriate method.

If she chooses Norplant implants:

- Make sure there is no medical condition that would be a problem or require more frequent followup.
- Clearly discuss the benefits of the method emphasizing the following points:
 - It is very effective.
 - It is easy to use.
 - It provides continuous protection for up to 5 years.
 - It is convenient, comfortable and reversible.
- Explain that Norplant implants do not provide protection against GTIs and other STDs, including HBV and HIV/AIDS. If the client is at risk for STDs, she also should use a barrier contraceptive.
- Explain common side effects, especially changes in the menstrual bleeding pattern, and be sure they are understood fully.
- Describe the insertion and the removal processes and what the woman should expect during and afterwards.

Figure 2-1. Steps in Counseling for Norplant Implants (continued)

**Pre- and Postinsertion
Counseling**

Procedure/
Examination
Area



- Review client assessment data to determine if the client is an appropriate candidate for implants or if she has any problems that should be monitored more frequently while they are in place.

(Insert the six capsules.)

- Give postinsertion counseling, including how she should care for the insertion site and what to do if she experiences any problems or side effects. Special emphasis should be given to menstrual bleeding changes.
- Provide information on warning signs for medical problems and the need to return to the clinic immediately should any occur.
- Assure the client she can return to the same clinic at any time to receive advice and medical attention and, if desired, to have the capsules removed.
- Have the client repeat the instructions.
- Answer any remaining client questions.
- Complete the client record.

**Followup/Return
Visit Counseling**

Counseling/
Examination
Area

- Check whether the client is satisfied.
- Inquire about problems and respond to concerns about side effects or any problems.
- Reassure the client that the capsules can be removed at any time if desired.
- Repeat instructions regarding need for removal and (if desired) replacement with a new set after 5 years.

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Table 2-1. Important Facts About Norplant Implants

Who can use implants?	
<p><i>Implants are appropriate for women who:</i></p> <ul style="list-style-type: none"> • Want a convenient, reliable and reversible long-term method of contraception • Are delaying the start of their family, have completed their family or do not want children • Find taking a pill every day inconvenient 	<p><i>Implants are not appropriate for women who:</i></p> <ul style="list-style-type: none"> • Are considering having children soon • May have little tolerance for menstrual bleeding irregularities (counseling will help identify or overcome this concern) • Express serious concern about the insertion or removal procedure (again, counseling will help overcome this)
Benefits and limitations of implants	
<p><i>Benefits:</i></p> <ul style="list-style-type: none"> • Reliable, long-term method of continuous protection that lasts for 5 years • Not tied to sexual intercourse • Very effective • Reversible at any time • No daily action required • Easy to use and require no further action other than followup visits and return for removal; do not interfere with normal daily activities • Comfortable—once the insertion site has fully healed (about one week), the implants should not cause any pain and are not noticeable in most women • One of the lowest doses of any hormonal contraceptive and contain no estrogen • Few side effects 	<p><i>Limitations:</i></p> <ul style="list-style-type: none"> • Changes in menstrual bleeding pattern are common (counseling should prepare the woman adequately for this). • Insertion and removal are minor surgical procedures and therefore may be associated with infection, bleeding or bruising (discoloration of the arm). • The woman cannot discontinue the method on her own (counseling should, however, prepare her for this). • The outline of the capsules may be visible under the skin of some women, especially when the skin is stretched. • Norplant implants do not protect the woman from GTIs and other STDs, including HBV and HIV/AIDS.

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TIPS ON GOOD COUNSELING

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

Remember: Counseling should be part of every interaction with the client.

COUNSELING AND CONTINUATION: REALISTIC EXPECTATIONS

Though the rationale for having family planning programs in some countries is the desire to limit 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. Over the long term, programs are more likely to attract and keep clients when they offer services that meet their needs (Gallen, Lettenmaier and Green 1987).

Although continuation rates with Norplant implants generally have been high—up to 76-95% after one year, and from 65-92% after two years—a high continuation rate alone does not necessarily reflect user satisfaction (Sivin 1988). The most valid continuation rates are those achieved where clients have adequate access to followup care, especially removal services.

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THREE

INDICATIONS AND PRECAUTIONS

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 clients 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 overemphasized. As a consequence, clients sometimes are prevented 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 permanent. (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. Finally, in many countries, new information is slow in arriving and the **contraindication** list remains the standard 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. In addition, 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**, a brief statement is included explaining the **rationale** for categorizing the condition as such.

WHO CLASSIFICATION SYSTEM

Recently, a scientific working group consisting of 26 participants from 16 countries met at the World Health Organization (WHO) to review medical criteria for selected methods of contraception. The group recommended appropriate eligibility criteria for the initiation of specific methods based on available clinical and epidemiological data (WHO 1994).

In the WHO classification system, the suitability of different contraceptive methods is determined by weighing the health risks and benefits relative to specific "conditions." (A **condition** is defined to include both a woman's **biologic characteristics** such as age or reproductive history and any **known**, pre-existing **medical condition(s)** such as diabetes or hypertension.)

In the WHO system, the presence of a specific **condition** affecting eligibility for using a contraceptive method falls into one of four categories:

Class 1: A condition for which there is **no restriction** for the use of the contraceptive method. (Method may be used in any circumstance.)

Class 2: A condition where the **benefits** of using the method generally **outweigh** the

theoretical or proven **risks**. (Method may be used.)

Class 3: A condition where the theoretical or proven **risks usually outweigh the benefits** of using the method. (Method usually is not recommended unless other more appropriate methods are not available or acceptable.)

Class 4: A condition which represents an **unacceptable health risk** associated with the use of the contraceptive method. (Method should not be used.)

The WHO system complements the one used in this manual. For example, like the WHO system, a brief rationale is included for **why** a particular condition is assigned to one of the four categories. The rationales included in this manual, however, are adapted not only from those presented in the WHO document but also from those provided in the USAID manual, *Recommendations for Updating Selected Practices in Contraceptive Use*, produced by the Technical Guidance Working Group (TGWG 1994) and selected references from the contraceptive literature. (For the reader's convenience, the WHO classification for each condition is included for each precaution.)

In addition, at the end of the chapter there is a discussion of conditions that formerly were considered restrictions for use of progestin-only contraceptives (POCs) such as Norplant implants.

CONTRACEPTIVE CHOICE AND WOMEN'S REPRODUCTIVE HEALTH CARE

When a woman selects a contraceptive method, she and the health care worker should consider the degree to which the client values her future fertility as well as the degree to which she is willing to risk a potential health problem (e.g., use of a progestin-only contraceptive with active liver disease).

In some countries, women who want no more children often are denied voluntary sterilization. For such women, Norplant implants have distinct advantages over other reversible methods (e.g., long-acting, highly effective and limited followup required unless there is a problem).

In addition, under most circumstances, a woman's risk of dying from pregnancy is many times greater than her risk of dying from using Norplant implants or any other modern contraceptive method. In fact, the higher a country's maternal mortality rate, the more important it is to offer women the widest choice of effective methods.

As a consequence, protocols that list the indications and precautions for use of Norplant implants should be flexible in order to maximize the client's access to quality family planning services. To achieve this objective, they should be designed to help the service provider consider not only the woman's individual history and living conditions but also the local maternal health situation.

INDICATIONS FOR USE

Norplant implants are an appropriate method for a woman who:

CONDITION	RATIONALE
Prefers a long-term method which does not require taking contraceptive action daily or before sexual intercourse. (This includes women who have trouble using barrier methods or remembering to take a pill every day.)	Once Norplant implants are inserted, the client does not need to do anything except return to the clinic for followup visits and have the implants removed or replaced in 5 years (Population Council 1990; WHO 1990).
Has the number of children she wants but does not want a permanent method (voluntary sterilization) at this time.	Norplant implants can be used indefinitely provided the client develops no serious medical problems and replaces them on schedule every 5 years (Population Council 1990; WHO 1990).
Is breastfeeding for 6 weeks or more postpartum and wants contraception. ¹	Breastfeeding is not affected by the use of progestins, and their use may increase the volume and quality of breastmilk (WHO 1988). Because Norplant implants are a hormonal contraceptive, they are not considered the first choice for breastfeeding women. The level of LNG in breastmilk, however, has not been shown to cause any clinically important effects on infant health or growth through adolescence (Pardthaisong, Yencht and Gray 1992; WHO 1988). (At present, there are no data available about possible adverse effects when used before 6 weeks postpartum.)
Smokes (any age, any amount)	Because small amounts of progestins such as LNG have no effect on cardiovascular or blood clotting problems, Norplant implants can be used safely by women who smoke.

¹ If a client is fully breastfeeding, insertion can be delayed for up to 6 months provided she:

- has no vaginal bleeding or spotting (remains amenorrheic), and
- gives no supplementary feeding (Labbok, Cooney and CoLy 1994).

PRECAUTIONS FOR USE

The rationales for the precautions listed in this section are based on the most recent epidemiologic and clinical data regarding medical criteria for progestin-only contraceptives (McCann and Potter 1994; TGWG 1994; WHO 1994). For women with any of the following conditions, health care workers need to assess the appropriateness of Norplant implants for **each client**, not only in terms of her special needs but also in relation to the health care climate in which she lives.

CONDITION	PRECAUTION	RATIONALE
Pregnancy (known or suspected)	<p>Norplant implants should not be inserted during pregnancy and should be removed if intrauterine pregnancy is confirmed and will be carried to term. (WHO class 4)</p> <p>If the possibility of pregnancy cannot be excluded by history, examination or pregnancy testing, insertion of implants should be delayed until the next menstrual period. In the interim, help the client choose another method (e.g., condoms or spermicide).</p>	<p>Current data show that the low dose of LNG released from the implants does not cause any significantly increased risk of birth defects, spontaneous abortions or stillbirths (Population Council 1990; TGWG 1994; WHO 1994). Although the amount of hormone released is small, implants should not be inserted if the woman is pregnant.</p>
Unexplained vaginal bleeding (only if serious problem suspected)	<p>Unexplained vaginal bleeding or spotting could be due to pregnancy or caused by a serious problem. Until the cause of the bleeding is determined and any serious problem treated, the client should not use Norplant implants.² (WHO class 4)</p>	<p>Because Norplant implants can cause intermenstrual spotting or bleeding, an underlying condition (i.e., normal or ectopic pregnancy, cervicitis, other pelvic pathology and, rarely, cancer of the genital tract) may be masked (McCann and Potter 1994; WHO 1994).</p> <p>None of these conditions, however, are worsened—and some are prevented—by use of POCs (Herbst et al 1992; Parazzini et al 1991; Parkin et al 1988; Pike 1987; Sadan et al 1989; Speroff, Glass and Kase 1989).</p>

² Changes in the menstrual bleeding pattern (so-called irregular bleeding), which usually are not serious, may occur in up to 10% of noncontracepting women (ages 15 to 35) (TGWG 1994). Therefore, insertion should be restricted **only** if a serious condition is suspected (WHO 1994).

PRECAUTIONS FOR USE *(continued)*

CONDITION	PRECAUTION	RATIONALE
<p>Jaundice (symptomatic viral hepatitis)</p>	<p>Norplant implants should be used only if more appropriate methods are not available or acceptable. (WHO class 3)</p> <div data-bbox="482 602 840 874" style="border: 1px solid black; padding: 5px; margin: 10px 0;"> <p>Note: For women who are asymptomatic (fully recovered or carriers), there is no restriction on the use of Norplant implants. (WHO class 1)</p> </div>	<p>There is no evidence that LNG causes liver disease, such as viral hepatitis, or gall bladder problems (RCGP 1982; WHO 1994). Although the hormone may be poorly metabolized in women with impaired liver function, Norplant implants are not likely to clinically worsen the liver disease (McEwan 1983; Speroff, Glass and Kase 1989) and are safer than pregnancy in women with active hepatitis.</p>
<p>Liver tumors (benign or malignant)</p>	<p>Unless more appropriate methods are not available or acceptable, Norplant implants are not recommended. (WHO class 3)</p>	<p>There is no evidence that progestins affect the development of benign liver tumors; however, there is theoretical concern that use of Norplant implants may increase a woman's risk of malignant liver tumors (hepatoma) (WHO 1994).</p>
<p>Breast cancer (current or past with no current evidence of disease)</p>	<p>For women with current or past breast cancer, Norplant implants are not recommended unless other more appropriate methods are not available or acceptable. (WHO class 3)</p>	<p>There is no evidence that low-dose progestins cause breast cancer; however, breast cancer is a hormonally-sensitive tumor (Population Council 1990; WHO 1989; WHO 1994).</p>
<p>Breast lumps</p>	<p>Norplant implants can be used safely by women with benign breast disease or a family history of breast cancer. (WHO class 1)</p>	<p>Only clients with suspicious breast lumps (e.g., firm, nontender or fixed which do not change during menstrual cycles) need to be evaluated before inserting Norplant implants.</p>

PRECAUTIONS FOR USE *(continued)*

CONDITION	PRECAUTION	RATIONALE
Taking drugs for epilepsy or tuberculosis (rifampin)	Clients taking drugs for these disorders should be carefully counseled about the potential reduction in the effectiveness of Norplant implants. (WHO class 3)	Long-term use of drugs for epilepsy (except valproic acid) and rifampin for tuberculosis causes the liver to metabolize progestins very rapidly and may decrease the effectiveness of all POCs (except injectables). ³ Blood levels of LNG are quite low to begin with in women using Norplant implants. Therefore, women taking these medications may require more frequent followup and a backup method (see Chapter 1) (Angle, Huff and Lea 1991).

CONDITIONS NEEDING MORE FREQUENT FOLLOWUP CARE

Women who have any of these conditions may need more frequent followup care.

CONDITION	ACTION	RATIONALE
Diabetes mellitus	Diabetics who choose Norplant implants should be observed and followed to be sure the disease is controlled. (WHO class 2)	Although Norplant implants slightly affect carbohydrate metabolism they do not pose an additional risk of thrombosis even for insulin-dependent diabetics who do not have vascular problems. (Their use can, however, require more medication or insulin to maintain control of the diabetes.)

³ Because griseofulvin usually is used only for a short period of time (2 to 4 weeks), women taking it for fungal infections can continue to use Norplant implants. They should use a backup contraceptive method while taking griseofulvin and until the start of their first menstrual period after stopping the antibiotic.

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CONDITIONS NEEDING MORE FREQUENT FOLLOWUP CARE (*continued*)

CONDITION	ACTION	RATIONALE
High blood pressure (BP) (mild hypertension: BP < 180/105)	Women with mild hypertension at the time of insertion should be followed to be sure it is controlled. (WHO class 1)	There have been no statistically significant trends of increased blood pressure in implants users (WHO 1994).
High blood pressure (severe hypertension, with or without vascular problems: BP > 180/105)	Even in women with moderate or severe hypertension, the benefits of using Norplant implants generally outweigh the risks (i.e., pregnancy). (WHO class 2)	There is a theoretical concern that Norplant implants may lower high-density lipoproteins (HDL) in women with underlying vascular problems (e.g., neuropathy or retinopathy) (WHO 1994).
Headaches (severe, recurrent vascular or migraine)	Women with a history of severe vascular or migraine headaches should be followed to be sure their headaches do not worsen with use of Norplant implants. (WHO class 2)	There is little or no information that changes in severe headaches may occur when implants are used (Population Council 1990; WHO 1990). If headaches worsen (e.g., are more frequent, last longer or cause blurred vision), consideration should be given to removing the implants (Deitch 1994).
Depression	Women with a history of depression should be followed when using Norplant implants. Removal of implants should be considered if depression worsens or recurs to a serious degree.	Depression may be related to the progestin (LNG) in the implants (Population Council 1990; WHO 1990).
Women who cannot tolerate changes in their menstrual bleeding pattern	Women who express concern regarding changes in their menstrual pattern (irregular or more frequent bleeding) may want to consider a 3-month trial of progestin-only pills before having Norplant implants inserted, or they may choose another method.	Menstrual pattern changes are the most frequent reason for discontinuation of POCs (Sivin 1988). Because Norplant implants insertion and removal are minor surgical procedures, the client should be as sure as possible of her choice before insertion.

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CONDITIONS FOR WHICH THERE ARE NO RESTRICTIONS FOR USE

In the past, precautions for use of progestin-only contraceptives were based primarily on experience with high-dose (50 µg estrogen or greater) 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., heart attacks and blood clots) have been associated with use of the older, high-dose COCs, it is now known that low-dose COCs (estrogen less than 35 µg) and POCs do **not** increase the risk of cardiovascular problems (heart attack or stroke) or thromboembolic disorders (blood clots) in healthy women (Grimes and Herbst 1994; McCann and Potter 1994).

The conditions for which there are **no** restrictions (i.e., WHO class 1) for the use of Norplant implants, as well as other POCs, include:

CONDITION	RATIONALE
Gall bladder disease (symptomatic or asymptomatic)	Norplant implants have no effect on the development of gall bladder disease or the clinical course of women with symptoms (WHO 1994).
Pre-eclampsia (history)	In the absence of any pre-existing vascular disease, Norplant implants may be used (WHO 1994).
Smoking (any age, any amount))	Because progestins do not increase the risk of cardiovascular disease, women (of any age) who smoke and have no other risk factors can use Norplant implants (WHO 1994).
Surgery (with or without prolonged bed rest)	Because POCs do not increase the risk of blood clotting problems, there is no restriction for use (McCann and Potter 1994; WHO 1994).
Thromboembolic disorders (e.g., blood clots in the legs, lungs or eyes), superficial thrombophlebitis and varicose veins	Most experts now believe it is estrogens, not progestins, that cause blood clotting; therefore, women with a current or past history of thromboembolic disorders can safely use a low-dose POC such as Norplant implants (McCann and Potter 1994; WHO 1994).
Valvular heart disease (symptomatic or asymptomatic)	Because POCs do not increase the risk of blood clotting problems, even women with complications such as pulmonary hypertension, irregular heart rhythm (fibrillation) or history of subacute bacterial endocarditis (SBE) can use Norplant implants (McCann and Potter 1994; WHO 1994).

In **summary**, eligibility criteria for use of Norplant implants presented in this chapter are intended to provide a sufficient margin of safety to protect women from potential health risks while at the same time ensuring that they are not denied the widest choice of contraceptive methods (WHO 1994).

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FOUR

CLIENT ASSESSMENT

BACKGROUND

Because Norplant implants contain only levonorgestrel, one of the two types of steroid hormones present in combined oral contraceptives, they do not have estrogen-related side effects. As a consequence, there are fewer precautions for their use.

While Norplant implants may be appropriate for nearly all women, clinic staff need to know how to assess those women who:

- may need additional evaluation before they can use Norplant implants, or
- have medical conditions which may require more frequent followup care.

Remember: An added benefit of medical assessment is that it helps distinguish those women who will be more likely to use Norplant implants successfully.

CLIENT ASSESSMENT

In assessing potential implants clients, clinic staff should:

- Check clients for any condition that may be a precaution for Norplant implants use.
- Evaluate clients by medical history and, if needed, physical exam, 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 implants.
- Make sure that they understand what to expect during the insertion.

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

- persistent, unexplained vaginal bleeding (i.e., between menses or after intercourse);
- jaundice (i.e., symptomatic viral hepatitis);
- cancer of the breast (current or past) or suspicious breast lumps; or
- taking drugs for epilepsy or tuberculosis (may decrease effectiveness of the implants).

In addition, while a client with any of the following conditions may use Norplant implants, she may require more frequent or special followup:

- diabetes,
- hypertension,
- severe migraine (vascular) headaches, and
- mental depression.

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

Clients may not always have exact information about these conditions; therefore, health workers must know how to assess the accuracy of what the clients tell them. If necessary, they may need to restate their question(s) in several different ways. Also, they should take into account the social, cultural or religious factors that might influence how a client (and her partner) responds.

The findings from the client assessment determine whether a physical examination is necessary (i.e., if the client's response suggests a precaution for implants use, a brief physical examination or further questioning may be necessary).

Pelvic examinations are recommended as good health care, but are **not** a requirement for provision of Norplant implants **unless pregnancy is suspected**, and then only if the client is thought to be more than 6 weeks from her last menstrual period (LMP).

Pregnancy testing usually is not necessary except in cases where it is difficult to confirm pregnancy by pelvic exam (i.e., 6 weeks or less from the LMP) or the results of the pelvic examination are equivocal (e.g., the size and consistency of the uterus are difficult to determine because the client is overweight or has a retroverted uterus). In these situations, a highly sensitive pregnancy test (positive within 10 days after conception) may be helpful, if readily available and not expensive. If **pregnancy testing** is not available, counsel the client to

use a barrier method until her menses occur or the possibility of pregnancy is confirmed.

How To Be Reasonably Sure the Client Is Not Pregnant

You can be reasonably sure the client is not pregnant if she has no signs or symptoms of pregnancy (e.g., breast tenderness or nausea) and:

- has not had intercourse since her last menses; or
- has been correctly and consistently using a reliable contraceptive method; or
- is within the first 7 days after the start of her menses (day 1-7); or
- is within 4 weeks postpartum (for women who are not breastfeeding); or
- is within the first 7 days postabortion; or
- is fully breastfeeding, is less than 6 months postpartum and has had no menstrual bleeding (see below).

Source: Technical Guidance Working Group 1994.

RELYING ON THE LACTATIONAL AMENORRHEA METHOD (LAM)

The lactational amenorrhea method (LAM) is highly effective (98% protection during the first 6 months postpartum) (Labbock, Cooney and Coly 1994). A service provider can be reasonably sure that a fully or nearly fully breastfeeding woman is not pregnant if she is still within the first 6 months postpartum and has remained amenorrheic.

When a woman is more than 6 months postpartum, you still can be **reasonably** sure that she is not pregnant if she has kept her breastfeeding frequency high, she is still amenorrheic and has no clinical signs or symptoms of pregnancy (Labbok, Cooney and Coly 1994; TGWG 1994).

CLIENT ASSESSMENT CHECKLIST

When conducting the client assessment, it may be helpful for service providers to use a checklist so that no important information is left out. A **Sample Client Assessment Checklist** is presented in **Appendix B**.

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Labbok M, K Cooney and S Coly. 1994. *Guidelines for Breastfeeding and the Lactational Amenorrhea Method*. Institute for Reproductive Health: Washington, D.C.

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INFECTION PREVENTION¹

BACKGROUND

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

Another concern is the increasing danger of transmission of hepatitis B or AIDS to clients, health care providers or clinic staff.² Using disposable items to reduce this risk often is unnecessary. In addition, most of these disposables are expensive, difficult to dispose of safely and create environmental pollution problems. Furthermore, adequate supplies of disposable items, such as surgical gloves, often are not available in many countries.

To reduce the risk of infection as well as allow safe reuse of instruments and other items, contaminated waste must be properly disposed of and instruments and other items should be decontaminated, thoroughly cleaned and sterilized by autoclaving (high-pressure steam) or dry heat. If sterilization is not possible, high-level disinfection (HLD) (by boiling or steaming) is the only

acceptable alternative. (See **Appendix C** for information on processing surgical instruments and other items.) The emphasis in this chapter is on the use of infection prevention practices that are practical and feasible in any country and setting.

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 microorganisms. **Protective barriers** are physical, mechanical or chemical processes which help prevent the spread of infectious microorganisms from client to client, clinic staff to client and client to staff.

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

¹ Adapted from: Tietjen LG et al. 1995. *Infection Prevention for Family Planning Service Programs*, 2nd ed. JHPIEGO Corporation: Baltimore, Maryland.

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

- **Asepsis** and **aseptic technique** are general terms used 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 and other items).
- **Antisepsis** is the prevention of infection by killing or inhibiting the growth of microorganisms on skin and other body tissues by using a chemical agent (antiseptic).
- **Decontamination** is the process that makes objects **safer** to be handled by staff **before** cleaning (i.e., reduces, but does not eliminate, the number of microorganisms on instruments and other items). Objects to be decontaminated include large surfaces (e.g., pelvic examination or operating tables) and surgical instruments, gloves and other items contaminated with blood or body fluids.
- **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 from inanimate objects.
- **High-level disinfection (HLD)** by boiling, steaming or the use of chemicals, eliminates **all** microorganisms

except **some** bacterial endospores from inanimate objects.

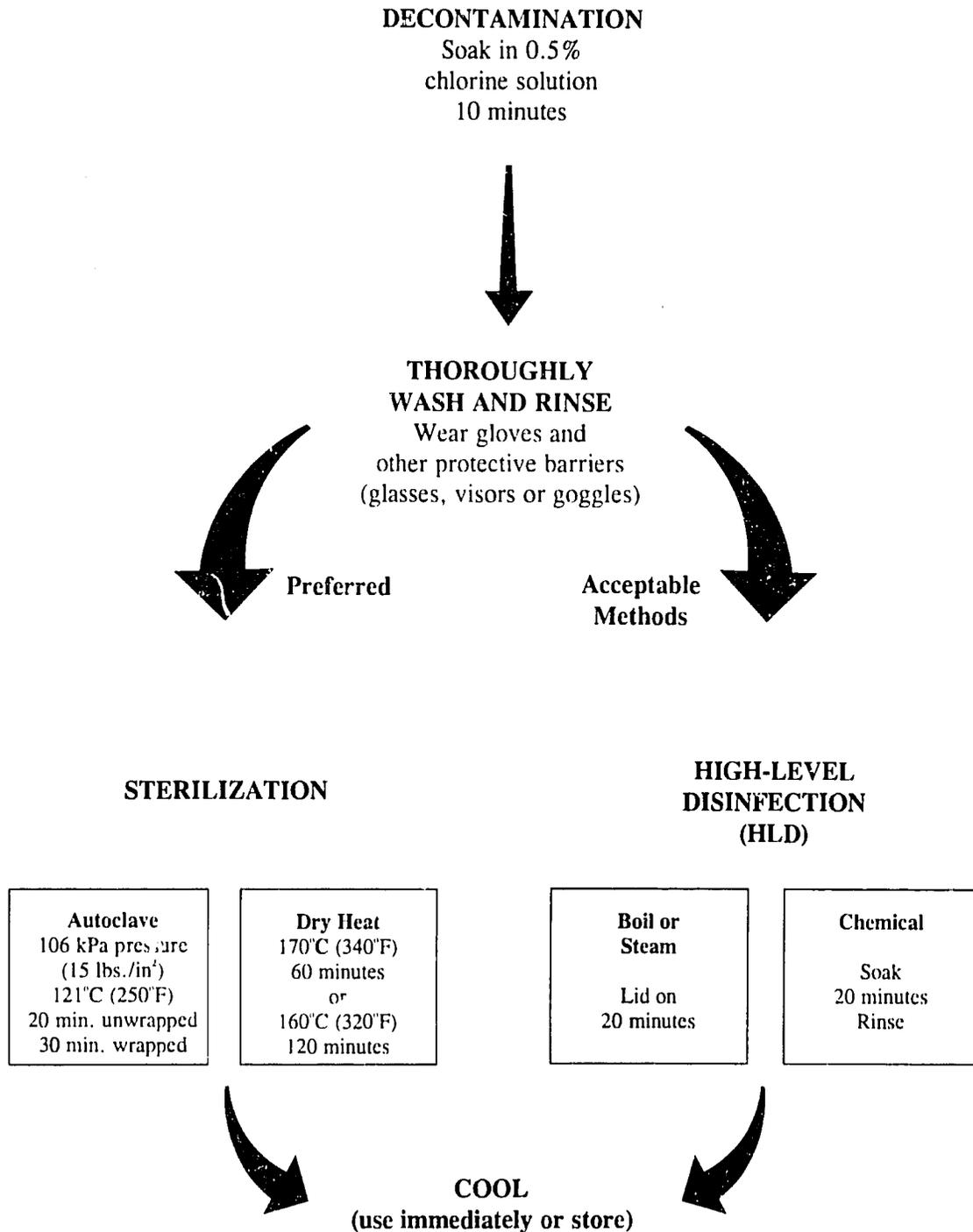
- **Sterilization** is the process that eliminates **all** microorganisms (bacteria, viruses, fungi and parasites) **including** bacterial endospores from inanimate objects.

WHICH PROCESS TO USE

As summarized in **Figure 5-1**, **decontamination** is the first step in processing **soiled** (contaminated) surgical instruments, gloves and other items. For example, soaking contaminated items briefly in 0.5% chlorine solution rapidly kills HBV and HIV, thereby making instruments and other items safer to be handled during cleaning (American Association of Operating Room Nurses 1990). 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.

After instruments and other items have been decontaminated, they need to be cleaned and then final processed by either sterilization or HLD (Tietjen and McIntosh 1989). As outlined in **Table 5-1**, which method is used for final processing (i.e., sterilization or HLD) depends on whether the instruments will touch only intact (unbroken) skin, intact mucous membranes or broken skin, or tissue beneath the skin which normally is sterile (Spaulding et al 1968).

Figure 5-1. Processing Surgical Instruments, Gloves and Other Items



Source: WHO 1990.

Table 5-1. Final Processing (High-Level Disinfection and Sterilization) for Surgical Instruments, Gloves and Other Items

Tissue	Final Processing	Examples
Intact mucous membranes or broken skin	High-level disinfection (HLD) destroys all microorganisms except some endospores. ^a HLD should be preceded by decontamination and cleaning.	Uterine sounds and vaginal specula
Tissue beneath the skin which normally is sterile	Sterilization destroys all microorganisms, including endospores. Sterilization should be preceded by decontamination and cleaning. ^b	Surgical instruments such as needles and syringes, scalpels and trocars for insertion/removal of implants and surgical gloves

^a 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 (*Clostridia tetani*) and gangrene (*Clostridia sp.*). Bacterial endospores can be killed reliably **only** by sterilization.

^b If sterilization is not available, HLD is the **only acceptable** alternative (see **Figure 5-1**).

Adapted from: Spaulding et al 1968.

**When is sterilization absolutely essential?
When is HLD an acceptable alternative?**

Most authorities recommend that the final step in processing instruments and other items used for surgical contraceptive procedures, such as voluntary sterilization or insertion/removal of Norplant implants, should be sterilization. While sterilization, when correctly performed, clearly is the safest and most effective method for processing instruments, if it is neither available nor suitable (e.g., for laparoscopes), then HLD is the **only acceptable** alternative (see **Table 5-1**).

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

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). The following actions create protective barriers for infection prevention:

- handwashing;
- wearing gloves (both hands), either for surgery or when handling contaminated waste materials or soiled instruments;
- using antiseptic solutions for prepping the skin prior to surgery or cleaning wounds;
- using drapes during surgical procedures;

- wearing appropriate attire (e.g., goggles, mask or apron) when contact with blood or body fluids is possible (e.g., cleaning instruments and other items); and
- decontaminating, cleaning and either sterilizing or high-level disinfecting surgical instruments, gloves and other items after use.

HANDWASHING AND GLOVES

Thorough handwashing coupled with the use of protective gloves, when inserting or removing Norplant implants or handling contaminated waste materials, are key components in minimizing the spread of disease and maintaining an infection-free environment (Garner and Favero 1986). In addition, understanding when sterile or high-level disinfected 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 a tap or bucket, and soap.

For most activities, a brief handwashing with plain 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, and
- putting on **sterile** or **high-level disinfected** surgical gloves for inserting or removing Norplant implants.

Handwashing is indicated **after**:

- any situation in which hands may be contaminated, such as:
 - handling soiled instruments and other items, or
 - touching mucous membranes, blood or other body fluids (secretions or excretions), and
- removing gloves.

Remember: Wash hands **after** removing gloves because gloves may have invisible holes or tears (Bagg, Jenkins and Barker 1990; Martin et al 1988).

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 dipping hands repeatedly into basins containing standing water. Even with the addition of an antiseptic agent, such as Dettol® or Savlon®, microorganisms can survive and multiply in these solutions.

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- Choose from several options when running water is not 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.
 - Use an alcoholic handrub which does not require water.

Note: A nonirritating alcohol solution can be made by adding either glycerine, propylene glycol or Sorbitol® to the alcohol (2 ml in 100 ml 60-90% alcohol solution) (Garner and Favero 1986). Use 3 to 5 ml for each application and rub the solution over the hands for about 2 minutes, using a total of 6 to 10 ml per scrub (Larson et al 1990; Rotter, Koller and Wewalka 1980).

- Dry hands with a clean towel or air dry; shared towels quickly become contaminated. (Carrying one's own small towel or handkerchief is a good way to avoid using dirty towels.)
- Collect used water in a basin and discard in a latrine if a drain is not available.

When to Wear Gloves

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 **disposable gloves** is preferable; however, surgical gloves can be washed and either sterilized by autoclaving or high-level disinfected by steaming or boiling before reuse. Gloves may be made

of rubber (latex) or synthetic materials such as vinyl.

Which Gloves to Use

- **Clinicians:** Sterile surgical gloves should be used when inserting or removing Norplant implants. When sterilization procedures are not available, surgical gloves can be **high-level disinfected** by steaming or boiling.

Remember: Neither steaming nor boiling will kill all bacterial endospores reliably.

- **Cleaning Staff:** Clean utility gloves should be worn when processing instruments, equipment and linens; for handling contaminated waste and when cleaning contaminated surfaces.

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

Instructions are provided in **Appendix D** for how to process surgical gloves, by sterilization or HLD, and store them safely.

ANTISEPSIS

Infection following minor surgical procedures, such as Norplant implants insertion or removal, may be caused by microorganisms from the skin of the client or from the hands of the health care worker (Larson et al 1990). Washing hands before and after each case (i.e., insertion or removal) and cleaning the client's skin with antiseptic solution help prevent infection at the operative site.

Selection of Antiseptics

Antiseptics do not have the same killing power as the chemicals used for HLD. Thus, antiseptic solutions **never** should be used to high-level disinfect objects such as instruments or surgical gloves.

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

- Alcohols (60-90% ethyl, isopropyl or “methylated spirit”)
- Chlorhexidine gluconate (4%) (e.g., Hibiclens[®], Hibiscrub[®], Hibitane[®])
- Chlorhexidine gluconate and cetrimide, various concentrations (e.g., Savlon)
- Iodine (1-3%); aqueous iodine and alcohol-containing (tincture of iodine) products
- Iodophors, various concentrations (e.g., Betadine[®])
- Parachlorometaxylenol (PCMX or chloroxylenol), various concentrations (e.g., Dettol)

PROCESSING INSTRUMENTS, GLOVES AND OTHER ITEMS

In working to create an infection-free environment, it is important that the rationale for each of the 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 insertion or removal of implants, 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**.

After completing either Norplant implants insertion or removal, and while still wearing gloves, dispose of contaminated objects (gauze, cotton and other waste items) in a leak-proof container or plastic bag. (Do not allow waste items to touch the outside of the container or bag.) **Following this**, surgical instruments, needles and syringes and 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.

Table 5-2. Infection Prevention Guidelines for Processing Instruments, Gloves and Other Items

WASTE DISPOSAL AND DECONTAMINATION	
STEP 1:	After completing either insertion or removal of implants, 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 container filled with a 0.5% chlorine solution for 10 minutes before allowing staff and cleaning personnel to handle or clean them. Before immersing assembled needles and syringes, fill with chlorine solution. (This step is necessary to help prevent transmission of HBV and HIV/AIDS to clinic staff.)
STEP 3:	If using disposable needles and syringes, remove from decontamination solution and place in puncture-proof container. If reprocessing syringe only (the recommended practice) or both needle and syringe, flush solution from syringe. Carefully remove needle from syringe and either place the needle in a puncture-proof container for disposal or clean as described below.
STEP 4:	All surfaces (such as the procedure table or instrument stand) that could have been contaminated by blood also should be decontaminated by wiping down with chlorine solution.
STEP 5:	Briefly immerse both gloved hands in the bucket containing the chlorine solution and then carefully remove by turning them inside out. If disposing of gloves, place in the leakproof container. If the gloves are reusable, deposit the gloves in the chlorine solution and soak for 10 minutes.
CLEANING AND RINSING	
STEP 6:	After decontamination, thoroughly clean instruments with water, liquid soap or detergent and a soft brush, taking care to clean all teeth, joints and surfaces. Rinse well after cleaning to remove all soap or detergent (some detergents can render chemical disinfectants inert). Dry instruments before further processing. Surgical drapes should be washed with liquid soap or detergent and water, rinsed with clean water and air or machine dried.
STEP 7:	Wash syringe (and needle) in soapy water and rinse (three times) with clean water. (If processing needle, be sure to clean hub area of needle. Put syringe and needle back together and rinse by flushing [3 times] with clean water. Detach needle from syringe and examine for damage. Dispose of damaged needles in puncture-proof container.)

Table 5-2. Infection Prevention Guidelines for Processing Instruments, Gloves and Other Items *(continued)*

STERILIZATION

Instruments, surgical gloves, syringes (and needles if reused) and surgical drapes should be sterilized by autoclaving. If necessary, metal instruments and glass syringes can be sterilized by dry heat.

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 1 hour and then cooling—is from 2 to 2½ hours) or 160°C (320°F) for 2 hours (total cycle time is from 3 to 3½ 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 or stored in dry sterile containers (1 week only). Wrapped instruments, gloves and drapes can be stored for up to 1 week if the package remains dry and intact and up to 1 month if sealed in a plastic bag.

HIGH-LEVEL DISINFECTION

High-level disinfection by boiling, steaming or the use of chemicals is recommended if sterilization is not possible. Surgical (metal) instruments, syringes (and needles if reused) and surgical gloves should be steamed or boiled for 20 minutes and allowed to dry.

Alternatively, instruments can be soaked for 20 minutes in glutaraldehyde, 8% formaldehyde or 0.1% chlorine solution prepared with boiled water, thoroughly rinsed in boiled water and air dried. Use immediately or store for up to 1 week in a clean, dry, high-level disinfected container with a tight-fitting lid or cover.

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Table 5-3. Steps in Processing Surgical Instruments, Gloves and Other Items

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Process	Decontamination is the first step in handling used items; reduces risk of HBV or HIV/AIDS.	Cleaning removes all visible blood, body fluids and dirt.	Sterilization destroys all microorganisms, including endospores.	High-Level Disinfection destroys all viruses, bacteria, parasites, fungi and some endospores.
Instruments/Items	Decontamination	Cleaning	Sterilization ^a	High-Level Disinfection
Procedure table top, or other large surface areas	Wipe off with 0.5% chlorine solution.	Wash with liquid soap or detergent and water if organic material remains after decontamination.	Not necessary	Not necessary
Surgical drapes	Not necessary (Laundry staff should wear protective gowns, gloves and eyewear when handling soiled linens.)	Wash with liquid soap or detergent and water. Rinse with clean water; air or machine dry.	Autoclave at 121°C (250°F) and 106 kPa (15 lb/in ²) for 30 minutes.	Not practical
Surgical gloves	Soak in 0.5% chlorine solution for 10 minutes prior to cleaning. Rinse or wash immediately. ^b	Wash with liquid soap or detergent and water. Rinse with clean water and check for holes. If they will be sterilized, dry inside and out (air or towel dry) and package (see Appendix D).	Preferable: Autoclave at 121°C (250°F) and 106 kPa (15 lb/in ²) for 30 minutes. Do not use for 24 to 48 hours.	Acceptable: Steam for 20 minutes and allow to air dry in steamer for 4 to 6 hours (see Appendix D). Boil in water for 20 minutes. (After cooling, gloves should be worn "wet" as drying and storing without contaminating them is difficult.)
Surgical instruments including trocars for implants insertion	Soak in 0.5% chlorine solution for 10 minutes prior to cleaning. Rinse or wash immediately. ^b	Using a brush, wash with liquid soap or detergent, and water. Rinse with clean water. If they will be sterilized, air or towel dry.	Preferable: Dry heat for 1 hour after reaching 170°C (340°F), ^c or Autoclave at 121°C (250°F) and 106 kPa (15 lb/in ²) for 20 minutes if unwrapped, 30 minutes if wrapped.	Acceptable: Boil for 20 minutes and air dry before use or storage. Chemically high-level disinfect by soaking for 20 minutes. Rinse well with boiled water and air dry before use or storage (see Appendix C).

Table 5-3. Steps in Processing Surgical Instruments, Gloves and Other Items (continued)

Instruments/Items	Decontamination	Cleaning	Sterilization ^a	High-Level Disinfection
Hypodermic needles and syringes	Fill assembled needle and syringe with 0.5% chlorine solution. Flush (x3) and either dispose of syringe, or, soak for 10 minutes prior to cleaning. Rinse by flushing (x3) with clean water.	Disassemble, and wash with liquid soap or detergent, and water. Rinse with clean water, air or towel dry syringes (only air dry needles).	Preferable: Dry heat for 2 hours after reaching 160°C (320°F) (glass syringes only), ^c or Autoclave at 121°C (250°F) and 106 kPa (15 lb/in ²) for 20 minutes if unwrapped, 30 minutes if wrapped.	Acceptable: Boil or steam as for surgical gloves. (Chemical HLD is not recommended because chemical residues may remain even after repeated rinsing with boiled water. These residues may interfere with the action of drugs being injected.)
Storage containers for instruments	Soak in 0.5% chlorine solution for 10 minutes prior to cleaning. Rinse or wash immediately. ^b	Wash with liquid soap or detergent and water. Rinse with clean water, air or towel dry.	Dry heat for 1 hour after reaching 170°C (340°F), or Autoclave at 121°C (250°F) and 106 kPa (15 lb/in ²) for 20 minutes if unwrapped, 30 minutes if wrapped. Sterilize when empty or contaminated, or weekly.	Boil container and lid (see Appendix C). If container is too large: 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. High-level disinfect when empty or contaminated, or weekly.
Norplant implants (never reuse)	Not necessary	Not necessary	Come in sterile packages. Discard if package seal broken.	Never acceptable

^a If unwrapped, use immediately; if wrapped, may be stored up to 1 week prior to use.

^b Avoid prolonged exposure (> 20 minutes) to chlorine solution to minimize discoloration and corrosion of instruments and deterioration of rubber or cloth products.

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

Adapted from: Perkins 1983.

Infection Prevention

(The surfaces of procedure tables or instrument stands also should be decontaminated before reuse by wiping with a cloth soaked in a disinfectant cleaning solution.) **Next**, instruments and reusable items such as surgical gloves, syringes and needles (if reused) should be thoroughly **cleaned** with liquid soap or detergent and water and completely rinsed before further treatment. **Finally**, instruments, gloves and surgical drapes should be **sterilized**. If sterilization is not possible, **HLD** is the only acceptable alternative (see **Appendix C** for details on processing surgical instruments and other items).

For a detailed description of **how to** decontaminate and clean instruments, syringes (and needles if reused) and linens, see **Appendix E**.

CLINIC SITE FOR INSERTION AND REMOVAL

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

- have adequate lighting,
- have tile or concrete floors to facilitate cleaning,
- be kept free of dust and insects, and
- be well ventilated. (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 waste items.

PREPARATION OF CLIENTS

Although skin cannot be sterilized, pre-operative 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 implants.

Remember: When done correctly, the rate of infection following implants 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 implants are minor surgical procedures (i.e., small skin 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: INSERTION AND REMOVAL

To minimize the client's risk of infection after insertion or removal clinic staff should strive to maintain an infection-free environment. To do this the clinician should:

- Have the client wash her **entire arm thoroughly with soap and water** and rinse well to be sure all traces of soap have been removed. (Residual soap decreases the effectiveness of some antiseptics.) This step is particularly important when client hygiene is poor.
- Wash hands thoroughly with soap and water.
- Put sterile or high-level disinfected gloves on both hands. (A separate pair of gloves must be worn for each client to avoid cross-contamination.)
- Prep the insertion or removal site with an antiseptic by holding the cotton or gauze swab with a sterile or high-level disinfected sponge forceps. (If the swab is held with a gloved hand, care must be taken **not** to contaminate the glove by touching any unprepped skin.)
- After inserting or removing all six capsules and before removing gloves, decontaminate instruments by placing them in a container filled with 0.5% chlorine solution. Before disposing of or soaking the needle and syringe, fill with chlorine solution. (Following insertion, separate the plunger from the trocar.

Dried blood makes them difficult to separate later). Soak for 10 minutes; then rinse **immediately** with clean water to avoid discoloration or corrosion of metal items.

Remember: As capsules are removed, decontaminate them by placing in a small bowl containing 0.5% chlorine solution.

- The surgical drape (if used) must be washed before reuse. After using, place in a dry, covered container and remove to the designated area for washing.
- While still wearing gloves, dispose of contaminated objects (gauze, cotton and other waste items) in an appropriately marked leak-proof container with a tight-fitting lid or a plastic bag.
- If **disposing** of surgical gloves, immerse both gloved hands briefly in chlorine solution, carefully remove the gloves by turning inside out and place in the waste container.
- If **reusing** surgical gloves, immerse both gloved hands briefly in the chlorine solution to decontaminate the outside of the gloves. Then, to ensure that both surfaces of the gloves are decontaminated, remove them by turning inside out and place in the chlorine solution. Soak for 10 minutes.
- Wash hands with soap and water.

MAINTENANCE OF A SAFE ENVIRONMENT

Maintaining a safe, infection-free environment is an ongoing process which requires frequent retraining and close supervision of clinic staff. With diligent application of recommended practices,

infections following insertion and removal of Norplant implants 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 of the procedure.

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INSERTION

BACKGROUND

Most problems associated with **removal** of Norplant implants are due to **improper or careless insertion** (Darney and Klaisle 1995). Therefore, only trained clinicians (physicians, nurses and midwives) should insert and remove Norplant implants (Emerling et al 1993). (An experienced health care provider can insert a set of implants in 10 to 15 minutes.)

Remember: Correct insertion—with the capsules inserted just beneath the skin (subdermally)—make removals relatively trouble-free.

To further minimize postinsertion problems (e.g., infection or spontaneous expulsion), all phases of the insertion process must be performed carefully and gently, using recommended infection prevention practices (see **Chapter 5**).

The material presented in this chapter 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 for the clinician to become proficient in insertion of Norplant implants.

CLIENT ASSESSMENT

In many countries, Norplant implants are inserted at the first clinic visit. Under these circumstances, to minimize the risk of problems, particularly the possibility of the client being pregnant at the time of insertion, a brief assessment of the woman's

health should be conducted (see **Chapter 4** and **Appendix B**).

TIMING OF INSERTION

Norplant implants may be inserted at any time during the menstrual cycle, when it is reasonably certain that the client is **not** pregnant or at risk of being pregnant (see **Chapter 4**). Optimal times for inserting implants are:

- during menstruation (within 7 days from onset),
- postpartum (within 4 weeks) if not breastfeeding,
- postabortion (immediately or within the first 7 days), or
- while fully breastfeeding (if after 6 weeks and before 6 months postpartum).

If the client currently is using a contraceptive method and wishes to switch to Norplant implants, timing of insertion will depend on the method being used (see **Table 6-1**). Inserting Norplant implants at these recommended times will minimize the possibility of pregnancy.

A backup barrier method should be used for at least 7 days if the client has been using no contraceptive method and insertion is done **after** day 7 of the menstrual cycle. If the client is using **another contraceptive method** and wants to switch to Norplant implants, the best time to do so is shown in **Table 6-1**.

Table 6-1. Current Contraceptive Users: Optimal Times for Switching to Norplant Implants

Current Method	When to Insert
Natural family planning or barrier methods	Before day 7 of the menstrual cycle
Combined oral contraceptives	After the last (21st) active pill and for the next 7 days
Progestin-only pill (minipill)	On the day the last pill in the pack is taken
Progestin-only (or estrogen and progestin) injectables	Any time up to the time of the next scheduled injection
IUD Users	IUD removed: Before day 7 of menstrual period IUD in place: Any time, but do not remove IUD for 7 days after insertion.

PREPARATION

The insertion/removal kit supplied by the United States Agency for International Development (USAID) contains all the instruments needed for insertion of implants (see **Appendix F** for contents).

It is important that the instruments be in excellent condition (e.g., the trocar and scalpel must be sharp). In addition, check that all instruments and other items have been sterilized or high-level disinfected (see **Chapter 5** and **Appendix C**).

Norplant capsules are packed in sterile, heat-sealed, paper-backed pouches. They will remain sterile for the duration of the labeled 5-year shelf life as long as they are not damaged and are stored away from moisture and excessive heat.

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

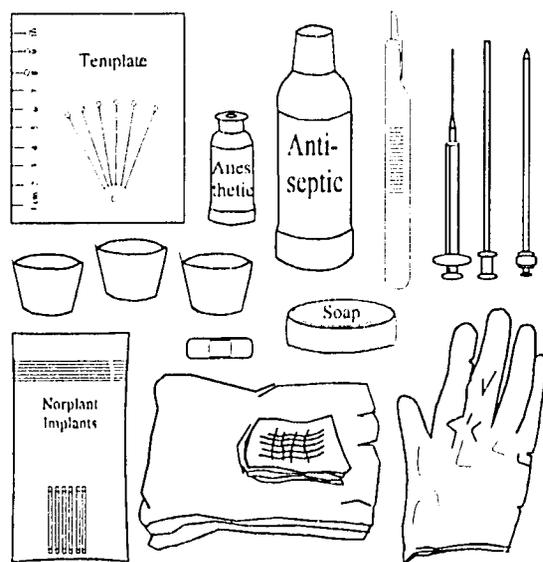
- examining table for the woman to lie on;

- arm support or side table;
- soap for washing the arm;
- set of six capsules in sterile pouch;
- sterile (or clean), dry surgical drape;
- three sterile (or high-level disinfected) bowls (one for the antiseptic solution, one for cotton balls soaked with boiled or sterile water to remove talc from gloves and one to hold capsules);
- pair of sterile (or high-level disinfected) surgical gloves;
- antiseptic solution;
- local anesthetic (1% concentration **without** epinephrine);
- syringe (5 or 10 ml) and 2.5 to 4 cm (1 to 1½ inches) long needle (22 gauge);
- #10 trocar with plunger;

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- scalpel with #11 blade;
- plastic template for marking position of capsules in fan like pattern;
- ordinary bandaid or sterile gauze with surgical tape;
- sterile gauze and compresses; and
- epinephrine for anaphylactic shock (readily available for emergency use).

Figure 6-1. Basic Materials for Insertion



Adapted from: Population Council 1990.

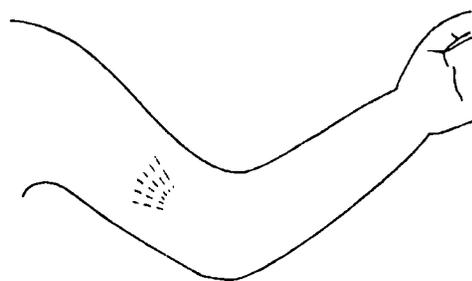
GENERAL PROCEDURE

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

First, have the client wash her entire arm with soap and water. Then swab the inner upper arm with an antiseptic and inject the local anesthetic. Make a small, shallow

incision, which just penetrates the skin, about 8 cm (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 (subdermally) one at a time in a fan-shaped pattern. The fan should open away from the elbow so that the two outermost capsules form an angle of about 75° (Figure 6-2).

Figure 6-2. Insertion Site



Sutures are not required to close the incision; a simple bandaid will do.

Remember: It is important that the capsules be placed subdermally. Deep placement will make removal much more difficult.

STEP-BY-STEP INSTRUCTIONS FOR INSERTION

Before starting the procedure, again check to be sure whether the client:

- is taking any drugs that would decrease the effectiveness of the Norplant implants (see Chapter 1),

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Insertion

- has ever had a local anesthetic before, and
- is allergic to local anesthetics or other drugs.

Getting Ready

STEP 1: Have client **wash her entire arm 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.

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

STEP 3: Ask the client to lie down on the table so that the arm she uses less rests on the table or arm support. Her arm should be well-supported and able to be comfortably extended straight or slightly bent, as the clinician prefers. (**Figure 6-2**).

STEP 4: Determine the optimal insertion area (8 cm/3 inches) above the elbow fold. Use the template (pattern) and mark 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 5: Prepare an instrument tray and open the sterile instrument pack without touching the instruments and other items.

STEP 6: Carefully open the sterile pouch containing the 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 capsules).

If a sterile cup or bowl is not available, the capsules can be dropped into a high-level disinfected bowl or onto the tray containing the instruments. Alternatively, partially open the pouch and remove the capsules one at a time, as needed, using sterile or high-level disinfected forceps. **Do not** touch the inside of the package or its contents except with a sterile or high-level disinfected instrument.

Note: If a capsule falls on the floor, it is **contaminated**. Open a new package and continue with the procedure. (Never attempt to sterilize or high-level disinfect contaminated capsules.)

Pre-Insertion Tasks

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

STEP 2: Put sterile or high-level disinfected gloves on both hands. (A separate pair of gloves must be worn for each client to avoid cross-contamination.)

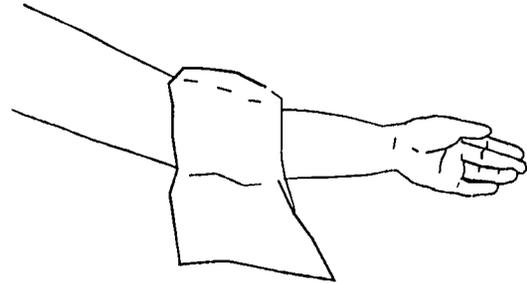
Note: Do not use powder with gloves. The tiny powder (talc) granules may fall into the insertion site and cause scarring (fibrous reaction). If gloves are powdered, wipe off fingers with sterile gauze soaked with sterile or boiled water.

STEP 3: Arrange instruments and supplies so that they are easily accessible. **Count to make sure there are six capsules.**

STEP 4: Prep the insertion site with an antiseptic solution. Use a sterile or high-level disinfected sponge forceps to hold 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 to 13 cm (3 to 5 inches) and allow to air dry (about 2 minutes) before proceeding. Wipe off excess antiseptic only if necessary to see the template marks.

STEP 5: If a sterile surgical drape with a hole in it is available, it should be used to cover the arm. The hole 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 (**Figure 6-3**). (Alternatively, a decontaminated, cleaned and machine- or air-dried cloth can be used.)

Figure 6-3. Surgical Draping



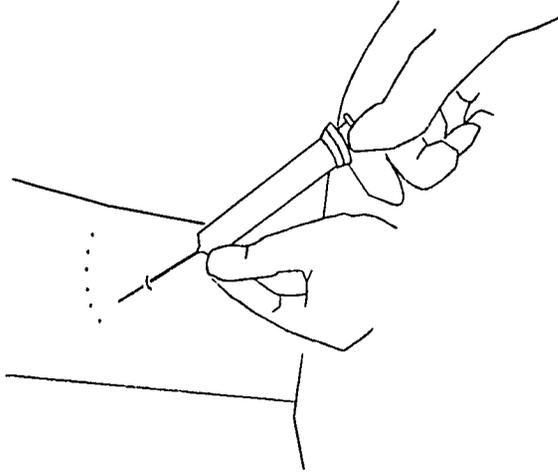
Adapted from: Population Council 1990.

STEP 6: 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 7: Insert the needle just under the skin at the incision site (point closest to the elbow). Next, pull back on the plunger to be sure the needle is not in a blood vessel (aspirate). Inject a very small amount of anesthetic to raise a small wheal (raised area). Then, without removing the needle, gently advance it under the skin for about 4 cm (1½ inches) (**Figure 6-4**). This will raise the dermis up from the underlying soft tissue. Slowly withdraw the needle, “laying a track” of anesthetic.

Insertion

Figure 6-4. Injecting the Anesthetic



Source: Population Council 1990.

Experience has shown that three equally spaced tracks which follow the fan-shaped pattern of the capsules (i.e., 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 (cc) is sufficient in each of the tracks.** Finally, gently rub the area injected to spread it around; this will improve the anesthetic's effectiveness.

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

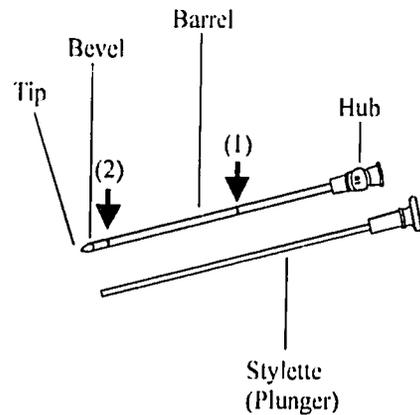
Inserting the Capsules

Before starting, gently touch the incision site with the hypodermic needle or scalpel to be sure the anesthetic is working.

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

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. Mark (1), which is close to the hub, indicates how far the trocar should be introduced before loading each capsule. Mark (2), which is 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



Source: Population Council 1990.

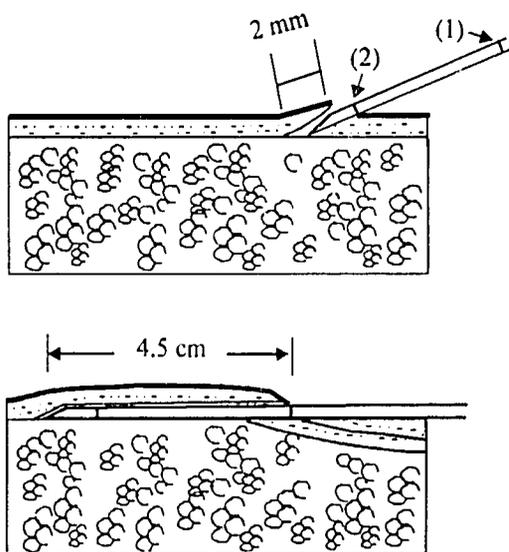
Note: Based on a recent study by Diaz et al (1991), if the trocar is **new**, it is not necessary to make a skin incision. These authors found no significant differences in pain, tenderness, edema (swelling), discoloration due to blood infiltration or scarring between an incision made by a scalpel or by the trocar directly. Added advantages of using a trocar are that it:

- eliminates the need for a scalpel, and
- prevents making an incision larger than required.

STEP 3: With the beveled tip of the trocar facing up and the plunger in place, insert the tip of the trocar through the incision at a shallow angle. 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 dermis (2 to 3 mm past the end of the bevel) (**Figure 6-6 upper**). **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 while **tenting the skin**. Advance the trocar slowly and smoothly toward mark (1) near the hub (**Figure 6-6, lower**). The trocar should be shallow enough so that it can be readily followed with a finger. **It should visibly raise (tent) the skin at all times.** Passage of the trocar will be smooth if it is in a proper, shallow plane.

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



Source: Wyeth-Ayerst 1990.

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.

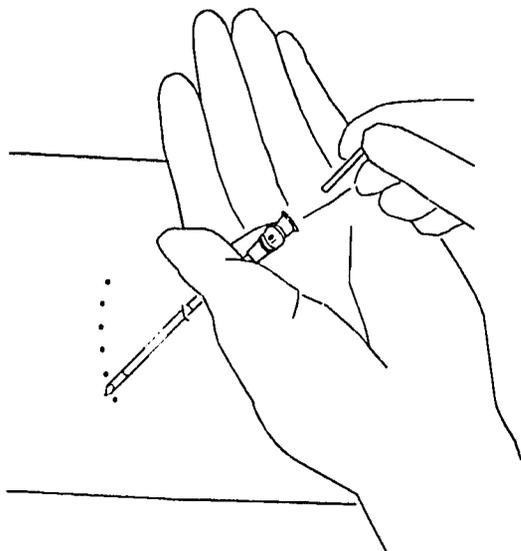
STEP 5: When the trocar has been advanced as far as mark (1), remove the plunger from the trocar.

STEP 6: Load the first capsule into the trocar. The thumb and forefinger, or tweezers or forceps, may be used to pick up the capsules and insert them in the trocar. If the capsules are picked up by hand, be sure the gloves are free of powder or other particles. (To avoid dropping a capsule while loading it in the trocar, keep your hand "cupped" under the trocar.) (**Figure 6-7**)

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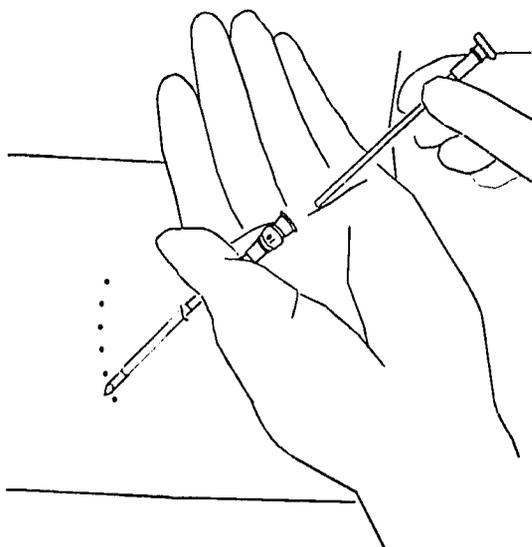
Insertion

Figure 6-7. Loading the Capsule



Push the capsule down to the top of the hub and reinsert the plunger (Figure 6-8).

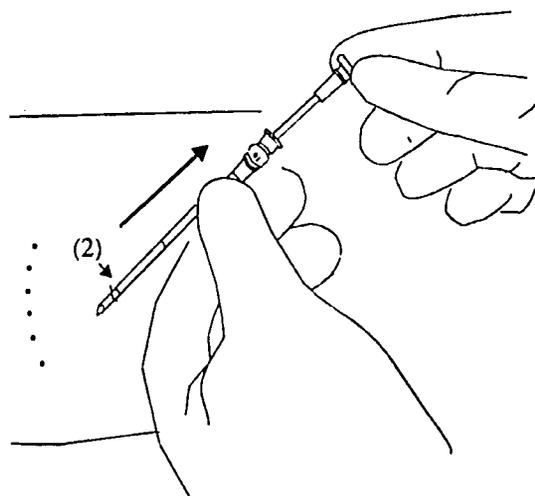
Figure 6-8. Inserting the Plunger



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 inserted about halfway into the trocar.)

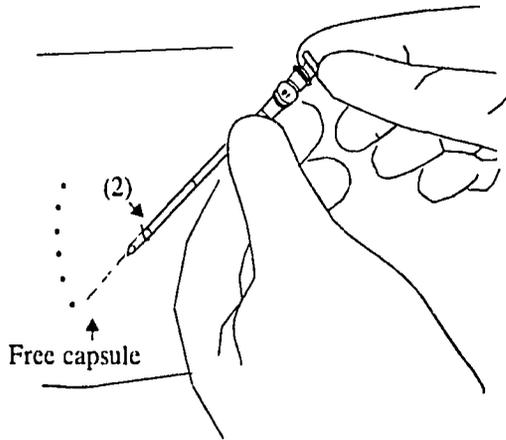
STEP 8: Hold the plunger firmly in place with one hand to stabilize it. With the thumb and forefinger, slide the barrel of the trocar back out of the incision **until** the lower mark (2) **just clears** the incision, and the hub touches the handle of the plunger (Figure 6-9). It is important to keep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

Figure 6-9. Sliding the Trocar Back



STEP 9: When the hub of the trocar touches the handle of the plunger, mark (2) should be visible in the incision and the capsule should now be lying beneath the skin, **free of the trocar** (Figure 6-10). Feel the end of the capsule with a finger to make sure it is free of the tip of the trocar.

Figure 6-10. Releasing the Capsule

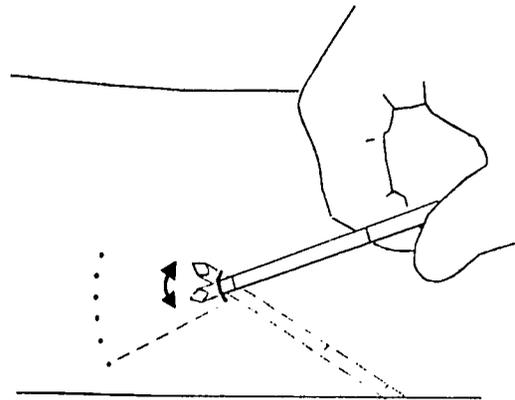


Note: Repeated sharpening shortens the trocar, lessening the distance to mark (2). Therefore, when using trocars which have been sharpened, be careful not to pull the trocar too far back or it will come out of the incision.

It is **important** that the capsule is free of the tip (point) of the trocar to avoid cutting it as the trocar is moved forward to insert the next capsule.

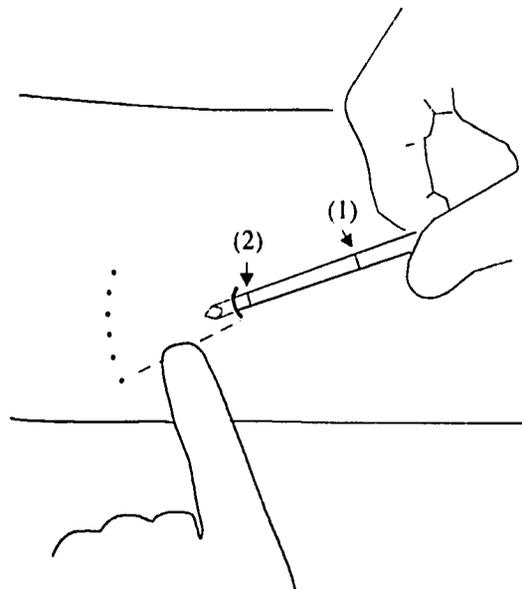
STEP 10: Without completely removing the trocar, laterally rotate the tip of the trocar to the right and back again (Figure 6-11) to be sure the first capsule is free.

Figure 6-11. Rotating the Trocar



Then slide it over about 15°, following the fan-like placement pattern marked on the arm. To do this, first fix the position of the first capsule with a forefinger and slowly advance the trocar along the side of this finger toward mark (1) (Figure 6-12). Doing this will ensure a suitable distance between each capsule and will keep the trocar from puncturing any of the previously inserted capsules.

Figure 6-12. Fixing the Position of the First Capsule



Insertion

When mark (1) is reached, load the next capsule into the trocar and proceed as before (**STEPS 5 - 9**) until all the capsules are inserted.

STEP 11: As you proceed, in order to minimize the risk of spontaneous expulsion of a capsule, 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.

Remember: The capsules should fan out, about 15° apart, so that the angle between the outer capsules (1 and 6) forms a total angle of about 75°.

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: Before removing the trocar, **palpate the capsules to make sure that all six have been inserted.**

STEP 14: The tips of **all** the capsules should be well clear of the incision (about 5 mm). If a capsule tip sticks out of or is too close to the incision, it should be repositioned by removing the capsule and re-inserting it correctly.

STEP 15: After the sixth capsule has been inserted and the position of each checked, carefully withdraw the trocar and press down on the incision with a gauzed finger for a minute or so to stop any bleeding.

Clean the area around the insertion site with a small amount of antiseptic solution applied to a cotton or gauze swab.

PROCEDURE TO FOLLOW AFTER INSERTION OF CAPSULES

Covering the Incision

- Bring the edges of the incision together and use a bandaid or surgical tape with sterile cotton to cover the incision. **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 be sure there is no bleeding and to minimize the bruising (subcutaneous bleeding).

Waste Disposal and Decontamination

- Before removing gloves, place instruments into a container filled with 0.5% chlorine solution for decontamination (see **Appendix C** for how to make a solution from household bleach). Before immersing the needle and syringe, fill with chlorine solution. (Do not disassemble.) Separate the plunger from the trocar and immerse (dried blood makes it difficult to separate them later). Soak for 10 minutes. Rinse **immediately** with clean water to avoid discoloration or corrosion of metal items.
- The surgical drape (if used) must be washed before reuse. Place in a **dry** covered container and remove to the designated washing area.

- While still wearing gloves, place all 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 **disposing** of gloves, immerse both gloved hands briefly in chlorine solution and then carefully remove gloves by turning inside out and place in the waste container.
- If **reusing** gloves, immerse both hands briefly in the chlorine solution to decontaminate the outside. Remove by turning inside out. To ensure that both surfaces of the gloves are decontaminated, place them in the chlorine solution and soak for 10 minutes.
- Wash hands thoroughly with soap and water.
- All waste material should be disposed of by burning or burying.

Client Care

- Place a note in the client's record indicating the 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 is helpful.)
- Observe the client for at least 15 to 20 minutes for bleeding from the incision or adverse effects before sending her home. She should be given written, postinsertion care instructions if available and appropriate.

CLIENT INSTRUCTIONS FOR WOUND CARE AT HOME

- There may be bruising, swelling or tenderness at the insertion site for a few days. This is normal.
- Keep the area around the insertion site dry and clean for at least 48 hours. The incision could become infected if the area gets wet while bathing.
- 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 3 to 5 days).
- Routine work can be done immediately. Avoid bumping the area, carrying heavy loads or applying unusual pressure to the site.
- After healing, the area can be touched and washed with normal pressure.
- If signs of infection occur, such as fever with inflammation (redness plus heat) at the site, or if there is persistent arm 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 expulsion of any capsules), remove all capsules.

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Insertion

KEY POINTS FOR SUCCESSFUL INSERTIONS

- Select the arm the client uses less for insertion of the capsules.
- Use recommended infection prevention practices to avoid infections.
- Make sure that the capsules are placed at least 8 cm (3 inches) above the elbow fold, in the inner aspect of the arm.
- The insertion incision should be small, just penetrating the skin. Use a scalpel tip or sharp trocar to make the incision.
- Insert the trocar with plunger in place through the incision at a shallow angle, superficially and just beneath the dermis. **Never force the trocar.**
- To ensure subdermal placement, the trocar should visibly raise (tent) the skin at all times.
- Make sure the capsule is completely free of the trocar before the next one is inserted. (To avoid damaging the previous capsule, fix the position of the previously inserted capsule with your forefinger and advance the trocar slowly along the side of this finger.)
- After insertion, if a capsule tip protrudes from or is too close to the incision, it should be carefully repositioned in the correct position (i.e., 5 mm from the incision).
- Do not remove the tip of the trocar from the incision until all the capsules have been inserted **and their position checked**. This will help ensure that all six capsules are positioned correctly and inserted in a superficial plane.
- The first and sixth capsules should form an angle of about 75°.
- Draw the location of the capsules in the client's record and write a note if anything unusual happened during the insertion.

TIPS FOR KEEPING A TROCAR SHARP

- Repeated use will cause the trocar to become dull; therefore, it should be examined carefully after every ten insertions.
- After use, separate the plunger from the trocar (this helps keep the trocar sharp).
- If it appears that the trocar is becoming dull, 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. Repeated grinding will shorten the trocar, lessening the distance to mark (2) near the tip of the trocar (Figure 6-5).
- Another problem due to repeated 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 50 to 100 insertions, the trocar should be **replaced**, not **resharpened**.

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SEVEN

POSTINSERTION AND FOLLOWUP 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 followup care (including counseling) and prompt management of side effects as well as other problems, should they occur (WHO 1990).

Most clients will **not** experience problems following insertion of Norplant implants. 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); and
- bleeding from the incision.

Because of these potential problems, it is recommended that all clients remain at the clinic for at least 15 to 20 minutes before being discharged.

CARE OF INSERTION SITE

Clients should be told and, if appropriate, 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 at the insertion site when the anesthetic wears off and for a day or two thereafter. 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 48 hours. The protective gauze pressure bandage should be left in place for 48 hours and the small adhesive bandage for at least **3 to 5 days** until the incision is healed. (The incision could become infected if the area gets wet while bathing.)
- The client can resume her normal activities immediately—child care, employment, household chores—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 and will not break.
- If signs of infection, such as fever with inflammation (redness and heat) occur at the insertion site or if 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 implants, as well as what to do if certain problems occur, promotes continued use (Population Council 1992). In particular she should know the answers to these common questions:

How widely have Norplant implants been researched and tested?

They have been studied for over 20 years and have been used by millions of women in 46 countries, including over a million women in the USA. The hormone they contain (levonorgestrel) has been used for more than 30 years in oral contraceptive pills. The capsules themselves are made of a medical-grade substance (Silastic tubing) that does not cause any reaction (allergy) and has been used in various procedures, including heart surgery, since the 1950s (Population Council 1990). (See **Chapter 1** for additional information.)

Can the capsules be seen or felt?

Since the incision is small, insertion does not leave a noticeable scar. The capsules are not visible in most women but can be felt under the skin. When they are visible, 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?

No. The capsules remain where they are inserted until they are removed. They are flexible and cannot break inside the woman's arm.

After the incision has healed, the skin over the capsules can be touched at any time. Also, the client 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.

How effective are Norplant implants?

No contraceptive is 100% effective; however, Norplant implants are one of the most effective contraceptives available. For every 100 women who use implants for a year, fewer than 1 will become pregnant. That is a lower failure rate than for the oral contraceptive pill and is comparable to voluntary sterilization.

Is the effectiveness affected by a woman's weight?

There is no correlation between effectiveness and a woman's weight. Concerns that implants are slightly less effective in women weighing 70 kg or more applies only to capsules made of the older, harder tubing previously used to make the capsules. Currently, only the new, softer tubing is used. Studies involving this new tubing have **not** shown a significant difference in pregnancy rates associated with a woman's weight (see **Chapter 1, Table 1-2**).

How quickly do Norplant implants become effective?

Implants become effective within 24 hours after insertion. (If they are **not** inserted during the first 7 days of the menstrual period, however, a backup contraceptive method should be used for at least 7 days.)

How long will Norplant implants be effective?

They protect against pregnancy for 5 years, but can be removed earlier. All **six** capsules are needed for protection, even if the method is used for less than 5 years.

Can a woman who is breastfeeding use Norplant implants?

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 Norplant implants beginning 6 weeks after childbirth. There is no reported experience with the use of implants earlier than 6 weeks after childbirth in breastfeeding women.

Do other drugs interact with the hormone in Norplant implants?

Certain drugs increase the ability of the liver to break down the hormone (levonorgestrel) thereby making the method less effective in preventing pregnancy. Such drugs include: rifampin, used to treat tuberculosis; and 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 (Angle, Huff and Lea 1991).

Remember: Counsel the woman to tell the health care worker that she is using Norplant implants whenever a new drug is given.

How soon after insertion can a couple resume sexual relations?

Couples should wait at least 24 hours before resuming sexual relations unless a backup contraceptive method (e.g., condoms or spermicide agent) is used.

When should the client return to the clinic?

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

- wants the implants removed for any reason,
- has any problems with the method that worry her,
- wants to have a child,
- is moving away and needs the address of a clinic in her new area that provides implants services, or
- thinks she might be pregnant.

What is the most common side effect?

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 implants. 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 (Darney et al 1990).

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 8 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; or
- a combination of these changes.

What kind of bleeding pattern a woman will have cannot be predicted. Most 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 with normal menses. In fact, in some studies, hemoglobin levels have been shown to rise in implants users. A followup 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 menstrual period (i.e., there is no "build up" of blood in the uterus). If a woman's menses have not returned after 1 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 a prospective Norplant implants user is counseled about menstrual bleeding changes, the less likely it is that this side effect will lead to her becoming unhappy with the method and requesting removal.

Should the Norplant implants 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 8** for details). Thorough counseling to reassure the client that the bleeding or spotting is not serious is the most helpful thing to do in this case.

Should a woman with prolonged bleeding (with or without anemia) have the Norplant implants removed?

Not usually. If the woman wants to continue using implants, she should be checked to be sure there are no other causes for the bleeding. Following this, the **first approach** should be counseling and reassurance that **prolonged spotting or moderate bleeding** (equivalent to normal menstruation but longer in duration) are common and expected in the first 3 to 6 months of Norplant implants use. If this is not sufficient for the woman, use of a low-dose COC or ibuprofen can be tried. (See **Chapter 8** for additional information and detailed instructions.)

For anemia, give nutritional advice on the need to increase iron intake. Use oral iron treatment (one tablet daily for 1 to 3 months) if hemoglobin is ≤ 9 gm/dl or hematocrit ≤ 27 .

What are other common reactions?

A small number of women using Norplant implants 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,
- depression,
- pimples and/or oily skin (acne),
- change of appetite,
- weight gain,
- breast tenderness (mastalgia),
- increased facial or body hair growth (hirsutism) or hair loss, and
- whitish vaginal discharge (leukorrhea).

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

Enlarged ovarian follicles, detectable only during a physical examination, may occur in implants users. They usually disappear spontaneously within a few months without need for medical or surgical treatment (see **Chapter 8**).

There are a number of other complaints reported by implants users or discovered by service providers that **may or may not** be associated with the method:

- breast (nipple) discharge;
- cervicitis (inflammation of the cervix, detected by service provider);
- general weakness (malaise);
- weight loss;
- itching (pruritus); and
- hypertension.

What are the warning signs of problems?

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

- pus or bleeding at the insertion site (this may indicate infection);
- expulsion of a capsule (this rarely occurs with proper insertion);
- delayed menstrual period, especially after a long interval of regular cycles;
- heavy vaginal bleeding (more than 2 pads or cloths per hour);
- prolonged vaginal bleeding (8 days or more);
- severe lower abdominal pain;
- episodes of migraine, repeated bad headaches or blurred vision; or
- jaundice.

When should Norplant implants be removed?

Norplant implants should be removed at the end of 5 years. The capsules can, however, be removed before 5 years if the user desires to stop the method, for either a personal or medical reason. The capsules should be removed by a service provider trained in removal. If the client wants to continue using Norplant implants, 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 removals are performed.

What happens if the Norplant implants are left in longer than 5 years?

The effectiveness of Norplant implants decreases after 5 years so the chance of becoming pregnant increases. If left in place, capsules will continue to release a small amount of LNG for many years (some calculations indicate as long as 20 years). Given the reduced effectiveness, however, capsules should be removed after 5 years and replaced with a new set if continued contraception with implants is desired.

How long does removal take?

The removal process usually takes from 10 to 20 minutes, but may take longer if some

of the capsules were not inserted correctly or 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 implants removed and wished to become pregnant, 20% conceived within 1 month of removal, more than 50% within 3 months, 63% by 6 months, 86% by 1 year and 93% within 24 months (see **Figure 1-9**). These rates of conception are similar to those for women using no contraception (Sivin 1988).

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 to be certain she clearly understands them.
- It is also useful to give the client printed materials (if appropriate) and a reminder card listing the date of insertion and removal date (see **Figure 7-1**).

FOLLOWUP 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 Norplant implants removed (in 5 years) or when removal is desired or needed (e.g., planned pregnancy or unacceptable side effects). Annual preventive health care visits, at which time the capsules can be checked, are recommended.

Figure 7-1. Sample Client Card

ABOUT YOUR NORPLANT IMPLANTS	
Name:	_____
Your capsules were inserted by:	_____
at:	_____
Date of insertion:	_____
Followup visit:	_____
Period of use:	5 years
Return for removal of the capsules on:	_____

When possible, the client should return to the same clinic where the implants 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 that she wants the implants removed.

The client should return to the same clinic, when possible, if she has any of the following medical problems:

- pus or bleeding at the insertion site;
- expulsion of a capsule;
- delayed menstrual period;
- heavy vaginal bleeding;
- prolonged vaginal bleeding;
- severe lower abdominal pain;
- episodes of migraine, repeated bad headaches or blurred vision; or
- jaundice.

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

- good clinical judgment in selecting acceptors;
- care, sensitivity and thoroughness in informing the user about implants and common side effects;
- skill in inserting and removing implants;
- knowledge of and ability to recognize real or potential problems; and
- capability to take appropriate clinical action in response to these problems, including knowing when (and where) to refer clients with serious problems.

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MANAGEMENT OF SIDE EFFECTS AND OTHER HEALTH PROBLEMS

BACKGROUND

Most side effects and other health problems associated with the use of Norplant implants are not serious. As mentioned previously, **changes in menstrual bleeding patterns** are by far the most common adverse effect. In addition to menstrual bleeding changes, women using Norplant implants occasionally develop **enlarged ovarian follicles**. Fortunately, they rarely cause symptoms and usually are discovered only incidentally at pelvic examinations. In addition, they generally shrink and disappear spontaneously and rarely require treatment. **Ectopic pregnancies** also have occurred although clinical studies have shown no increase in the rate of ectopic pregnancies per year among implants users compared with users of no contraceptive method. Finally, several other conditions which may or may not be associated with use of implants 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 chapter, additional information and guidelines for assessing and managing the most important of these side effects and other health problems are provided.

MENSTRUAL BLEEDING CHANGES

The most frequently reported side effect is a change in the menstrual bleeding pattern. Because the changes 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 **rarely** is enough to cause anemia, but there have been a few cases which required treatment with iron tablets. Fortunately, these bleeding problems gradually diminish over time (i.e., after 6 to 12 months).

Despite the fact that medical treatment for irregular bleeding or spotting usually is **not** necessary, many clinicians feel obligated to give some medication in an attempt to correct the altered bleeding pattern and to improve continuation.

Evaluation of Medical Treatment Regimens

To date, only one study has been published which addresses this problem. In that study, levonorgestrel (30 μg twice daily), ethinyl estradiol (50 μg daily) and a non-steroidal anti-inflammatory drug (NSAID) such as ibuprofen (800 mg three times daily) were compared to a placebo (Diaz et al 1990).

Treatment was initiated only **after** 8 days of bleeding. Duration (number of days) of total bleeding was determined after treatment with one of the three drugs listed above or with a placebo over a 1-year period. All three treatment groups performed better than the placebo. Ethinyl estradiol (EE) reduced bleeding over a 1-year period by 52 days while ibuprofen reduced bleeding by 35 days and levonorgestrel (LNG) by 28 days. In this study, EE was given for **20 days** on average 2.2 times during the 1-year study period while ibuprofen was given for **only 5 days** on average 2.7 times over the year.

Management of Side Effects and Other Health Problems

The advantage of using EE in the management of prolonged bleeding in Norplant implants users should be weighed carefully against potential disadvantages. For example:

- Treatment may conflict with the reason the client selected implants (e.g., because it is an estrogen-free method).
- Upset stomach (gastric intolerance) caused by EE caused 5 out of the 45 subjects to discontinue this treatment.
- Because the dose of LNG delivered by the implants is so low, the progestin effect on cervical mucus may be reduced by the addition of estrogen only.
- Ethinyl estradiol is expensive and seldom available, especially in rural areas.

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 the continuation rates were **not** assessed. Therefore, along with evaluating the effect of various medical treatments, a comparison study should be made of the effect on continuation of good counseling alone versus medical treatment.

Management of Vaginal Bleeding Problems

Irregular and even prolonged spotting or bleeding (8 days or more) are common and expected—over 65% of Norplant implants users during the first year (Sivin 1988). For example, moderate bleeding more than twice

as long as a normal menses (usually 5 to 7 days) occurs in 20-30% of implants users during the first 3 to 6 months. For a woman with **prolonged spotting or moderate bleeding**, the **first approach** should be counseling and reassurance. It should be explained that in the **absence of other causes** (e.g., cervicitis or cervical polyp), this type of bleeding is not harmful, even if prolonged for several weeks. Furthermore, these prolonged bleeding or spotting episodes typically become lighter and shorter in succeeding months.

If the woman is not satisfied, even after reassurance, and she wants to continue using implants, a short course (1 to 3 cycles) of treatment may be tried using:

- COCs (30 to 35 μg EE once daily for 21 days), or
- ibuprofen (or other NSAID) up to 800 mg 3 times daily for 5 days.

Combined oral contraceptives control or stop bleeding by rebuilding the endometrium while ibuprofen, which blocks prostaglandin synthesis, decreases uterine contractions and blood flow to the endometrium (Angle, Huff and Lea 1991). Combined oral contraceptives, which also contain a progestin, are preferred over estrogens (either 20 to 50 μg EE or 1.25 mg conjugated estrogens) because using only estrogens may reduce the contraceptive effect on the cervical mucus, and they are expensive and seldom available.

Heavy bleeding (greater than normal menstruation for a longer duration) is **very** uncommon with implants and usually can be managed by cyclic COCs (with or without ibuprofen).

If the bleeding is not reduced in 3 to 5 days or is much heavier (1 to 2 pads or cloths per hour):

- Determine whether there are other causes for uterine bleeding.
- Give 2 COC pills per day for the remainder of the cycle (at least 3 to 7 days), followed by 1 cycle (1 pill per day) of COCs.
- Alternatively (if available), give a 50 µg EE-containing COC or 1.25 mg conjugated estrogen (Premarin®) for 14 to 21 days.

Note: Check to be sure vaginal bleeding has decreased within 3 days.

If COCs or estrogens fail to correct the bleeding problem, the implants may need to be removed for medical reasons (excessive bleeding) or due to the client's wishes (TGWG 1994).

Do **not** perform a D&C unless **another** medical condition (e.g., endometrial polyp or incomplete abortion) is suspected. (Manual vacuum aspiration, not D&C, is the preferred method for emptying the uterine cavity.)

For anemia, give nutritional advice on the need to increase iron intake. Use oral iron treatment (one tablet, FeSO₄, daily for 1 to 3 months) if hemoglobin ≤ 9 gm/dl or hematocrit ≤ 27.

PERSISTENT OVARIAN FOLLICLES

If follicles (eggs and their surrounding cells) in the ovary develop while using Norplant implants, their disappearance sometimes is delayed, and they 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 pelvic exam. In the majority of women, the enlarged follicles will shrink and disappear on their own and should not require treatment. Rarely, they may twist or rupture so that surgery is required (Population Council 1990).

ECTOPIC PREGNANCIES

Ectopic pregnancies (implantation of the fertilized egg outside the uterus) have occurred among implants users. To date, clinical studies have shown no increase in the rate of ectopic pregnancies among implants users as compared with users of no contraceptive method. For example, the incidence among implants users is 1.3 per 1,000 woman-years as compared to 1.4 among noncontraceptive users (Sivin 1988). As mentioned in **Chapter 1**, if a woman **does** become pregnant with Norplant implants in place, she is 20-30% more likely to have an ectopic pregnancy. Furthermore, because the risk of ectopic pregnancy increases slightly with duration of Norplant implants use, it should be ruled out in any woman suspected of being pregnant (Croxatto 1993). Therefore, all women with Norplant implants who present with symptoms of pregnancy should be carefully evaluated.¹

¹ Symptoms of **ectopic pregnancy** may include spotting and lower abdominal cramping or pain, which usually begin shortly after the missed period.

MANAGEMENT OF SIDE EFFECTS

The steps in evaluating and managing side effects associated with Norplant implants use are outlined below.

SIDE EFFECT	ASSESSMENT	MANAGEMENT
Amenorrhea (absence of vaginal bleeding or spotting)	Check for pregnancy (intrauterine or ectopic) by checking symptoms, performing a pelvic examination (speculum and bimanual) and a pregnancy test if indicated and available (see Chapter 4).	<p>Amenorrhea occurs in about 7% of implants users in the first year and decreases thereafter (USFDA 1990). Amenorrhea for 6 weeks or more, especially after a pattern of regular menses, however, may signal pregnancy and should be evaluated.²</p> <p>If not pregnant, no treatment is required except counseling and reassurance. Explain that blood does not build up inside the uterus with amenorrhea. (The continued action of small amounts of a progestin, such as LNG, shrinks the endometrium, leading to decreased menstrual bleeding and, in some women, no bleeding at all.) Finally, advise client to return to the clinic if amenorrhea continues to be a concern.</p> <p>If intrauterine pregnancy is confirmed, counsel client regarding options. If the pregnancy will be continued, remove capsules and assure her that the small dose of levonorgestrel (LNG) to which she was exposed will have no harmful effect on the fetus.</p> <p>If miscarriage (spontaneous abortion) occurs (or pregnancy will not be continued) it is not necessary to remove the Norplant implants.</p> <p>If ectopic pregnancy is suspected, refer at once for complete evaluation.</p>

² If pregnancy cannot be confirmed by pelvic exam (and pregnancy test is not available), either refer client for pregnancy test, or counsel her to return in 2 to 4 weeks for repeat exam.

SIDE EFFECT	ASSESSMENT	MANAGEMENT
Amenorrhea <i>continued</i>		Do not give hormonal treatment (COCs) to induce withdrawal bleeding. It is not necessary and usually is not successful unless 2 or 3 cycles of COCs are given (TGWG 1994).
Bleeding/Spotting (prolonged spotting or moderate bleeding)	Perform pelvic examination (speculum and bimanual) to be sure bleeding is not due to other causes (e.g., genital tract lesions such as vaginitis, cervicitis, cervical polyps or uterine fibroids).	If an abnormality of the genital tract is found, treat the problem and counsel the client or refer for further evaluation. Do not remove implants. Advise client to return for additional counseling after management of problem(s).
Prolonged spotting: > 8 days		
Moderate bleeding: same as normal menses (50 to 80 ml per menses)		Reassure client that light, intermenstrual bleeding or spotting occurs in a large percentage of women using Norplant implants (50-60% of women during the first few months 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 6 to 12 months (Population Council 1990).
		If the client is not satisfied after counseling and reassurance, but wants to continue using implants, two treatment options are recommended: <ul style="list-style-type: none"> • a cycle of COCs (30 to 35 µg EE), or • ibuprofen (up to 800 mg 3 times daily for 5 days) or other NSAID (TGWG 1994).
		Be sure to tell the client to expect bleeding during the week after completing the COCs (21 pill pack) or during the last 7 pills if a 28 pill pack.
	If pregnancy (intrauterine or ectopic) or incomplete abortion is suspected, examine and perform pregnancy test if indicated and available.	See Amenorrhea above for management of pregnancy-related conditions.

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SIDE EFFECT	ASSESSMENT	MANAGEMENT
Bleeding (prolonged or heavy bleeding)	Perform pelvic examination (speculum and bimanual) to be sure bleeding is not due to other causes (e.g., genital tract lesions such as vaginitis, cervicitis, cervical polyps or uterine fibroids).	If an abnormality of the genital tract is found, treat the problem and counsel or refer for further evaluation. Do not remove capsules.
Prolonged bleeding: > 8 days		Advise client to return for additional counseling after management of problem(s).
Heavy bleeding: > normal menses	If pregnancy (intrauterine or ectopic) or incomplete abortion is suspected, examine and perform pregnancy test if indicated and available.	See Amenorrhea (p. 8-4) for management of pregnancy-related conditions.
	If no genital tract abnormality noted, check for significant anemia (pale conjunctiva or nail beds, low hematocrit or hemoglobin).	For hemoglobin ≤ 9 g/dl or hematocrit ≤ 27 , give iron (FeSO ₄ , 1 tablet daily for 1 to 3 months) and nutritional counseling. If anemia persists or client requests, remove capsules and help client choose another method.

Note: Despite the increased frequency of bleeding in some women, the monthly blood loss in Norplant implants users usually is less than with normal menses in noncontracepting women. In some users, hemoglobin levels increase over time. (More women have increases than have decreases in hemoglobin.) (Population Council 1990)

SIDE EFFECT	ASSESSMENT	MANAGEMENT
Bleeding (prolonged or heavy bleeding) <i>continued</i>	No other cause found, but client has prolonged bleeding (more than 8 days) or amount is more than normal menses.	If the client is not satisfied after counseling and reassurance, but wants to continue using implants, two treatment options are recommended: <ul style="list-style-type: none">• a cycle of COCs (30 to 35 µg EE), or• ibuprofen (up to 800 mg 3 times daily for 5 days) or other NSAID (TGWG 1994).
	No other cause found, but bleeding is: <ul style="list-style-type: none">• not reduced in 3 to 5 days, or• much heavier (1 to 2 pads per hour).	Be sure to tell the client to expect bleeding during the week after completing the COCs (21 pill pack) or during the last 7 pills if a 28 pill pack. If client wants to continue using implants, give: <ul style="list-style-type: none">• 2 COC pills per day for the remainder of the cycle (at least 3 to 7 days) followed by 1 cycle (1 pill per day) of COCs.• Alternatively (if available), switch to 50 µg EE-containing COC, 50 µg EE or 1.25 mg conjugated estrogen (Premarin) for 14 to 21 days (TGWG 1994).

Note: With either treatment, check to be sure bleeding has decreased within 3 days.

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SIDE EFFECT	ASSESSMENT	MANAGEMENT
Capsule expulsion	Check for partial or complete expulsion of capsules(s).	Remove partially expelled capsule(s). Check to determine if remaining capsules are in place. <ul style="list-style-type: none"> • If area of insertion is not infected (no pain, heat and redness), replace capsule(s). • If area of insertion is infected: <ul style="list-style-type: none"> - remove remaining capsules, - insert a new set in the other arm, or - help the client choose another method.
Infection at insertion site	Check area of insertion for infection (pain, heat and redness), pus or abscess.	If infection (not abscess): <ul style="list-style-type: none"> • clean area (soap and water or antiseptic), and • give appropriate oral antibiotic for 7 days. <p>Do not remove capsules. Ask client to return after 1 week. If no improvement, remove capsules and insert a new set in the other arm or help client choose another method.</p> <p>If abscess:</p> <ul style="list-style-type: none"> • Prep with antiseptic. • Incise and drain. • Remove capsules. • Perform wound care. • Give oral antibiotics for 7 days.
Lower abdominal/ pelvic pain (with or without symptoms of pregnancy)	Take history, perform abdominal and pelvic (speculum and bimanual) examinations. <p>Check vital signs:</p> <ul style="list-style-type: none"> • pulse, • blood pressure, and • temperature. 	<p>Refer immediately if the client has any of the following:</p> <ul style="list-style-type: none"> • Moderate to severe lower abdominal tenderness (rebound) • Elevated resting pulse (> 100 BPM) • Decreased blood pressure (< 90/60) • Elevated temperature (> 38.3°C) • Suspected/confirmed pregnancy and acute anemia (e.g., hemoglobin ≤ 9 gm/dl or hematocrit ≤ 27)

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SIDE EFFECT	ASSESSMENT	MANAGEMENT
Lower abdominal pain <i>(continued)</i>	<p>Examine to rule out:</p> <ul style="list-style-type: none"> • ectopic pregnancy, • PID, • appendicitis, and • ovarian cysts. <p>Do lab tests for Hb/Hct and a pregnancy test if indicated and available.</p>	<p>In some women with Norplant implants, ovarian follicles develop and their shrinkage (atresia) 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 6 months of use, generally are asymptomatic and often are palpable.</p> <p>In most cases the enlarged follicles disappear spontaneously and should not require treatment or removal of capsules. Rarely, they may twist or rupture, sometimes causing abdominal pain, and surgical intervention may be required.</p>
“Missing” capsules	<p>Usually due to capsules being inserted too deep (not palpable) or, rarely, to less than six inserted or a capsule spontaneously expelled and forgotten by the client.</p>	<p>Can almost always be detected by x-ray (see Chapter 9) or sonography. If regular sonography is used, the focal length needs to be increased to about 15 cm to accurately focus. Capsules best seen in cross-section (transverse) as a shadow (echo-free area) under each capsule. If six capsules are present, do nothing until removal. At that time, the special studies/tests may need to be repeated to localize the capsules and an expert in removal of Norplant implants consulted.</p>
Weight gain or loss (change in appetite)	<p>Compare preinsertion weight (if known) and current weight.</p> <p>Check for pregnancy.</p> <p>Check that the client is eating and exercising properly.</p>	<p>Counsel client that normal fluctuations of 1 to 2 kg (2 to 4 lbs) may occur.</p> <p>Review diet if weight change is excessive (\pm 2 kg or more). If weight gain (or loss) is unacceptable even after counseling, remove capsules and help client choose another method.</p>

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MANAGEMENT OF OTHER HEALTH PROBLEMS

Clients may present with other problems which **may or may not** be method-related. The assessment and management of these problems are presented below.

PROBLEM	ASSESSMENT	MANAGEMENT
Acne	Ask how and how often she cleans her face. Ask if she is currently under great stress.	Acne can worsen with implants use. Recommend cleaning face twice a day with an astringent like lemon, and avoid using heavy facial creams. Counsel as appropriate. If condition is not tolerable, help client choose another (nonhormonal) method.
Breast fullness or tenderness (mastalgia)	<p>Check for pregnancy.</p> <p>Check breasts for:</p> <ul style="list-style-type: none">• lumps or cysts, and• discharge or galactorrhea (leakage of milk-like fluid) if not breastfeeding. <p>If she is breastfeeding and breast(s) is tender, examine for breast infection.</p>	<p>If pregnant, manage as described in Amenorrhea (p. 8-4).</p> <p>If not pregnant, usually improves within 3 months of insertion of implants.</p> <p>Do not remove capsules unless client requests it after counseling.</p> <p>If physical examination shows lump or discharge suspicious for cancer (firm, nontender or fixed which does not change during menstrual cycles), refer to appropriate source for diagnosis. If no abnormality present, reassure.</p> <p>If breast(s) is not infected, recommend appropriate clothing for additional support.</p> <p>If breast infection, use warm compresses, advise to continue breastfeeding and give antibiotics as appropriate.</p>

PROBLEM	ASSESSMENT	MANAGEMENT
Chest pain (especially if it occurs with exercise, uncommon)	Assess for possible cardiovascular disease (CVD). Check: <ul style="list-style-type: none"> • blood pressure, and • heart for irregular beats (arrhythmias). 	If strong evidence for CVD, refer for evaluation. Low-dose progestins do not increase the risk of CVD; therefore, removal of implants is not necessary unless requested by the client.
Depression (mood changes or loss of libido)	Discuss changes in mood.	Depression may be related to the LNG; therefore, if client thinks her depression has worsened while using Norplant implants, help her choose another method. If the implants have not caused depression to worsen, they can be continued.
Excess hair growth (hirsutism) or hair loss	Review history, before and after insertion.	Pre-existing conditions such as excess facial or body hair might be worsened. Changes usually are not excessive, may improve over time and do not require capsule removal unless client requests it after counseling.
Headache (especially with blurred vision)	Ask if there has been a change in pattern or severity of headaches since insertion of implants. Perform physical examination, measure blood pressure. Examine as appropriate: <ul style="list-style-type: none"> • eyes (fundoscopic), and • neurologic system. 	If headaches are mild, treat with analgesics and reassure. Re-evaluate after 1 month if mild headaches persist. If headaches have changed since starting implants (i.e., numbness, tingling or loss of speech; visual changes or blurred vision) refer for further evaluation by a neurologist, remove implants and help client choose another (nonhormonal) method. ³

³ Rarely, women of all ages, but especially those in the childbearing years, who are overweight (> 20% of their ideal body weight), may develop benign intracranial hypertension (pseudotumor cerebri). This problem has been reported in fewer than 20 Norplant implant users in the US (Deitch 1994). The cause is unknown. Papilledema (swelling of the retina) is the key physical finding. Because no cause and effect relationship between LNG and other drugs, including vitamins, has been demonstrated for women developing this problem, removal may or may not improve the symptoms.

PROBLEM	ASSESSMENT	MANAGEMENT
High blood pressure	<p>Check blood pressure.</p> <p>Confirm that BP is truly elevated:</p> <ul style="list-style-type: none"> • > 180/105 on 1 visit, or • > 160/90 on 2 more visits, 1 week apart. 	<p>Counsel client that a mild increase in blood pressure (< 160/90) does not require removal of implants unless she requests it (WHO 1994). If blood pressure is truly elevated, help the client choose another method. In addition, tell her that high BP usually goes away within 1 to 3 months. Take BP monthly to be sure it returns to normal. If after 3 months it has not returned to normal, refer for further evaluation.</p> <p>If BP > 180/105 or she has vascular problems (neuropathy or retinopathy), the implants should be removed (WHO 1994). Help her choose another method.</p>
Jaundice	<p>Acute jaundice occurring after insertion is not method-related. Check for:</p> <ul style="list-style-type: none"> • active liver disease (hepatitis), • gall bladder disease, or • benign or malignant liver tumors. 	<p>Levonorgestrel has little effect on liver function and does not increase the risk of gall bladder disease or liver tumors. If the client has jaundice due to viral hepatitis and does not want to stop using implants, it is unlikely that they will worsen liver disease and their use is safer than pregnancy (McCann and Potter 1994).</p>
Nausea/ Dizziness/ Nervousness	<p>Check for pregnancy by reviewing symptoms, performing a pelvic examination (speculum and bimanual) and a pregnancy test (if indicated and available).</p>	<p>If pregnant, manage as described in Amenorrhea (p. 8-4).</p> <p>If not pregnant, reassure that this is not a serious problem(s) and usually disappears with time.</p>
Thromboembolic disorders (including blood clots in legs, lungs or eyes)	<p>Assess for active blood clotting problem.</p>	<p>Norplant implants do not increase the risk of blood clotting problems (WHO 1994); therefore, remove capsules only at client's request. If there is strong evidence of blood clotting disorder, refer for further evaluation.</p>

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REMOVAL

BACKGROUND

Unlike insertion, removal of Norplant implants does not have to be timed to the menses and can be done at any time. As has been stressed throughout other sections of this manual, correct insertion—with the capsules placed subdermally—makes the removal procedure much easier (Darney and Klaisle 1995).

While all types of clinicians (physicians, nurses and midwives) can be trained to insert and remove the capsules, a clinician **skilled in removal** should be consulted if difficulty in removing the capsules is anticipated.¹ Clinicians need to work gently, carefully and patiently when removing capsules. As with insertion, using the recommended infection prevention practices (see **Chapter 5**) is essential to minimizing infections following removal of the implants and the risk of disease transmission.

The material presented in this chapter 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 for the clinician to become proficient in removal of Norplant implants.

REMOVAL METHODS

The **standard** removal method using Crile or mosquito forceps to grasp the implants was developed in the early 1980s. Details of this technique were published in 1990 by the Population Council and in the WHO guidelines for Norplant implants and are fully described in this chapter.

Since that time, however, several investigators have reported modifications to the **standard** method such as the “pop-out” technique described by Darney et al in 1992. The fact that improvements in the method of removal continue to be sought, while changes in the insertion technique have been few, suggests that the standard removal technique is not entirely satisfactory. This observation is supported by the experience in several countries. Removal requires more patience and skill than insertion. Moreover, with atypically placed capsules (i.e., those inserted too deep and/or in an irregular pattern), removal using any technique takes longer and is associated with more blood loss than insertion (WHO 1990).

Recently, Praptohardjo and Wibowo (1993) reported a new method for removal of subdermal contraceptive implants, called the “U” technique. The major differences between the “U” and **standard** techniques are:

¹ Difficulty in removing capsules can be anticipated if the capsules are not easily palpable (inserted too deep) or are not inserted in a fan-like pattern (atypically inserted).

Removal

- position of the skin incision, and
- use of the Norplant implants-holding forceps, a modified no-scalpel vasectomy (NSV)-holding forceps, in which the diameter of the tip is reduced from 3.5 to 2.2 mm.

This new method also is described in detail in this chapter.

PREPARATION

It is important that the instruments be in excellent condition (e.g., the scalpel must be sharp and the forceps should have a very tight grasp). In addition, check that all instruments and other items have been sterilized or high-level disinfected (see **Chapter 5 and Appendix C**).

The following items are needed for each removal (**Figure 9-1**):

- examining table for the woman to lie on;
- arm support or side table;
- soap for washing the arm;
- sterile (or clean), dry surgical drape;
- three bowls (one for the antiseptic solution, one for cotton balls soaked with boiled or sterile water to remove the talc from gloves and one containing 0.5% chlorine solution for decontaminating removed capsules);
- pair of sterile (or high-level disinfected) surgical gloves;

- antiseptic solution;
- local anesthetic (1% concentration **without** epinephrine);
- syringe (5 or 10 ml) and 2.5 to 4 cm (1-1½ inches) long needle (22 gauge);
- scalpel with #11 blade;
- curved and straight forceps (mosquito and Crile);
- ordinary bandaid or sterile gauze with surgical tape;
- sterile gauze and compresses; and
- epinephrine for anaphylactic shock (readily available for emergency use).

Figure 9-1. Basic Equipment and Materials for Removal



Adapted from: Population Council 1990.

The insertion/removal kit supplied by USAID contains all the instruments needed for insertion and removal of Norplant implants using the **standard** method.

PREREMOVAL COUNSELING

Before removing the capsules, talk with the client about her reason for removal and answer any questions. Ask the client about her present reproductive goals (e.g., Does she want to continue spacing or limiting births?). Briefly describe the removal process and what she should expect both during the removal and afterwards.

GENERAL PROCEDURES

An easy removal depends on correct insertion. Routinely, removals take slightly longer than insertions—usually from 10 to 20 minutes.

If the capsules were placed properly they will be easier to remove; if they were placed too deep, removal could be difficult.

It is helpful to locate the capsules first with ungloved fingers. Most clinicians choose to mark the position of each capsule with a ballpoint or marking pen. Then, the client's arm is swabbed with an antiseptic before the local anesthetic is injected. The anesthetic should be injected **under** the ends of the capsules nearest the incision site; **anesthetic applied over the capsules makes them difficult to feel (palpate)**.

Generally, only one small incision will be needed through which all six capsules will be removed. The incision should be no longer

than 4 mm. Where the incision is placed will depend on the position of the implants (i.e., correctly or typically placed) and removal method used—the **standard** or “**U**” technique (see below).

The first capsule to be removed should be the one that is easiest to reach (i.e., closest to the surface or nearest the incision). If the last one or two capsules prove difficult to remove, heroic measures should not be taken to remove them. If all six capsules are not removed in 20 to 30 minutes, stop the procedure. The client should be provided with a backup contraceptive method (if desired) and asked to return when the area is fully healed (in about 4 to 6 weeks), when a second attempt can be made. (Hard-to-find capsules can be located by x-ray or ultrasound.) Finally, clinicians need to work gently, carefully and patiently.

STEP-BY-STEP INSTRUCTIONS FOR REMOVAL

Before starting the procedure, check to be certain the client is not allergic to local anesthetics.

Getting Ready

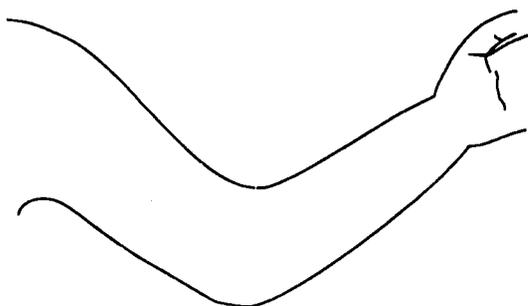
STEP 1: Have the client wash her entire arm with soap and water, and rinse, being sure to remove all traces of soap. (Residual soap decreases the effectiveness of some antiseptics.) This step is particularly important when client hygiene is poor.

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

Removal

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 should be well-supported and able to be comfortably extended straight or slightly bent, as the clinician prefers.

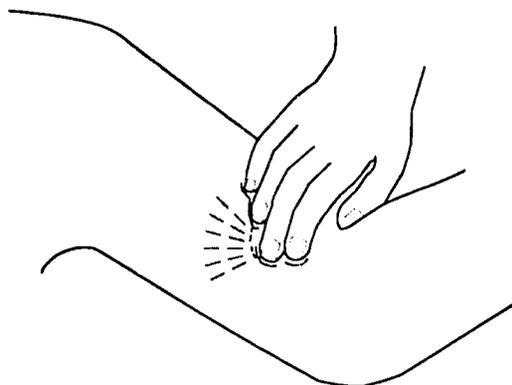
Figure 9-2. Positioning the Arm



STEP 4: 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 the original capsule placement should be noted and a diagram may be available.)

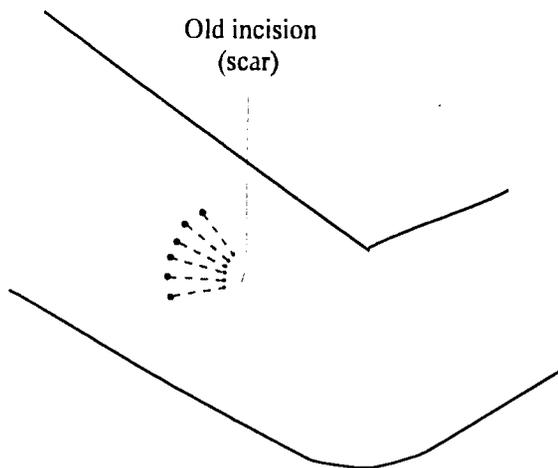
Tip: To make locating the capsules easier, moisten fingertips with a small amount of soapy water or antiseptic solution, such as Betadine or Savlon. Doing this decreases friction between the clinician's fingertips and the client's skin and allows the capsules to be more easily felt.

Figure 9-3. Palpating the Capsules



STEP 5: Confirm the position of each capsule by making a mark at both ends of the capsules (tips) using a ballpoint or marking pen (**Figure 9-4**).

Figure 9-4. Marking the Capsules



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

Preremoval Tasks

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

STEP 2: Put sterile or high-level disinfected gloves on both hands. (A separate pair of gloves must be worn for each client to avoid cross-contamination.)

Note: Do not use powder with gloves. The tiny granules (talc) may fall into the removal site and cause scarring (fibrous reaction). If gloves are powdered, wipe off the fingers with sterile gauze soaked with sterile or boiled water.

STEP 3: Arrange supplies and instruments so that they are easily accessible.

STEP 4: Prep the removal site with an antiseptic solution. Use a sterile or high-level disinfected sponge forceps to hold a cotton or gauze swab soaked with antiseptic solution. (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 to 13 cm (3 to 5 inches) and allow to air dry before proceeding. Wipe off excess antiseptic only if necessary to see pen marks.

STEP 5: If a sterile surgical drape with a hole in it is available, it should be used to cover the arm. The hole should be large enough 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

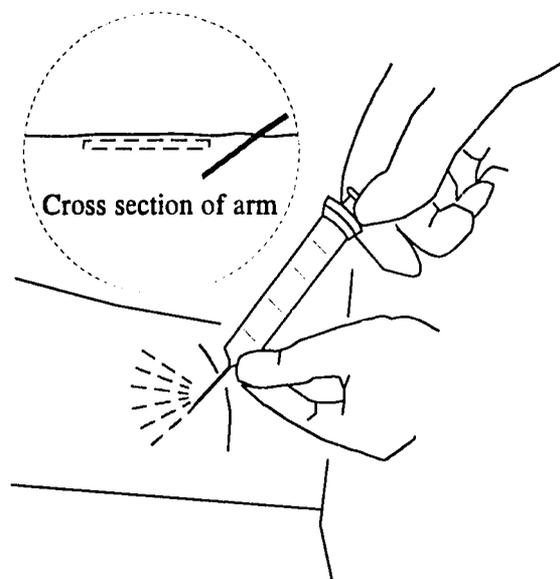
decontaminated, cleaned and machine- or air-dried cloth can be used.)

STEP 6: Again, locate the six capsules by palpation.

STEP 7: After determining the absence of known allergies to the anesthetic agent or related drugs, fill a syringe with about 3 ml of a local anesthetic (1% **without** epinephrine). Insert the needle just under the skin where the incision will be made. Next, pull back on the plunger to be sure the needle is not in a blood vessel (aspirate). Inject a small amount of anesthetic to raise a small wheal (raised area).

Gently advance the needle under the first capsule, about one third of its length (1 cm). Slowly withdraw the needle while injecting anesthetic (about 0.5 ml) to raise the end of the capsule (**Figure 9-5**).

Figure 9-5. Injecting the Anesthetic Under the Capsules



Source: Population Council 1990.

Removal

Remember: Correctly injecting the local anesthetic under the tips of the capsules is critical to an easy and rapid removal.

Without removing the needle, slide the tip over and insert it under the next capsule. Repeat this process until the ends of all six capsules are raised. **Never** put anesthetic over the capsules because the tissue swelling makes it difficult to palpate the capsules. If necessary, additional small amounts of anesthetic can be added as the removal process continues. Before starting, gently touch the incision site with the hypodermic needle or scalpel to be sure the anesthetic is working.

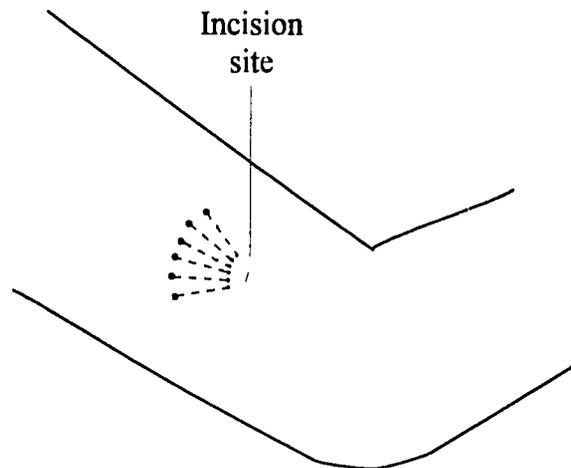
Note: To prevent local anesthetic toxicity, the total dose should not exceed 10 ml (10 grams/liter) of a 1% local anesthetic **without** epinephrine.

PROCEDURE TO REMOVE CAPSULES: STANDARD METHOD

STEP 1: Choose a point for the incision that is equidistant from the ends of **all** the capsules and which is close to and about 5 mm **below** the distal (toward the elbow) ends of the capsules (**Figure 9-6**).

If appropriate, the removal incision may be made at the point of the previous 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.)

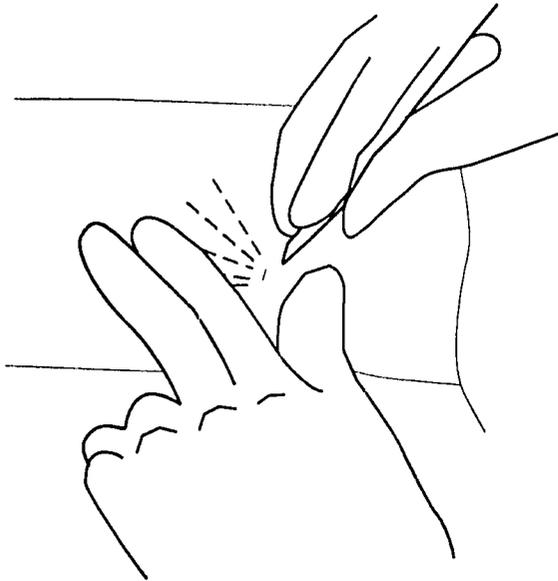
Figure 9-6. Location of Incision in the Standard Technique



Adapted from: Population Council 1990.

STEP 2: At the site chosen, make a small **transverse** incision of about 4 mm or less with a scalpel. **Do not make a large incision** (**Figure 9-7**).

Figure 9-7. Making the Incision

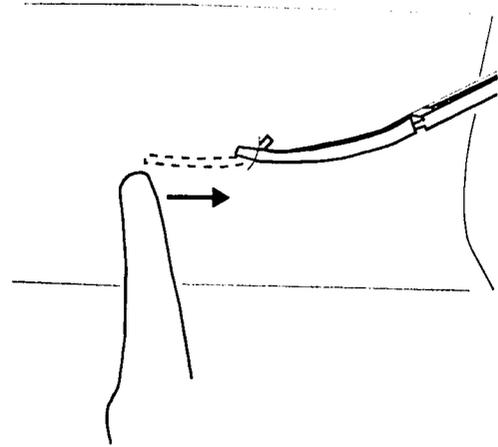


Note: If another set of capsules is to be inserted, usually the same incision can be used for both removal and insertion of a new set (see **Second Insertions** in this chapter).

STEP 3: Begin by selecting the capsule closest to the surface or nearest the incision.

STEP 4: Push the tip of the capsule gently toward the incision with the gloved fingers of one hand until it can be seen at the incision. When the tip is visible in the incision, insert the curved forceps (mosquito or Crile) with the jaws curving up and grasp the end of the capsule (**Figure 9-8**).

Figure 9-8. Grasping the Capsule with the Curved Forceps



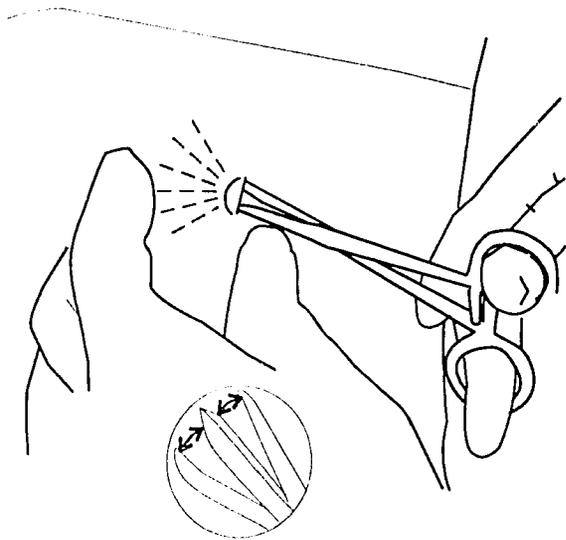
Note: If the capsules cannot be easily moved into the incision, this may be due to scarring (fibrous tissue formation) around the tips of the capsules. (See **Steps 4A and 4B** for how to break up the scar tissue.)

STEP 4A: Insert the curved forceps through the incision with the jaws pointed up toward the skin and advance until they are below the ends (tips) of the capsules nearest the elbow. Then open and close the forceps' jaws (blunt dissection) to break up the scar tissue surrounding the tip of the capsule (**Figure 9-9**). Repeat until the tips of all six capsules are freed up (easily moveable).

Removal

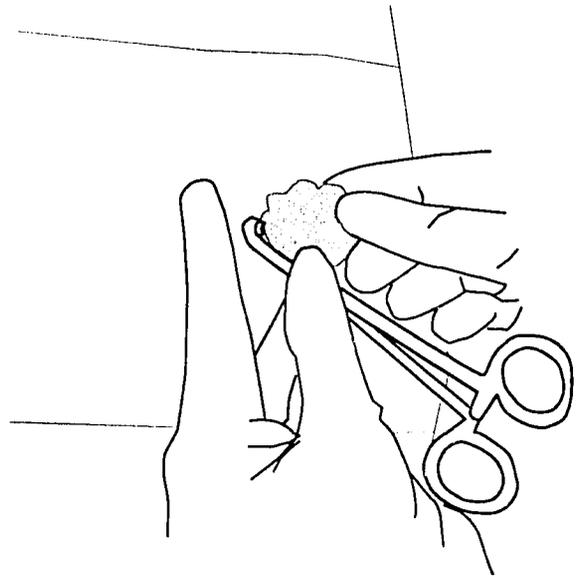
STEP 4B: Next, push the tip of the first capsule as close to the incision as possible. While pressing on (stabilizing) the capsule with the first (forefinger) and middle fingers of one hand, re-insert the curved forceps under the end of the capsule (jaws pointing up toward the skin), grasp the capsule near the tip (5 to 10 mm) and gently pull it into the incision (**Figure 9-8**).

Figure 9-9. Breaking Up Scar Tissue (Blunt Dissection)



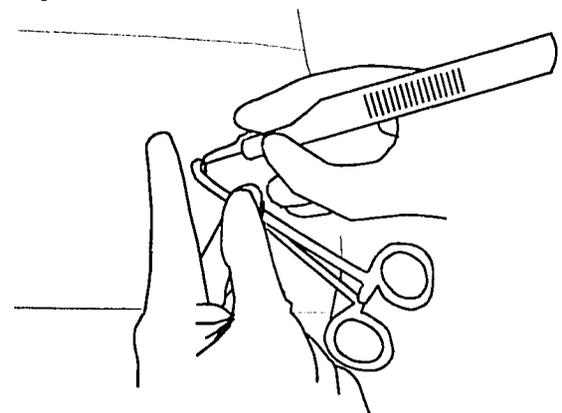
STEP 5: Clean off and open the fibrous tissue sheath surrounding the capsule by rubbing vigorously with sterile gauze to expose the tip of the capsule (**Figure 9-10**).

Figure 9-10. Opening the Fibrous Sheath with Sterile Gauze



Alternatively, if the fibrous tissue sheath cannot be opened by rubbing, the scalpel can be used. To avoid cutting the capsule, use the back side (non-sharp edge) of the scalpel (**Figure 9-11**).

Figure 9-11. Opening the Fibrous Sheath with the Scalpel

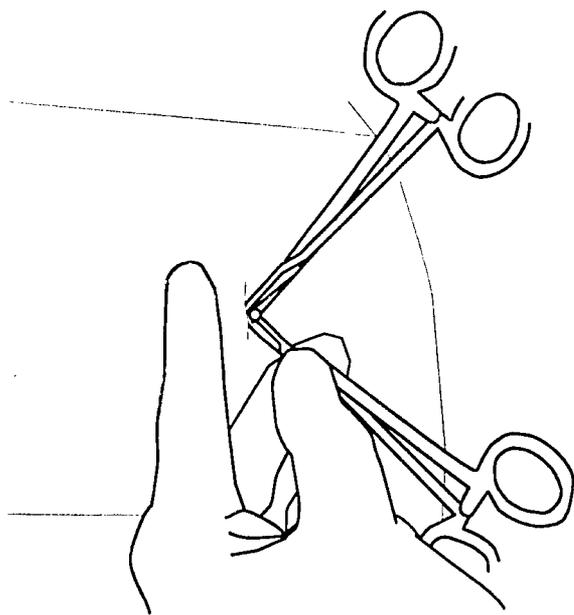


Adapted from: Population Council 1990.



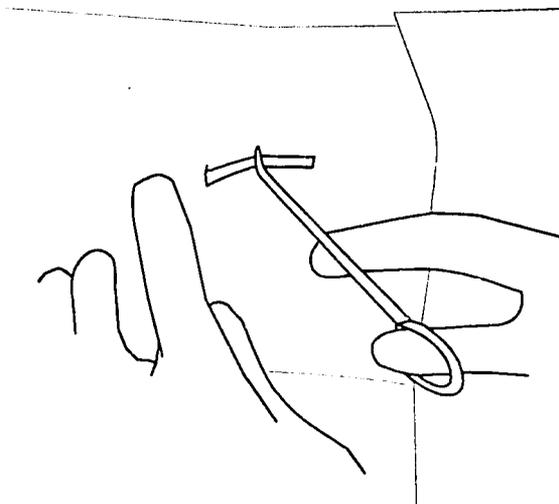
STEP 6: Grasp the freed tip of the capsule with a second pair of forceps (**Figure 9-12**). Release the first forceps and slowly and gently remove the capsule with the second forceps (**Figure 9-13**). Because tissue usually does not adhere to silicone rubber, the capsule should slide out easily. If for some reason the capsule does not come out easily, remove any remaining fibrous tissue from the capsule by gently rubbing with sterile gauze or scraping with the scalpel blade.

Figure 9-12. Grasping the Freed Capsule with the Second Forceps



Adapted from: Population Council 1990.

Figure 9-13. Capsule Removal



Adapted from: Population Council 1990.

Note: As capsules are removed, place them in a small bowl containing 0.5% chlorine solution for decontamination prior to disposal. Capsules can be easily counted in the bowl to be sure all six have been removed. In addition, by looking at the capsules in the bowl, the clinician can tell whether or not the capsules are broken—undamaged capsules will float; broken capsules will sink gradually to the bottom.

STEP 7: The next capsule that appears easiest to retrieve should be selected and removed. Repeat using the same technique (**Steps 4 to 6**) to remove the remaining capsules.

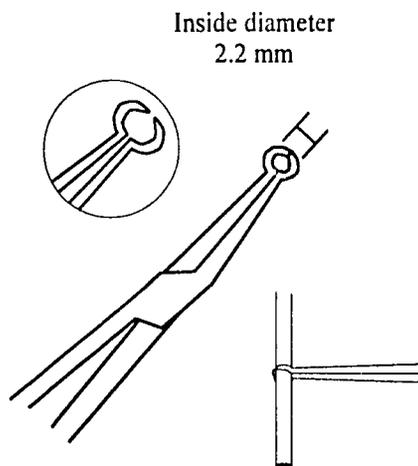
Remember: If additional anesthetic is required, inject it only **under** the capsules so as to not obscure them.

Before ending the procedure, **count to be sure that all six capsules have been removed.** It is important to show the client all six capsules to reassure her. (If the client wishes to continue using Norplant implants, see subsequent section on **Second Insertions.**)

**PROCEDURE TO REMOVE CAPSULES:
“U” TECHNIQUE**

The forceps used for the “U” technique removal method is a modified no-scalpel vasectomy (NSV)-holding forceps with a tip diameter of 2.2 mm (**Figure 9-14**).

Figure 9-14. Norplant Implants-Holding Forceps

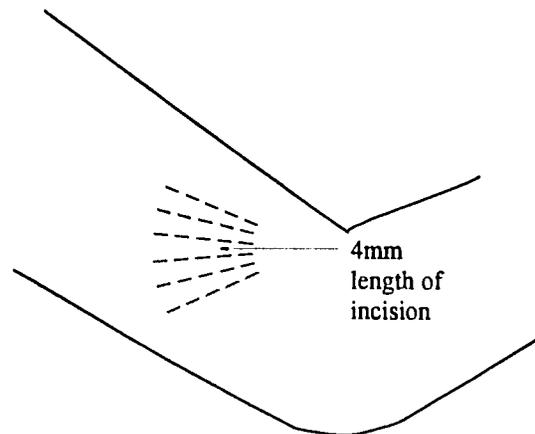


Source: Praptohardjo and Wibowo 1993.

To use this removal technique, carefully palpate the area to locate and mark the capsules. Next, wash hands and put on sterile or high-level disinfected gloves. Clean and prep the skin and inject the local anesthetic in the client's arm as previously described (**Getting Ready and Preremoval Tasks**).

STEP 1: Choose a point for the incision between capsules 3 and 4, about 5 mm from the tips of the capsules nearest the elbow (**Figure 9-15**).

Figure 9-15. Location of Incision in the “U” Technique



Adapted from: Praptohardjo and Wibowo 1993.

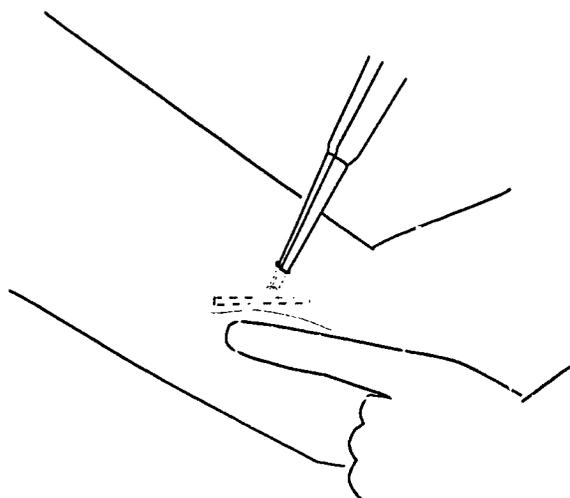
Note: If another set of capsules is to be inserted, usually the same incision can be used for both removal and insertion of the new set (see below, **Second Insertions**).

STEP 2: Make a small vertical incision with a scalpel parallel to (and between) the long axis of the capsules.

STEP 3: Begin by gently inserting the **Norplant implants-holding forceps** through the incision. (With this technique it is not necessary to bluntly dissect the underlying tissue as with the **standard** method.)

STEP 4: Now stabilize the capsule that is closest to the incision by placing the index finger (forefinger) parallel to (along the length of) the capsule (**Figure 9-16**).

Figure 9-16. Stabilizing the Capsule

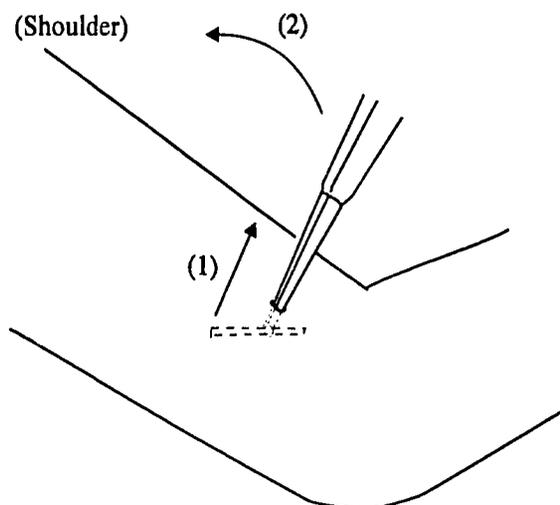


Source: Praptohardjo and Wibowo 1993.

STEP 5: Next, advance the forceps until the closed tip touches the capsule. Then, open the forceps and grasp the capsule at right angles to its long axis about 5 mm above the distal tip (**Figure 9-17**).

Finally, after grasping the capsule gently pull it toward the incision (1) and flip the handle of the forceps 180° toward the client's shoulder (2) to expose the capsule.

Figure 9-17. Grasping the Capsule and Flipping the Forceps



Source: Praptohardjo and Wibowo 1993.

STEP 6: Clean off and open the fibrous tissue sheath surrounding the capsule by rubbing with sterile gauze to expose the tip of the capsule for easy removal (**Figure 9-10**). Alternatively, if the fibrous tissue sheath cannot be opened by rubbing, the scalpel can be used (**Figure 9-11**).

STEP 7: Use the curved forceps (mosquito or Crile) to grasp the exposed part of the capsule. Release the Norplant implants-holding forceps and slowly and gently remove the capsule (**Figure 9-13**). Finally, place the capsule in a small bowl containing 0.5% chlorine for decontamination prior to disposal.

Because tissue usually does not adhere to silicone rubber, the capsule should slide out very easily. If for some reason the capsule does not come out easily, remove any remaining fibrous tissue from the capsule by gently rubbing with sterile gauze or the non-sharp edge of the scalpel.

Removal

STEP 8: The next capsule that appears easiest to retrieve on either side of the incision should be removed. Repeat using the same technique (**STEPS 3-7**) to remove the remaining capsules.

Remember: If additional anesthetic is required, inject it only **under** the capsules, so as not to obscure them.

Before ending the procedure, **count to be sure that all six capsules have been removed**. It is important to show the client all six capsules to reassure her. (If the client wishes to continue using the Norplant implants, see section on **Second Insertions**.)

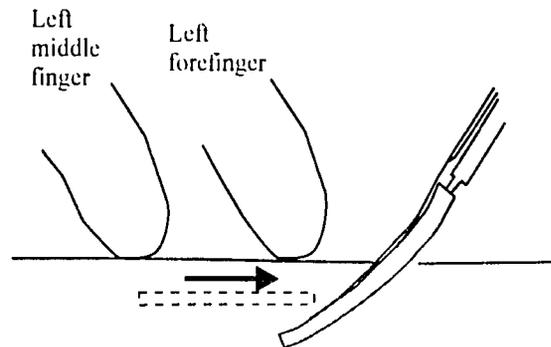
REMOVING HARD-TO-RETRIEVE CAPSULES

Occasionally, one or more of the capsules may be difficult to remove. For example, even after bluntly breaking up the scar tissue, the tip of a capsule cannot be pushed close to the incision site or the capsule has been inserted too deep (i.e., into the subcutaneous or fatty tissue). If this occurs, the "U" technique may be used to remove these capsules. Alternatively, follow these steps for removal:

STEP 1: Feel both tips of the capsule with the forefinger and middle finger. Keeping the middle finger on the tip of the capsule nearest the client's shoulder and the forefinger on the tip nearest the elbow, push the capsule as close to the incision as possible (**Figure 9-18**).

STEP 2: Insert the forceps (curved mosquito or Crile) into the incision until the jaws are well beneath the capsule. At the same time, keep pressure on the capsule with your fingers to stabilize it (**Figure 9-18**).

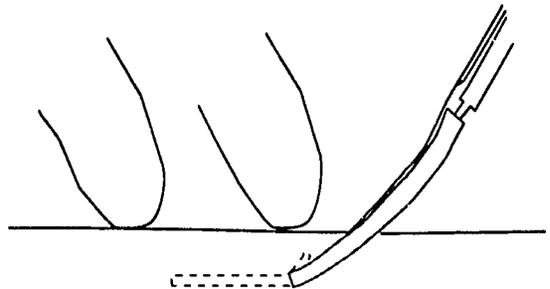
Figure 9-18. Stabilizing the Capsule and Inserting the Forceps



Source: Population Council 1990.

STEP 3: Firmly grasp the capsule from below with the jaws of the curved forceps (**Figure 9-19**).

Figure 9-19. Grasping the Capsule from Below

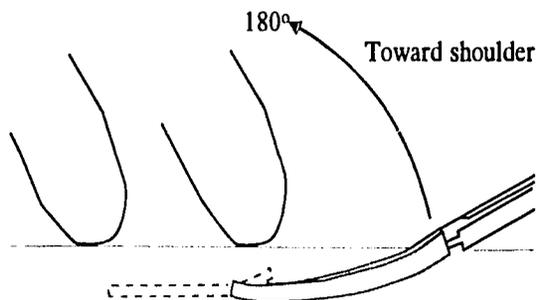


Adapted from: Population Council 1990.

STEP 4: Because 1 to 2 cm of the forceps now are inside the incision, do **not** try to pull the capsule out. Instead, while continuing to push the capsule toward the incision, flip the handle of the forceps 180° toward the client's

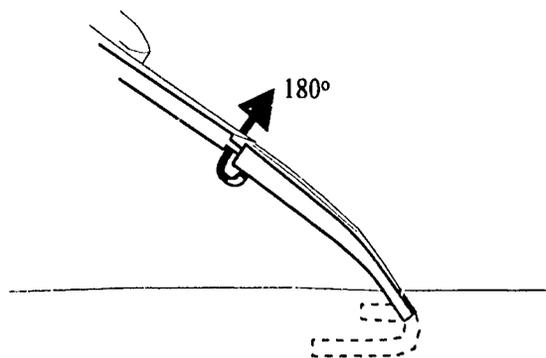
shoulder and grasp the handle with the opposite hand (Figure 9-20).

Figure 9-20. Flipping the Forceps



Note: If the capsule does not become visible after flipping (Step 4): Twist the forceps 180° around its main axis (Figure 9-21). With gentle pulling, the tip of the capsule should then become visible in the incision on the opposite side of the forceps.

Figure 9-21. Twisting the Forceps to Show the Capsule



STEP 5: Clean off and open the fibrous tissue sheath surrounding the capsule by rubbing with sterile gauze to expose the tip of the capsule. Alternatively, if the fibrous

tissue sheath cannot be opened by rubbing, the scalpel can be used.

STEP 6: After opening the fibrous sheath, use the second forceps to grasp the part of the capsule that becomes visible. Release the first forceps and gently remove the capsule.

STEP 7: Any remaining “difficult-to-remove” capsules can be removed using the same technique. If necessary, inject additional small amounts of local anesthetic **under** any remaining capsules.

ALTERNATIVE REMOVAL TECHNIQUE: THE “POP-OUT” TECHNIQUE

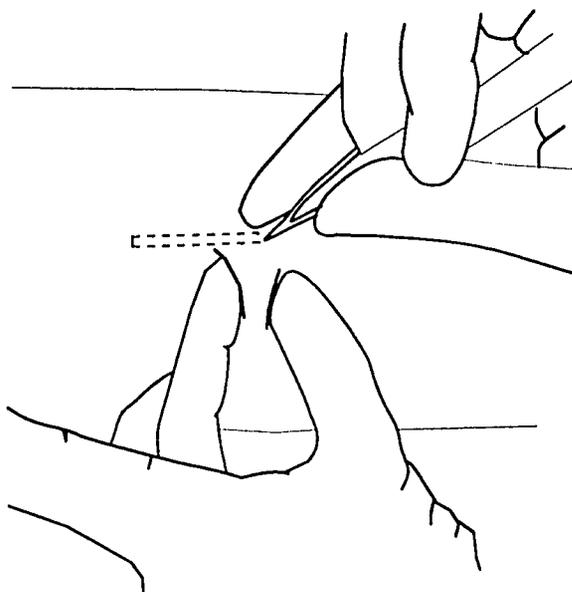
In 1992, Darney, Klaisle and Walker reported a simpler technique for removing some or all of the capsules. This method, called the “pop-out” technique, does not involve the use of forceps. As a result the capsules can be removed with less discomfort and bleeding and usually through a smaller incision. Also, the amount of trauma and bruising is less and the scar is smaller and less visible. Using this approach, the risk of breaking the capsules during removal is reduced. The only **disadvantage** of the “pop-out” technique is that it **may not work** if the capsules were atypically placed (e.g., not in a fan-like pattern) when inserted or if inserted too deep.

To use this technique, carefully palpate the area to locate and mark the capsules. Next, wash hands and put on sterile or high-level disinfected gloves. Clean and prep the skin and inject the local anesthetic in the client's arm as previously described (**Getting Ready and Preremoval Tasks**).

Removal

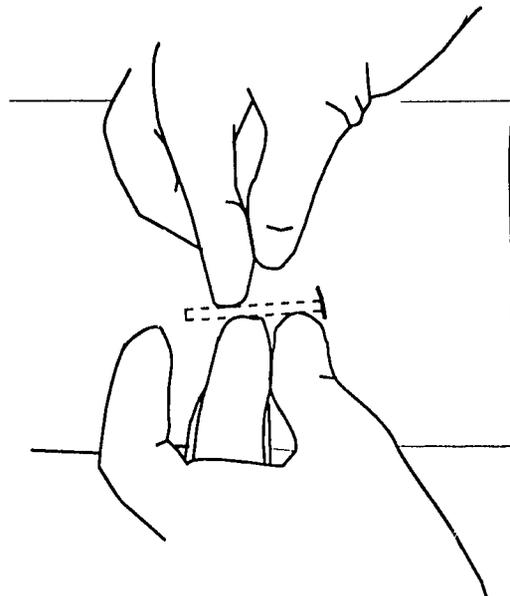
STEP 1: Confirm the location of the capsule which is most centrally positioned and equidistant from the tips of the others. Push on the proximal end (closest to the client's shoulder) of the selected capsule with a finger. When the distal tip (nearest the elbow) is clearly visible (i.e., pushes up under the skin) make a small incision (2 to 3 mm) over the tip with the scalpel (**Figure 9-22**).

Figure 9-22. Making the Incision



STEP 2: Apply pressure with the thumb and middle (second) finger to the distal tip of the capsule in order to bring the tip into better position under the incision (**Figure 9-23**).

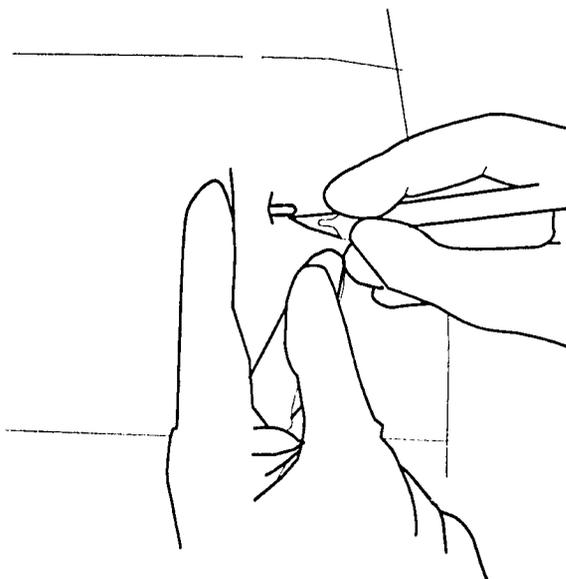
Figure 9-23. Positioning the Distal Tip Under the Incision



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 9-24**).

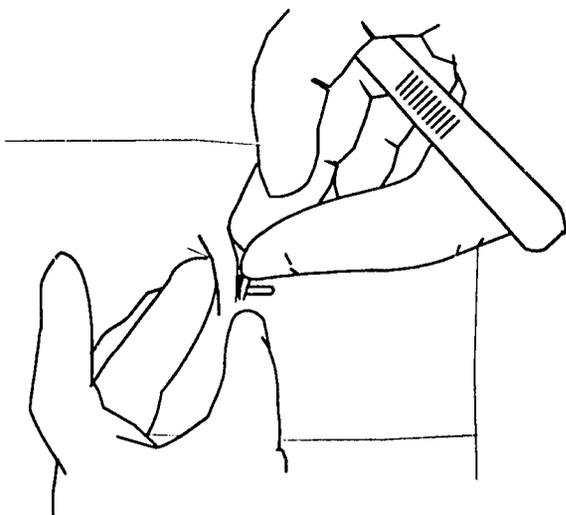
Note: If the scalpel is required to open the fibrous sheath covering the distal end of the capsule, care must be taken to avoid accidentally cutting the capsule.

Figure 9-24. 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 9-25**).

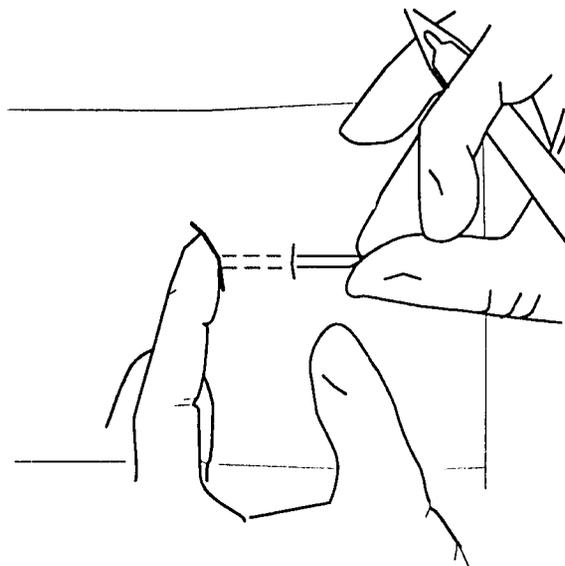
Figure 9-25. Exposing the Distal Tip of the Capsule



STEP 5: With gentle pressure on the proximal end of the capsule (nearest the shoulder), it will “pop-out” of the incision

and can be grasped easily and gently removed (**Figure 9-26**).

Figure 9-26. “Popping Out” the Capsule



Once the first capsule is removed, the remaining ones are “popped out” using the same approach.

Note: 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.

It may not be possible to remove all six capsules using this technique. If difficulty is encountered, remove the remaining capsules using one of the other removal techniques.

Before ending the procedure, **count to be sure that all six capsules have been removed.** The incision is closed with a

Removal

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.

REMOVAL TIPS

Capsules that Are Difficult to Remove

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 20 to 30 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 4 to 6 weeks). Usually the remaining capsules will be readily located and removed at the second visit.

Remember: The client should be given a backup contraceptive method to use while waiting to have the remaining capsule(s) removed **if she does not wish to become pregnant.**

Capsules that Cannot be Palpated

There are two ways to locate 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 are also radiopaque, usually can be detected by x-ray (set at 50-55 kilovolts and 4-5 milliamperes, exposure time 0.03 seconds). Their depth usually cannot be determined by a single x-ray. Thus, further examination may 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). Special adjustments (positioning of the ultrasound probe) may be necessary to focus the ultrasound image.

Capsules that Are Broken

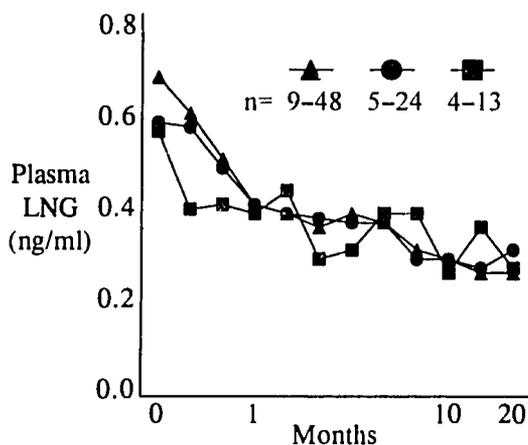
Removal of the capsules is more difficult if they are broken during attempts to get them out. Once the capsule is damaged, it may break again with each attempt to grasp it with the forceps. Rarely, removal of a broken capsule may require an additional incision at the proximal end of the capsule (end nearest the shoulder) so that the remaining piece can be removed more easily.

SECOND INSERTIONS

If the client wants to continue using Norplant implants, a new set of capsules can be inserted at the time the current set is removed. When levonorgestrel levels following first insertion were compared with those following insertion of a second set of implants, no significant difference was observed after placement in the same site or in the opposite arm (**Figure 9-27**).

- The capsules may be placed through the same incision in the same general direction as the previous set.
- Alternatively, the capsules can be inserted in the opposite direction. Be sure the tips of the capsules do not lie so close to the elbow fold as to interfere with movement.

Figure 9-27. Levonorgestrel Plasma Levels. Levels after first insertion of Norplant implants (▲) and after insertion of a second implants set at the same (●) or opposite (■) site.



Adapted from: Croxatto, Diaz and Sivin 1991.

- A new incision should be necessary only if there is too much soft tissue trauma (bruising) in the area of the original insertion or if there is not enough room between the incision and the elbow fold.
- In the unlikely event that the removal site is unsuitable, or at the client's request, the new set can be inserted in the other arm.

PROCEDURE TO FOLLOW AFTER REMOVAL OF CAPSULES

Covering the Incision

- If the client does not want another set of implants, clean the area around the

incision site with a small amount of antiseptic solution applied to a cotton or gauze swab. Use the forceps to hold the edges of the incision together briefly (10 to 15 seconds). This will help reduce bleeding from the incision. Then proceed with bandaging the incision area.

- With the edges of the incision together, close with a bandaid, or surgical tape with sterile cotton. Sutures are not necessary and may increase scarring.² Check for any bleeding.

Waste Disposal and Decontamination

- Before removing gloves, gently place instruments into a container filled with a 0.5% chlorine solution for decontamination (see **Appendix C** for how to make solution from household bleach). Before immersing the needle and syringe, fill with chlorine solution (do not disassemble). Soak all items for 10 minutes, then rinse **immediately** with clean water to avoid discoloration or corrosion of metal items.
- The surgical drape (if used) must be washed before reuse. Place in a **dry** covered container and remove to the designated washing area.
- While still wearing gloves, place all contaminated objects (capsules, gauze, cotton and other waste items) in a properly marked, leak-proof container with a tight-fitting lid or in a plastic bag.

² If removal required extensive blunt dissection, or to minimize bleeding, cover the removal area with a dry compress (pressure dressing) and wrap gauze snugly around the arm.

Removal

- If **disposing** of gloves, immerse both gloved hands briefly in chlorine solution and then carefully remove gloves by turning inside out and place in the waste container.
- If **reusing** gloves, place both gloved hands briefly in the chlorine solution to decontaminate the outside. Remove by turning inside out. To ensure that both surfaces of the gloves are decontaminated, place them in the chlorine solution and soak for 10 minutes.
- Wash hands thoroughly with soap and water.
- All waste material should be disposed of by burning or burying.

Client Care

- Place a note in the client's record indicating the date of removal and specifying any unusual events that may have occurred during removal.
- Observe the client for at least 15 to 20 minutes for bleeding from the incision or adverse effects before sending her home.

CLIENT INSTRUCTIONS FOR WOUND CARE AT HOME

- There may be bruising, swelling or tenderness at the insertion site for a few days. This is normal.
- Keep the area around the removal site dry and clean for at least 48 hours. (The

incision could become infected if the area gets wet while bathing.)

- If used, 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 3 to 5 days).
- Routine work can be done immediately. Avoid bumping the area, carrying heavy loads or applying unusual pressure to the site.
- 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 arm pain for several days, return to the clinic.
- The client should be told when to come back for a followup visit, if needed. Discuss what to do if she experiences any problems. Answer any questions.
- The fibrous sheaths in the arm (tracks where the capsules were located) may be felt for some time. This sensation will disappear within a few months.

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 should take only slightly longer than insertions—usually from 10 to 20 minutes.
- Palpate the area to identify the location of each capsule and mark the position of each capsule with a pen.
- Use recommended infection prevention practices to avoid infections.
- Inject small amounts (usually not more than 3 ml total) of the local anesthetic **under** the capsule ends nearest the original incision site. If anesthetic is applied over the capsules, it will obscure them and make removal more difficult.
- If the capsules are positioned correctly only one small incision (up to 4 mm) should be necessary for removal of all six capsules.
- Remove first those capsules that are nearest the point of the incision or closest to the surface of the skin.
- Add incremental amounts of anesthetic only **under** the capsule tips.
- Control bleeding by applying pressure.
- Do not take extraordinary measures to remove the last one or two capsules if they are difficult to reach. If removal takes more than 30 minutes, ask the client to return when the incision site is fully healed (in about 4 to 6 weeks) and try again or refer to a more experienced clinician.
- Finally, and most importantly, the clinician should work gently, carefully and patiently to avoid injuring the client's arm.

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PROVIDING QUALITY SERVICES

BACKGROUND

Successful family planning service programs are characterized by:

- realistic goals setting,
- emphasis on quality and client satisfaction,
- provision of services in a manner acceptable to the client,
- efficient and effective management and monitoring systems,
- efficient logistics, and
- a good referral system.

The previous chapters focused on the technical competence and skills required to provide Norplant implants services. The **objective** of this chapter is to provide clinicians and clinic managers with information on **how to improve and maintain quality services**.

Quality of care refers to the way in which individuals and couples are treated by the health care system providing services. The quality of care process involves three steps:

- setting standards of care which describe how services will be provided and what the expected results (indicators) will be;
- assessing quality of care by gathering information (data) on whether the standards of care are being met; and

- ensuring (or improving) quality of care by taking corrective action when standards are **not** being met.

Remember: A high quality program is client-oriented and helps individuals achieve their desired reproductive goals.

SETTING QUALITY OF CARE STANDARDS IN NORPLANT IMPLANTS SERVICES

The **first task** for clinicians and program managers concerned with improving client satisfaction and increasing use of Norplant implants is to define the quality of care (standards) they would like to provide within their specific service delivery program. These **standards of care** will form the basis for subsequent **quality assessment** and **quality assurance** (improvement) activities (Jain, Bruce and Mensch 1992).

A quality of care standard is a specific and clear statement of expectation which is:

- measurable,
- attainable,
- relevant, and
- frequency-bound (i.e., how often will it occur, as, for example, "for all clients").

There are several key aspects of service delivery which contribute to client satisfaction. Setting standards of care in these areas helps clinicians and managers **assess** and **improve** the quality of services being offered. Bruce (1990) has defined these as follows:

- **Choice of contraceptives** refers to the variety of contraceptive methods available to an individual/couple. Clinicians should have the knowledge and skills required to offer several family planning methods in order to provide the one most appropriate for each client's needs.
- **Information given to clients** refers to information that enables clients to choose and use a contraceptive method with satisfaction and provides a good understanding of the method. This information should be part of the counseling process (see **Chapter 2**) and includes how the methods work, precautions for use, benefits and limitations, how to use the method selected and any potential side effects. When this task is performed appropriately, clients should be able, for instance, to correctly explain and use the method chosen.
- **Client-provider interaction** refers to the provider's skill in establishing a positive atmosphere and two-way communication to assist clients in discussing any fears, misgivings or biases that they may have about a specific contraceptive method or family planning in general (see **Chapter 2** and **Appendix A**).

- **Technical competence** refers to the level of the clinical skills of providers, their observance of protocols (written descriptions of steps to be followed during service provision) and use of recommended infection prevention practices in delivering family planning services. Clinical tasks required for the provision of implants services are described in **Chapters 4 through 9**.
- **Continuity of care** refers to the mechanisms by which clients can have any side effects treated, switch their method if desired and receive supplies easily (see **Chapters 7 and 8**).
- **Appropriate range of services** refers to providing accessible and acceptable health care which supports the reproductive health needs of clients (i.e., integrated as opposed to vertical health care programs).

ASSESSING QUALITY OF SERVICES

The **second step** in the quality of care process is assessing whether clients are receiving care at the level described in the clinic standards. **Quality assessment** involves gathering data to determine the level of achievement of standards set by the clinic (Donabedian 1988; Kumar, Jain and Bruce 1989). For example, this assessment process can identify deficiencies in service provision, which in turn will determine the steps required to improve the overall quality of services.

The assessment process includes:

- determining quality of service issues,
- specifying indicators of quality care,
- specifying the data that should be collected to measure the indicators, and
- identifying strategies for collecting and processing the data.

There are many sources from which data for monitoring quality can be obtained. The most common sources include:

- observation of clinic services (e.g., capsule insertion);
- review of client records;
- data retrieved from clinic logs which show patterns of use, contraceptive method mix or quantities of service provided (e.g., implants acceptors);
- client interviews; and
- self-assessment by clinic staff.

Once the data have been analyzed, a judgment can be made to determine whether quality is good or bad, satisfactory or unsatisfactory.

Remember: High-quality service does **not** necessarily involve use of technically sophisticated equipment in expensive clinic facilities. Each clinic must make a judgment according to its own situation and available resources.

Clinic staff and managers should regularly review their efforts to improve the quality of care provided to the client. These efforts should involve periodic assessments of various elements of quality. For implants, this process should involve the entire service delivery team and be an ongoing activity.

Examples of “how to” assess each of the key quality of care indicators are listed below.

Assessing Choice of Contraceptive Method

- Provider discusses all methods appropriate to reproductive goals of the client.
- Provider refers client for methods unavailable at service delivery site.
- Client receives her method of choice, appropriate to her reproductive goals.
- All contraceptive methods supplied at the clinic are stored according to established guidelines.
- Established logistic guidelines are followed in the distribution of contraceptive commodities.

Assessing Information Given to Clients

- Provider gives overview of all methods.
- Provider gives in-depth information on method chosen:
 - how it works,
 - how it is used,
 - side effects and other health problems and their management,
 - potential complications,

Providing Quality Services

- followup requirements, and
- how to obtain resupply (e.g., oral contraceptives, condoms, etc.).
- Client correctly explains method chosen:
 - how it is used,
 - possible side effects and what to do if side effects occur,
 - when to return, and
 - where to return.
- Method-specific informational materials are available (brochures, samples, etc.).
- Acceptable privacy is provided for:
 - counseling, and
 - examination (when necessary).
- Consent form is available and signed by client (when appropriate).

Assessing Client-Provider Interaction

- Provider establishes good rapport with client in order to assess her personal situation (e.g., family circumstances, nature of sexual relationships, etc.).
- Client feels:
 - welcomed by staff,
 - at ease and comfortable asking questions, and
 - that staff and providers treat her with respect.

Assessing Technical Competence of Provider¹

- Provider can explain contraceptive methods available:

- benefits and limitations,
- mechanism(s) of action,
- indications and precautions for use,
- how they are used, and
- side effects and other health problems and their management.

- Provider is proficient in clinical procedures (according to guidelines).
- Provider uses recommended infection prevention practices.
- Client receives a contraceptive method which is:
 - appropriate based on her health status (is safe for her to use), and
 - appropriate for her sexual lifestyle (including risk of GTIs and other STDs).
- Provider is capable of managing GTIs and other STDs (this is especially important for IUD services).
- Basic items (equipment and supplies) needed to deliver available methods are in stock.
- Supervision is adequate.

Assessing Mechanisms to Ensure Continuity of Care

- Resupply for continuing users (e.g., oral contraceptives, injectables or condoms) is available.
- Provider informs and encourages client to return as needed.

¹ Requires existence of written family planning guidelines and up-to-date job descriptions for each clinic position.

- Followup/return schedule is appropriate for method.

Assessing Organization of Services

- Clients perceive that:
 - privacy for counseling is acceptable;
 - privacy for examination is acceptable;
 - waiting time is acceptable;
 - time with provider is acceptable;
 - hours/days are convenient; and
 - staff is appropriate in terms of gender, ethnic group and age.
- Clients perceive that the health care facility is adequate:
 - waiting room,
 - examination room,
 - cleanliness/hygiene,
 - water, and
 - toilet facilities.

Assessing Outcomes

Data are collected for:

- number of new acceptors,
- complication rate for specific methods,
- continuation rate (of any method),
- new clients recommended by other users, and
- clients achieving reproductive goals.

ENSURING QUALITY OF SERVICES

The **third and final step** in the quality of care process involves quality assurance activities. **Quality assurance (QA)** is an

ongoing process to objectively and systematically assess and monitor client care based, in part, on the pre-established service standards and on the client's feedback and needs. Traditionally, the QA process has involved service providers and managers reviewing data obtained during the assessment in order to identify the problems and explore possible solutions (reactive process).

Recently, the purpose of quality assurance has been expanded to ensure that gradual **and** continuous improvements are made in **all** clinic functions, not just problem areas (proactive process). The latter is part of the **continuous quality improvement** approach (Leebov and Ersoz 1991). Continuous quality improvement (CQI) is a methodological approach to achieving stated or implied standards which:

- is based on the belief that staff members at **any level** can make valuable suggestions about ways to improve services;
- recognizes that many problems result from poorly designed or implemented **systems** and **processes**, rather than individuals; and
- assumes that **any** aspect of family planning service delivery, **not just problem areas**, can benefit from some improvement. The differences between the traditional QA system and the CQI approach are listed in **Table 10-1**.

10/

Table 10-1. Traditional Quality Assurance (QA) Versus Continuous Quality Improvement (CQI) Approach

Aspects	QA	CQI
Quality standards	Quality is based on pre-determined program objectives and is monitored periodically.	Quality is based on clients' feedback and needs. Quality is monitored continuously and is built into the work process.
Problem solving	Problem solving and decision making are done by senior managers and specialists.	Problem solving and decision making are done in collaboration with staff and based on hard data.
Improvement process	Short-term improvements are made, often at point of crisis (reactive).	Gradual, continuous improvements are made in all functions (proactive).
Program clients	Clients are not usually consulted for their opinions.	Clients are partners and are regularly consulted.
Work environment	Staff work individually.	Staff work in teams.
Performance recognition	Authority is rewarded.	Capabilities are rewarded.
Source of problems	Problems come from people.	Problems come from complex processes and systems.
Style of supervision	Control and direct staff.	Encourage staff to take initiatives.
Financial perspective	Quality costs money.	Quality saves money.

Adapted from: Llewelyn Leach 1992; Mayer 1992.

The principles of CQI were presented in a recent issue of *The Family Planning Manager* (Wolff et al 1993). This report also provides a detailed discussion of **what** a clinic manager or service provider needs to do in order to prepare for CQI, **how** to initiate it and the **steps** involved in implementing the CQI approach.

Improving the Quality of Care

In working to improve the quality of care provided, it is important for the clinic staff to first **state** the problems they would like to address and then **identify** the steps to be followed to solve them. To achieve this objective, some (or all) of the following

questions need to be answered by clinic staff:

- **Is the clinic adequately prepared and organized to offer a given standard of care?** *Example:* Review existing resources (supplies and equipment), client flow, staff training and allocation of responsibilities.
- **What is the process involved in providing a given standard of care?** *Example:* Review steps required and used to provide a specific service (e.g., Norplant implants insertion), including sequence of events.

- **Which part(s) of the service delivery process is not being satisfactorily performed?** *Example:* Identify step(s) which is not properly performed (e.g., infection prevention practices for insertion of implants).
- **What are the causes of the problem?** *Example:* Identify causes which may explain the problem identified.
- **What can be done to improve the process?** *Example:* Suggest solutions which can be implemented at clinic and managerial levels (e.g., provision of recommended infection prevention supplies).
- **Who should be involved in planning and implementing the solution?** *Example:* Assign responsibilities for monitoring improvements (e.g., role of each staff member in improving recommended infection prevention practices).
- **What indicators of success can be used to assess performance?** *Example:* Use indicators already defined in the statement of standard to monitor progress (e.g., reduction in the number of infections following insertion of Norplant implants).

Table 10-2 provides an illustrative example of how quality assurance could be applied to the infection prevention standards in a clinic-based program providing Norplant implants.

Remember: The best programs are never perfect and new ways to improve the quality of services are always evolving.

In summary, providing quality services is an ongoing activity. The quality of care process described in this chapter is designed to monitor and evaluate client care objectively and systematically, based on pre-determined standards. Its purpose is to assist clinic staff and managers in eliminating or correcting identified problems and to assure that client care is the best it can be given the resources available.

Table 10-2. Steps in Family Planning Quality Assurance Process

STEPS	EXAMPLE
<p>STEP 1: Establish a standard for the clinic based on what is valued or important in client care. The standard is a statement of:</p> <ul style="list-style-type: none"> • what will be done, • by which staff, and • to achieve what results. <p>Assess whether the clinic is achieving the stated standard.</p> <p>Review whether the clinic is adequately prepared to meet the standard.</p>	<p>Standard: Recommended infection prevention (IP) practices will be followed by providers during insertion of Norplant implants to minimize risks to clients and clinic personnel.</p> <p>Observe implants service provision using a checklist.</p> <p>Assess competency of clinicians and support staff in following recommended IP practices.</p> <p>Staff trained in IP practices? Adequate space and equipment to process instruments? Selection and use of gloves? Antiseptics? Client and staff traffic flow reduce risk of infection? IP supplies and equipment available?</p>
<p>STEP 2: Review the process involved in meeting the standard.</p>	<p>Process: Decontamination, cleaning, sterilization or HLD</p> <p>Findings: Standard is not met because cleaning is not performed satisfactorily.</p>
<p>STEP 3: Identify causes of problem(s) and suggest solution(s).</p>	<p>Possible Causes: Lack of knowledge of how to do cleaning and lack of consumable supplies (e.g., disinfectants or gloves)</p> <p>Corrective Measures: Staff should be given on-the-job training and provided with necessary supplies.</p>

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ORGANIZING AND MANAGING A NORPLANT IMPLANTS SERVICE

BACKGROUND

Norplant implants, although not as easy to provide as other types of reversible contraceptive methods such as pills and injectables, often can be introduced into family planning programs using existing personnel, facilities, and referral and service delivery channels. There are, however, certain management and organizational requirements at the clinic level which need to be met before quality services can be offered. For example, even when managers design policies and allocate resources for Norplant implants programs, clinicians have the responsibility for organizing the physical and human resources needed for the actual provision of these services.

In practice, the following types of questions should be addressed by service providers to ensure that they are adequately prepared to provide quality Norplant implants services:

- Is the clinic well equipped and the space organized for a smooth client flow?
- Have the staff been trained in both counseling for and delivery of Norplant implants services?
- Are staff members competent?
- Are supplies and other aspects of logistics well organized?

The objective of this chapter is to assist clinic managers and service providers in organizing and managing resources in their

clinics in order to improve the delivery of services.

FACILITIES

Contraceptive methods, such as pills and condoms, can be provided through both clinic-based and community-based services. Because Norplant implants insertion and removal are minor surgical procedures, this service should be delivered **only** through clinic-based services.

There are two main types of **clinic-based service facilities**: those that provide family planning as part of **integrated maternal and child health/family planning (MCH/FP) primary health care services** 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 may provide clinic-based family planning services as part of their family health care practice. In many settings, they form an increasingly important group who can supply Norplant implants services, provided their offices meet the space and personnel requirements (especially for counseling) for delivery of quality Norplant implants services.

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, 40-90% of the population live in rural areas and urban slums and have only limited access to clinics. These people often are not willing or able 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 followup care and voluntary removal on demand, may be more difficult.

Norplant implants 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 implants 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, where clients can be examined and implants inserted and removed;

- cleaning area/utility room where instruments and gloves can be processed and linens washed;
- area for sterilization (or high-level disinfection) of instruments and other items and space for their storage;
- storage area for medical supplies; it should be cool, dry, secure and well-ventilated; and
- area for office work, maintenance and storage of records and informational materials.

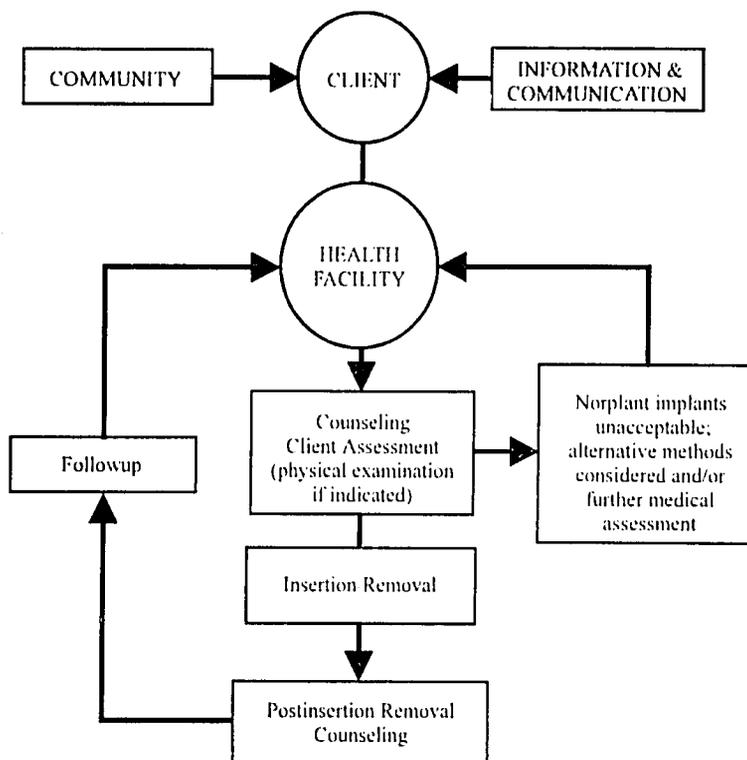
Several of these functions may share a common space, especially in health facilities that are not very busy. As the caseload increases, a separate area may need to be assigned to each function.

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 11-1 shows how a potential user might enter and proceed through a well-arranged health facility offering family planning services. The flow will be different according to the types of services offered. For example, at those sites that provide family planning as part of an integrated MCH/FP service, clients will be recruited from the clinic registration area as well as internally from other MCH units. For those sites which specialize in FP, however, client flow will be set up according to the number of trained providers and counselors.

Figure 11-1. Client Flow for Norplant Implants Services



Adapted from: World Health Organization 1990b.

Regardless of the type of service site, client flow should be organized in such a way that clients are first welcomed in an area where **initial** and **group** counseling activities can be conducted. **Individual** counseling should then take place in an area where privacy can be assured. Counseling enables clients to make free and informed choices. Only after this should the client be examined (if necessary) in the examination or procedure room.

If an appropriately designed checklist is used for screening clients (see **Appendix B**), limited or no physical examinations may be needed for the majority of clients.

Remember: Provider/client counseling interactions should occur throughout the entire visit to the clinic.

It is important to note that a small number of clients may not be suitable candidates on medical grounds, or they may decide not to use Norplant implants after receiving additional information and counseling. Consequently, the program must be able either to provide alternative contraceptive methods or refer clients for these services.

MAKING SERVICES FOR NORPLANT IMPLANTS MORE ACCESSIBLE

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 clients. If the service point is too distant, a client may not return for followup visits—both because of the distance involved and the possible expense (e.g., fares, loss of pay for time off from work, child care fees).

Moreover, contraceptive acceptability studies have shown that educating men about contraceptives makes an important contribution to ensuring overall acceptability of a particular method. Furthermore, men potentially could be more involved in 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.

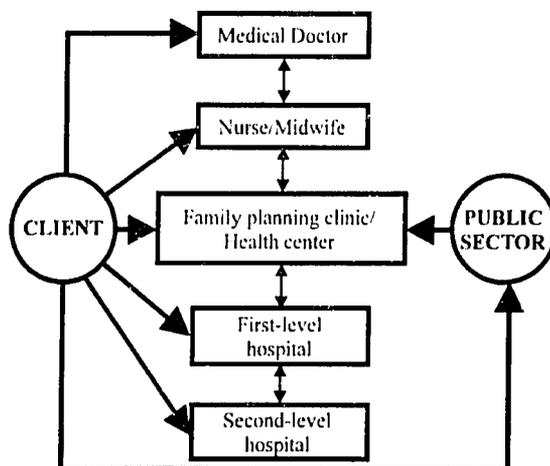
FOLLOWUP AND REFERRAL

Clinic staff should be aware of the service and referral network in their community and employ it appropriately. **Figure 11-2** illustrates the potential links between the client, the service delivery system and referral facilities. The various components of the system are:

Client: A potential or continuing user of Norplant implants services.

Public sector (community-based): A non-clinic facility, usually 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

Figure 11-2. Potential Links Between the Client, Service Delivery Channels and Referral Facilities



Adapted from: World Health Organization 1990a.

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: Paramedical staff working in family planning who have received specific training about Norplant implants. They should be trained to recognize and manage most problems and only refer serious ones. A physician should be available to provide assistance or for referral if needed.

Family planning clinic/health center (primary level): A health facility providing basic health care to a community.

Hospital (secondary level): A district or regional hospital with 50 to 100 beds and facilities for dealing with moderately serious problems but which has few, if any, medical specialists.

Referral hospital (tertiary level): A large or national hospital with approximately 300 beds and a large number of specialized personnel.

Norplant implants services may be provided in any of the above facilities. Most simple complaints or side effects can be handled at all sites. Management of more serious problems (e.g., difficult removal) may require referral to the nearest higher facility (secondary level or referral hospital). (For additional information on followup care and management of problems associated with Norplant implants use, see **Chapters 7 and 8.**)

PERSONNEL REQUIREMENTS

The number and type of staff needed in a clinic offering Norplant implants will vary with the size of the clinic, the other services provided, service hours and caseload. Consideration always should be given to employing female staff to provide contraceptive services because they may be more culturally acceptable than men.

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 which is consistent with the delivery of 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 implants sets, insertion/removal kits and other supplies;
- storing and logging in implants sets and other supplies;
- bookkeeping;
- scheduling appointments for clients;

- providing informational materials to clients and ensuring continuing availability of these materials;
- counseling clients (at various times);
- screening clients for medical precautions;
- performing and recording general physical examinations;
- processing surgical instruments and other items (infection prevention);
- preparing the supplies needed for each insertion and removal;
- inserting and removing implants;
- managing common side effects and other health problems and making referrals for serious complications;
- scheduling followup visits if necessary;
- being responsible for any outreach activities initiated at the clinic to recruit new clients;
- followup of clients who do not return for appointments;
- assessing user satisfaction with services;
- maintaining medical records; and
- 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 implants 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 implants, IUDs and voluntary sterilization) tend to be more labor- and time-intensive than other methods. These methods 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 experience, and they should be consistent with safe clinical practice. For example, a properly

trained assistant might easily receive the client, provide initial counseling and conduct the medical screening using a checklist such as that presented in **Appendix B**. Next, the nurse/midwife or physician can review the checklist, perform the physical/pelvic examination (if necessary), insert the capsules and provide client instructions and exit counseling. The assistant also can oversee/perform instrument cleaning, sterilization or HLD and general cleaning services. As the caseload increases, however, 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 (WHO 1985).

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 implants services and maintaining high staff morale.

RECORD KEEPING

Keeping specific and up-to-date records on each Norplant implants user can improve followup. Good record keeping also provides documentation for service statistics and program evaluation and helps ensure that clinic staff know where the client is when it's time for capsule removal (i.e., after 5 years).

It is not easy to maintain complete followup. Clients may forget to return for visits, they may give vague or inaccurate addresses or they may lose interest in followup. 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 followup.

There should be no difficulty in adapting client health records to include important information relevant to the use of implants. The clinical data that should be recorded for each client are indicated in **Chapter 4** and **Appendix B**. Prior to starting Norplant implants services, the existing recording and reporting system should be reviewed in order to incorporate implants into the program.

MATERIALS REQUIREMENTS

Before starting to provide Norplant implants, it is essential to arrange for supplies to be sure there is continuous delivery of the method. These supplies include all related materials, such as pregnancy test kits and the equipment and

consumable supplies (dressings, antiseptics and disinfectants) needed for implants services.

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

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, most importantly, very different service delivery costs. The data in **Table 11-1** 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 (WHO 1990b).

As an example, consider a unit cost of \$23.12 per implants set at the point of

manufacture. When used over the 5-year duration, the annual cost of Norplant implants would be \$4.62; however, not all women will use implants for a full 5 years. International experience with Norplant implants indicates that 80-90% of users continue use beyond the 1st year. The average (50%) duration of use reported has been 3.0 to 3.9 years.

Having implants removed earlier than 5 years obviously increases the annual cost. Thus the adjusted annual cost might be expected to range from \$5.93 to \$7.71. First-year continuation rates for most of the other methods are shown in **Table 1-4**. 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 **Table 11-1**, 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. This is due to the required infection prevention practices, consumable supplies such as surgical gloves, as well as the need for specially trained service providers. Service delivery costs for Norplant implants are similar to those for IUDs for the same reasons.

Table 11-1. Cost Estimates for Contraceptives

Method	Unit Cost ^a (US\$)	Duration Per Unit	Annual Cost (US\$)	Average Use in Practice	Adjusted Annual Cost (US\$)
Norplant implants	23.12	5 years	4.62	3-3.9 years	5.93-7.71
IUD (Copper T 380A)	1.10	10 years	0.11	2-2.7 years	0.22-0.30
Oral Contra- ceptive	0.18	1 month	2.34	2-2.7 years	2.57-2.92
Injectable	0.96	3 months	3.84	2-2.3 years	4.22-4.80
Diaphragm	3.30	1 year	3.30	1-1.5 years	3.50-4.00
Spermicide	2.00	20 uses	9.60	1-1.3 years	10.56-12.00
Condom	0.05	1 use	4.80	1-1.7 years	5.28-6.00

^a Does not include transport, distribution or service delivery costs, or import fees.

Adapted from: World Health Organization 1990b.

EQUIPMENT AND INSTRUMENTS

Insertion or removal of capsules 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 implants (e.g., insertion/removal kit, see **Appendix F**); and
- 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 implants insertions and removals. The quantity of instruments and materials needed at the clinic to perform Norplant implants insertions and removals is partly dependent on the availability of equipment for sterilization or HLD. For example, enough sets must be available to continue doing insertions/removals while other instruments are being decontaminated, cleaned and either sterilized or high-level disinfected. Shortening the time allowed to process instruments is **never** an acceptable solution (see **Chapter 5**).

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Remember: Equipment for sterilizing or high-level disinfecting instruments, (and personnel trained to use it), must be available before any Norplant implants program can begin.

ORDERING AND STORING NORPLANT IMPLANTS

All contraceptive delivery systems require adequate supply systems and staff to manage those systems. Norplant implants should be ordered in time to ensure that services are not slowed by lack of them, or they are never in such excess that they cannot be used before their shelf life has expired (5 years from the date of manufacture for Norplant implants).

Supplies

Maintaining a consistently adequate supply of Norplant implants sets 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 implants requirements are detailed in **Appendix G**.

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 (John Snow, Inc. 1990).

- 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

Only one Norplant implants set is required for each user in calculating the supplies needed for 1 year. Programs should order extra implants sets (about one per 20 acceptors), however, to allow for damage in storage or contamination during insertion (see **Appendix G, Table G-1**).

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 implants sets needed. A clinic which is resupplied

every quarter should have a maximum supply of 6 months and a minimum of 3 months (e.g., if 200 capsule sets are inserted per month, the maximum stock would be 1,260 and the minimum stock would be 630).¹

Storing

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

The packages 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 capsules.

A careful system of inventory/quality control must be established to ensure that the first sets 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.

¹ Based on estimates of inventory loss (see **Appendix G, Table G-1**)

REFERENCES

John Snow, Inc. and the Centers for Disease Control. 1990. *Family Planning Logistics Management Training Curriculum*. Family Planning Logistics Management Project, John Snow, Inc: Arlington, Virginia.

World Health Organization (WHO). 1985. *Strengthening of Supervisory Mechanisms in Maternal and Child Health/Family Planning Services*. WHO: Geneva.

World Health Organization (WHO). 1990a. *Injectable Contraceptives: Their Role in Family Planning Care*. WHO: Geneva.

World Health Organization (WHO). 1990b. *Norplant Contraceptive Subdermal Norplant Implants: Managerial and Technical Guidelines*. WHO: Geneva.

ADDITIONAL INFORMATION

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

John Snow, Inc. and the Centers for Disease Control. 1990. *Family Planning Logistics Management Training Curriculum*. Family Planning Logistics Management Project, John Snow, Inc: Arlington, Virginia. (200 pp).

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.

Management Sciences for Health. 1991. *The Family Planning Manager's Handbook*. Kumarian Press: West Hartford, Connecticut. (375 pp).

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 better managers, to train managers to improve their managerial effectiveness and as a reference when management problems need to be solved.

APPENDIX A

FAMILY PLANNING COUNSELING GUIDELINES

Contents

Section One: Framework for Family Planning Counseling

Helping Clients Get the Most from Counseling
Who Should Do Counseling?
Being a Good Counselor
Counseling Process
GATHER Counseling Technique
Steps in Family Planning Counseling
Summary
References

Section Two: How to Hold Group Discussions

SECTION ONE

FRAMEWORK FOR FAMILY PLANNING COUNSELING

HELPING CLIENTS GET THE MOST FROM COUNSELING

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 (or couple) select a method she is satisfied with and prepare the client to use the method safely and effectively.

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 the client remember are:

- **Brevity**

Ask the client what she already knows about family planning and specific contraceptive methods. This assists the provider in determining the information the client needs and ensures that the most important matters are emphasized.

- **First things first**

Give the 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 the instructions. If available (and appropriate) give the client printed material and remind her of instructions.

- **Organization**

Organize information into categories to make it easier to explain. Use memory aids such as acronyms to remind users of the important information they need to remember. For instance, the client using Norplant implants needs to remember the warning signs of potentially serious problems for which she 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 implants are effective for several years." The more helpful, specific instruction might be: "Norplant implants are effective for up to 5 years. Then they should be removed. At the time of removal, either a new set can be inserted or another contraceptive method selected."

WHO SHOULD DO COUNSELING?

Every health care 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 provider's sensitivity to the needs of clients is important, especially for provider-dependent methods such as IUDs and Norplant implants. Because insertion and removal of these methods require 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 providing family planning counseling, other staff probably will be curious about contraception. If they also are given information about available methods, they will be able to talk knowledgeably about family planning in the clinic and the community.

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

Good counseling of potential clients helps to ensure that clients 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 staff to counsel effectively now, the program will benefit in the future.

BEING A GOOD COUNSELOR

A good counselor knows that it will take a few minutes to put the client (or couple) at ease so that the client can talk about her beliefs and feelings about contraceptive methods. Taking time to do this will be cost-effective in the long run. For example, when counseling is done effectively, the client will be more satisfied with her choice and less likely to discontinue use after a short period of time.

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 adequately discuss all available contraceptive methods. 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. The counselor also 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.

A good family planning counselor:

- encourages maximum participation and involvement by the client (or couple); helps the client to convince herself instead of trying to convince the client;

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- is an information giver, facilitator and problem solver; suggests alternatives, helps the client to analyze and choose from known options, doesn't prescribe solutions and helps a client understand that she is making her own choice or decision;
- helps the client to reveal her personality and life situation rather than making assumptions; and
- determines the client's fears, concerns and other issues which could serve as barriers to effective learning.

General Advice When Counseling

- Clients may become embarrassed discussing methods of family planning. Try to set the tone of the visit in a low-key, nonpressured manner. Assure the client (or couple) that the conversation is confidential.
- Encourage the client to express her views by listening attentively and using nonverbal gestures, such as nodding, to encourage discussion.
- Be patient and never put pressure on the client to finish speaking.
- Use open-ended questions that require more than "yes" or "no" answers to increase the amount of information the woman gives to you.
- Be sensitive to any cultural and religious considerations and respect the client's views.
- Repeat the most important information and instructions.

- Give the client written information (if available and appropriate) to remind her of instructions.
- Finally, ask the client to repeat back to you the key points to assure her understanding.

Keys to good counseling

A good counselor:

- Understands and respects the client's rights
- Earns the client's trust
- Understands the benefits and limitations of all contraceptive methods
- Understands the cultural and emotional factors that affect a woman's (or a couple's) decision to use a particular family planning method
- Encourages the client to ask questions
- Uses a nonjudgmental approach which shows the client respect and kindness
- Presents information in an unbiased, client-sensitive manner
- Actively listens to the client's concerns
- Recognizes when she cannot sufficiently help a client and refers the client to someone who can
- Understands the effect of nonverbal communication

COUNSELING PROCESS

Counseling is an ongoing process which should be included in all aspects of family planning services. The medical and technical information important to effective counseling should not be presented and discussed at just 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 a method are more likely to be satisfied with it and, by talking about their positive experience, become the most effective means of promoting it (Gallen, Lettenmaier and Green 1987).

To counsel clients effectively, health care 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, like the decision to accept it, must be based on adequate information. This implies an understanding not only of the effectiveness of that method, but also of its limitations and the alternative choices available. To achieve this objective, all health care workers dealing with family planning clients should be trained in counseling techniques and develop good communication skills. In addition, appropriate educational materials must be produced for use by both **literate** and

nonliterate clients (Gallen, Lettenmaier and Green 1987).

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

- reproductive goals of the woman (spacing or timing births);
- subjective factors including 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;
- benefits and limitations of the method;
- reversibility;
- long- or short-term side effects; and
- need for protection against GTIs and other STDs including HBV and HIV/AIDS.

GATHER COUNSELING TECHNIQUE

The **GATHER** system is one method used to organize the elements of the counseling process (Gallen, Lettenmaier and Green 1987; Lettenmaier and Gallen 1987). This acronym is designed to help staff remember important points in an effective counseling session. **GATHER** is one approach to counseling; in practice, counseling should be tailored to the individual circumstances and may follow a different sequence or technique.

GATHER means:

- G Greet**
- A Ask**
- T Tell**
- H Help**
- E Explain**
- R Return visit/refer**

The GATHER technique is outlined in **Table A-1**.

STEPS IN 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 followup counseling. Counseling should, however, be part of every interaction with the client. Because information and counseling preferably may come from more than one source, clinic staff need to work as a team. In addition, staffing patterns as well as client load may require shifting counseling activities to alternate staff or locations to meet varying needs.

Initial Counseling

At the time of client reception, initial counseling (or education) may be provided by any clinic staff trained in family planning counseling. It is intended to provide the client with general information on all methods and other services offered by the clinic. Such education can be effectively provided in a group setting. Initial counseling helps the client **identify** an appropriate method for herself or her

spouse. Counseling in waiting areas with individuals or groups provides:

- an 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 fully breastfeeding as a contraceptive method for clients up to 6 months postpartum, and
- 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 **Section Two** of this Appendix.

Method-Specific Counseling

Individual, method-specific counseling should take place in a private counseling area or an examination room. During this phase of counseling, the service provider should:

- Ask the client about her reproductive goals and assesses her need for protection against GTIs and other STDs including HBV and HIV/AIDS. This should help tailor the range of methods presented to her in more detail.
- Ask the client which method(s) interests her and what she knows about the method(s). This gives the service provider the opportunity to correct false rumors and misinformation, and to provide true information.

Table A-1. The GATHER Technique

Steps	Activities
GREET the woman	<p>Greet the woman (or couple) with a warm and personalized welcome.</p> <p>Spend a few minutes putting the woman at ease—this will encourage her to relax and reveal more information to you than she would if she were feeling tense and anxious. Many people, particularly the young, feel embarrassed about discussing their method of contraception with someone.</p>
ASK for information	<p>Establish age, marital status, cultural orientation and motivation for the visit without being judgmental or biased.</p> <p>Encourage the client to discuss any previous experiences of contraceptive methods. How did she find out about them? What did she particularly like or dislike about them?</p> <p>Collect basic medical information to ensure there are no reasons why she should not use a specific method.</p>
TELL her about family planning	<p>Be direct and specific and use simple words. Emphasize the most important points the woman needs to remember.</p> <p>Explain all available methods and how they are used.</p> <p>Use support materials such as pamphlets, brochures and samples to emphasize points.</p> <p>Let her handle samples of different methods.</p>
HELP her select a method	<p>Inform the client of the characteristics, benefits, limitations and side effects of each method.</p> <p>Explain that barrier methods may also be needed to protect against GTIs and other STDs, including HBV and HIV/AIDS.</p> <p>Do not decide for her; let the client choose the method.</p> <p>Give more details about the selected method and let the client repeat it back to you.</p> <p>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 provided.</p>
EXPLAIN how to use the method	<p>Ask the client to repeat all instructions.</p> <p>Encourage her to ask questions or state any remaining concerns.</p>
REFER	<p>Specific return visit instructions should be provided.</p> <p>Be sure the woman knows whom to contact if she has questions.</p> <p>Refer the client to an appropriate clinic for followup care as needed. For most women, a clinic near home is the best option.</p>

Adapted from: Gallen, Lettenmaier and Green 1987.

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- Tell the client about and discuss in greater detail how the method(s) in which she is interested works, its effectiveness, benefits and limitations.
- Help the client choose a method. Based on the client's needs and history, the service provider should advise the client on the suitability of any method in which the client expresses an interest. This process leads to selection of a contraceptive.
- Advise the client on the possible need for further medical assessment depending on the method selected.

Note: At this time the service provider conducts any physical and laboratory investigations, if indicated, to confirm the suitability of the chosen contraceptive method.

After completing the client assessment, the selected contraceptive method is provided to the client if it is available. If it is **not** possible to start the method at this time, she should be given an alternative method or instructions on what to do in order not to become pregnant in the interim. If the method can be provided at this time, the service provider should:

- Explain simply and clearly how to use the method (or in the case of Norplant implants or the IUD, explains how it will be inserted) and possible problems.
- Provide the method.
- Discuss with the client the need for return visit(s). Depending on the method, emphasis should be placed on the

continuing need for supplies and their availability, advice about side effects, detecting problems early, changing methods and the availability of removal services for Norplant implants and IUDs.

- Ask the client to repeat all instructions to be sure she understands them.

It is important for the service provider to recognize that:

- Clients are less likely to stop practicing family planning 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).

Followup Counseling

When providing followup counseling, providers and counselors need to listen carefully and be prepared to answer any questions. Doing this helps the client accept any side effects or other problems that may occur.

The specific objectives of followup counseling are:

- Review information provided previously.
- 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, repeat instructions for use.

- Provide supplies as appropriate.
- Answer the client's questions.
- Reassure and treat minor side effects (if possible).
- Check for any medical problems and refer for evaluation if necessary.
- Help the client change or stop a method if she desires.

SUMMARY

Using these guidelines, clients can be adequately counseled. Health professionals, however, 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 recognize the difference between serious problems that require referral and minor problems that are manageable.

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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; and
- Give information which may provide answers to questions some people may be too shy to ask.

When to hold group discussions:

- While clients wait in clinics; or
- When community groups meet in schools, clubs and other places.

Suggestions for 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 not in the group look after the 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.

APPENDIX B

**SAMPLE CLIENT ASSESSMENT CHECKLIST
FOR NORPLANT IMPLANTS**

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

CONDITIONS	YES	NO
First day of menses more than 7 days ago	<input type="checkbox"/>	<input type="checkbox"/>
Breastfeeding and less than 6 weeks postpartum	<input type="checkbox"/>	<input type="checkbox"/>
Bleeding/spotting between periods or after intercourse	<input type="checkbox"/>	<input type="checkbox"/>
Breast cancer or lump in the breast	<input type="checkbox"/>	<input type="checkbox"/>
Abnormal yellow skin or eyes (jaundice)	<input type="checkbox"/>	<input type="checkbox"/>
Taking drugs for epilepsy (seizures) or tuberculosis	<input type="checkbox"/>	<input type="checkbox"/>

Note: Clients may not always have exact information about or recall the answers to the conditions listed above. To be as certain as possible about the accuracy of the information it may be necessary to restate the questions in several different ways. Also, health care workers should take into account any social, cultural or religious factors that might influence how the woman (and her partner) responds.

Women who have any of the following conditions may need more frequent followup care.

CONDITIONS	YES	NO
Diabetes	<input type="checkbox"/>	<input type="checkbox"/>
Hypertension (mild or severe), with or without vascular problems	<input type="checkbox"/>	<input type="checkbox"/>
Severe migraine (vascular) headaches	<input type="checkbox"/>	<input type="checkbox"/>
Depression	<input type="checkbox"/>	<input type="checkbox"/>

APPENDIX C

INFECTION PREVENTION PROCESSES FOR SURGICAL INSTRUMENTS AND OTHER ITEMS¹

The **three basic steps** for processing instruments, gloves and other items used for Norplant implants insertion and removal are:

- decontamination,
- cleaning, and
- sterilization or high-level disinfection (HLD).

Details for the safe reuse of instruments, gloves and other items are provided in this appendix. (See **Appendix D** for information on processing surgical gloves and **Appendix E** for information on processing needles and syringes and linens.)

DECONTAMINATION

Decontamination is the first step in handling soiled surgical instruments and other items. It is important to decontaminate instruments and items that may have been in contact with blood or body fluids.

Immediately after use, place instruments and other items in a 0.5% chlorine solution for 10 minutes. This step rapidly inactivates HBV and HIV and makes items safer to handle by personnel who clean them.

Making Dilute Chlorine Solutions

The World Health Organization (WHO) recommends **0.5% chlorine solution** for decontaminating instruments before cleaning or when potable water is not available for making the solution (WHO 1989). For HLD, a 0.1% solution is satisfactory provided **boiled water** is used for dilution.

Table C-1 describes how to make 0.5% and 0.1% chlorine solutions using commercially available liquid bleach products. The general formula for making a dilute solution from a commercial preparation of any concentration is shown in **Figure C-1**.

¹ Adapted from: Tietjen LG et al. 1995. *Infection Prevention for Family Planning Service Programs*, 2nd ed. JHPIEGO Corporation: Baltimore, Maryland.

Table C-1. Preparing Dilute Chlorine Solutions from Liquid Bleach (Sodium Hypochlorite Solution) for Decontamination and HLD

Type or Brand of Bleach (Country)	Chlorine % Available	Ratio of Bleach to Water ^a	
		0.5%	0.1% ^b
JIK (Kenya), Robin Bleach (Nepal)	3.5%	1 : 6	1 : 34
Household bleach (USA, Indonesia), ACE (Turkey), Eau de Javal (France) (15° chlorum ^c)	5%	1 : 9	1 : 49
Blanquedor, Cloro (Mexico)	6%	1 : 11	1 : 59
Lavandina (Bolivia)	8%	1 : 15	1 : 79
Chloros (UK), Lejía (Peru)	10%	1 : 19	1 : 99
Chloros (UK), Extrait de Javel (France) (48° chlorum ^c)	15%	1 : 29	1 : 149

^a For the ratio of bleach to water, read as one part concentrated bleach to x parts water (e.g., JIK - 1 part bleach to 6 parts water for a total of 7 parts).

^b Use **boiled** water when preparing a 0.1% chlorine solution for HLD because tap water contains microscopic organic matter which inactivates chlorine.

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

Figure C-1. Formula for Making Dilute Chlorine Solution from Concentrated Solution

$$Total\ Parts\ (TP)\ water = \left[\frac{\% \text{ Concentrate}}{\% \text{ Dilute}} \right] - 1$$

Example: Make a dilute solution (0.5%) from 5% concentrated solution.

1. Calculate TP water: $\left[\frac{5.0\%}{0.5\%} \right] - 1 = 10 - 1 = 9$

2. Add 1 part concentrated solution to 9 parts water.

The approximate amounts (grams) needed to make 0.5% and 0.1% chlorine-releasing solutions from several commercially available compounds (dry powders) are

listed in **Table C-2**. The formula for making a dilute solution from a powder of any percent available chlorine is listed in **Figure C-2**.

Table C-2. Preparing Dilute Chlorine Solution from Dry Powder

Available Chlorine Required	Grams per Liter of Water	
	0.5%	0.1% ^a
Calcium hypochlorite (70% available chlorine)	7.1	1.4
Calcium hypochlorite (35% available chlorine)	14.2	2.8
NaDCC (60% available chlorine)	8.3	1.5
Chloramine (25% available chlorine)	20	4
NaDCD-based tablets (1.5 g of available chlorine per tablet)	4 tablets/liter	1 tablets/liter

^a Use **boiled** water when preparing a 0.1% chlorine solution for HLD because tap water contains microscopic organic matter which inactivates chlorine.

Adapted from: World Health Organization 1989.

Figure C-2. Formula for Making Dilute Chlorine Solution from Dry Powder

$$\text{Grams/Liter} = \left[\frac{\% \text{ Dilute}}{\% \text{ Concentrate}} \right] \times 1000$$

Example: Make a dilute chlorine solution (0.5%) from a dry powder (35%).

- Calculate grams/liter: $\left[\frac{0.5\%}{35\%} \right] \times 1000 = 14.2 \text{ g/l}$
- Add 14.2 grams ($\approx 14 \text{ g}$) to 1 liter of water.

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If items cannot be washed immediately after decontamination, rinse with cool water to prevent discoloration and corrosion (rusting) and to remove visible organic material before cleaning thoroughly. Personnel should wear gloves while handling soiled instruments. Inexpensive utility gloves work well for this.

Surfaces (especially procedure tables) that may have come in contact with 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.

CLEANING

Cleaning is a crucial step in providing safe, infection-free equipment and instruments. A thorough cleaning with water and liquid soap or detergent physically removes organic material such as blood and body fluids. Dried organic material can trap microorganisms in a residue that protects them against sterilization or HLD. Organic matter also can partially inactivate disinfectants, rendering them less effective (Porter 1987).

Utility gloves should be worn while cleaning instruments and equipment. Discard gloves if torn or damaged; otherwise, clean and leave 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.

If available, glasses, plastic visors or goggles should be worn while cleaning instruments and other items. This protects

staff from splashing contaminated water into their eyes.

Clean instruments with a brush (old toothbrushes work well) and soapy water. Give special attention to instruments with teeth, joints or screws where organic material can collect. After cleaning, rinse items thoroughly with water to remove detergent residue which can interfere with chemical disinfection.

If either hypodermic syringes (or needles and syringes) are being reused, disassemble only after decontaminating and then cleaning with soapy water, paying special attention to the hub area. Rinse 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 dry.

See **Appendix E** for detailed information on decontaminating and cleaning instruments, needles and syringes and linens and **Appendix D** for steps in processing surgical gloves.

STERILIZATION

Instruments and other items such as needles or scalpels that come into direct contact with tissues beneath the skin which are normally sterile, should be sterilized after first being decontaminated and thoroughly cleaned, rinsed and dried. **The sterilization process destroys all microorganisms, including bacterial endospores.** Bacterial endospores are particularly difficult to kill because of their tough coating. (Bacteria that form endospores include *clostridia tetani*, which causes tetanus.) Sterilization can be achieved by autoclaving (high-pressure steam), dry heat or by using chemicals ("cold sterilization").

Heat Sterilization

High-pressure saturated steam (autoclaving) or dry heat (by hot air oven) are the most readily available methods used for sterilization. Steam sterilization generally is the method of choice for instruments and other items used in family planning and health care facilities. Where electricity is a problem, instruments can be sterilized in a nonelectric steam autoclave using kerosene as a heat source.

Remember: 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, such as plastic and rubber, will melt and could burn. (Needles and other instruments with cutting edges should be dry-heat sterilized at temperatures not higher than 160°C/320°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 following box.

Sterile instruments should be used immediately unless they:

- have been wrapped in a double layer of muslin, paper or other appropriate material prior to steam sterilization; or
- can be stored in a dry sterile container with a tight-fitting lid.

Standard Conditions for Heat Sterilization

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

Note: Pressure settings (kPa or lbs/in²) may vary slightly depending on sterilizer used. Whenever possible follow manufacturer's recommendations.

Dry heat: 170°C (340°F) for 1 hour (total cycle time—placing instruments in oven, heating to 170°C, timing for 1 hour and then cooling—is from 2 to 2½ hours) or 160°C (320°F) for 2 hours (total cycle time is from 3 to 3½ hours).

The material used for wrapping instruments 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 1 week, **but only if kept dry and intact** (Perkins 1983). Placing a wrapped pack in a sealed plastic bag will increase its shelf life to 1 month. All packs and sterile containers should be labeled with an expiration date.

Chemical Sterilization

An alternative to steam or dry-heat sterilization is chemical sterilization by soaking for 8 to 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 and formaldehyde are the only practical liquid sterilants usable for instruments, such as laparoscopes, which cannot be heated. Because glutaraldehydes and formaldehyde require special handling

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and leave a residue on treated instruments, rinsing with **sterile** water (which can be prepared only by autoclaving) is preferable. (Because boiling does not inactivate some endospores reliably, using boiled water can contaminate sterile instruments.)

Although formaldehyde is less expensive than glutaraldehyde, it is more irritating to the skin, eyes and respiratory tract (Table C-3). When using either formaldehyde or glutaraldehyde, gloves should be worn, eyes should be protected, exposure time limited and both chemicals used only in a well-ventilated area.

Note: Chemical sterilization of needles and syringes is **not** recommended because chemical residues may remain even with repeated rinsing with sterile water. These residues may interfere with the actions of the drug being injected.

HIGH-LEVEL DISINFECTION

When sterilization equipment is either not available or not suitable, HLD is the **only** acceptable alternative. High-level disinfection destroys all microorganisms, including viruses causing hepatitis B and AIDS, but **does not reliably kill all bacterial endospores**. High-level disinfection can be achieved by boiling in water, steaming or soaking in chemical disinfectants such as 0.1% chlorine, 2-4% glutaraldehyde or 8% formaldehyde.

Because boiling and steaming require only inexpensive equipment, which usually is readily available, they are the preferred methods for small clinics or those located in remote areas. Regardless of the method selected, however, HLD is effective **only** when instruments and other items first are decontaminated and then thoroughly cleaned and rinsed **before** HLD.

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 5,500 meters (18,000 feet) it is **not** necessary to increase the steaming or boiling time (Favero 1985).

High-Level Disinfection by Boiling

Open or take apart all instruments and other items. Submerge in water and cover pan. Boil for 20 minutes. Timing should begin when the water is at a rolling (bubbling) boil and all items should be totally under the water. Nothing should be added to the container after the water begins to boil. After boiling for 20 minutes, remove boiled items using high-level disinfected forceps, place in a high-level disinfected container and allow to cool and air dry.

Use instruments and other items immediately or leave in a covered, **dry** high-level disinfected container. (The container used for drying the instruments can be used for storage only if there is no water in the bottom of the container.) Store for up to 1 week.

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Boiling Tips

- Always steam or boil for 20 minutes using a pot with a lid.
- Start timing when the water begins to boil.
- Items should be covered completely² with water.
- Do not add anything to the pot after the water begins to boil.

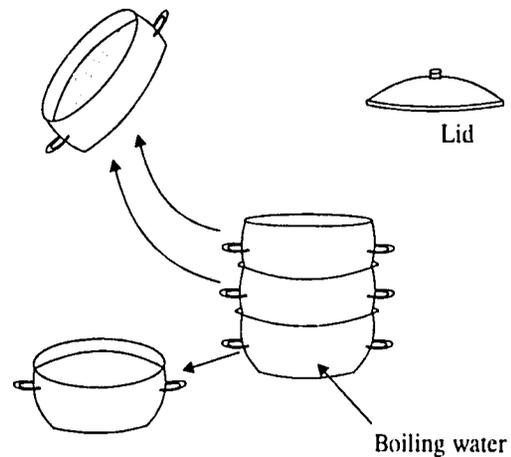
High-Level Disinfection by Steaming

Recently, a new process for high-level disinfecting surgical gloves by steaming (low-pressure moist heat) has been reported (McIntosh et al 1994). Steaming surgical gloves, which have been washed and thoroughly rinsed, in a steamer with one to three pans has been used as the final step in processing gloves for many years in Indonesia and other parts of South East Asia. Until now, however, the effectiveness of this process for HLD was never tested.

In the study reported, the steamer (Figure C-3) used consisted of:

- a bottom pan (approximately 31 cm in diameter) for boiling water,
- one, two or three circular pans with multiple, 0.5 cm (diameter) holes in their bottoms to permit the passage of steam up through them and water back down to the bottom pan, and
- a lid which fits on the top pan.

Figure C-3. Steamer Used for HLD

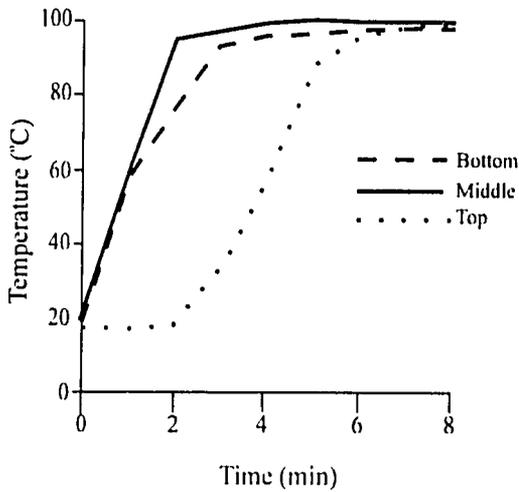


Two types of tests were conducted to determine whether surgical gloves could be high-level disinfected by this process.

In the first set of experiments, a thermocouple was placed inside a glove in each of the three pans, respectively, and the rate and extent of the temperature change recorded. As shown in Figure C-4, when from 5 to 15 pairs of surgical gloves were placed in each of the three pans, the temperature reached 96-98°C in less than 4 minutes in the bottom and middle pans and within 6 minutes in the upper pan. Thereafter, the temperature remained constant throughout the remaining 20 minutes.

² A recent report has documented that the interior temperature of a plastic cannula floating on the surface of boiling water reaches a temperature of 96-98°C in less than a minute (IPAS 1993). Therefore, for items which float (e.g., syringes, plastic MVA cannulae or rubber items), it is not absolutely necessary that they be fully covered by the water to achieve HLD.

Figure C-4. Temperature Rise in Gloves as a Function of Tray Position



In the second set of experiments, batches of new surgical gloves were contaminated with *Staphylococcus epidermidis*, *Staphylococcus aureus*, *Pseudomonas aeruginosa* and *Candida albicans* as well as *Bacillus subtilis* (heat-sensitive) and *Bacillus stearothermophilus* (heat-resistant) endospores. Next the gloves were placed in one of the three pans and steamed for 20 minutes. After this, they were removed from the pans and incubated for 24 hours in sterile media and then plated on blood agar. In all cases (6, 15 and 30 gloves per pan), there was no growth of any microorganisms or *B. subtilis* endospores at 24 hours and, as expected, only a reduction in the number of *B. stearothermophilus* endospores.

Based on the results of these experiments, it would appear that steaming is effective in high-level disinfecting surgical gloves.

Use of Steaming for HLD: Advantages and Disadvantages

At the present time steaming has several distinct advantages over boiling for the final processing of surgical gloves. Although boiling and steaming gloves are equally easy to do, to date no practical solution for drying boiled gloves has been discovered (i.e., it is difficult to prevent contamination while they are air-drying which takes up to 24 hours). As a result, health facilities lacking an autoclave either had to use new disposable sterile gloves for every surgical procedure or wear boiled (high-level disinfected) gloves "wet." With steaming, the gloves dry in less time (about 4 hours) and they are not contaminated while drying. Additional advantages are that steaming is less destructive and more cost-effective because it uses much less fuel than does boiling.

The major disadvantage of steaming is that if the steamers available locally are small, it is only practical to use them for small items (e.g., surgical gloves, MVA cannulae and syringes). Large boiling pots are easier to use with metal instruments and require less attention to be sure that the boiling process is being done correctly (Salle 1973; Spaulding 1939). (A boiling pot is easier to watch than one that is steaming.)

High-Level Disinfection by Soaking in a Chemical Solution

At present, only four chemicals are approved worldwide for use as high-level disinfectants:

- chlorine,
- glutaraldehyde,
- formaldehyde (formalin), and
- hydrogen peroxide.

Although **alcohols** and **iodophors** are inexpensive and readily available, they are no longer classified as high-level disinfectants (Rutala 1993). Alcohols do not kill some viruses, and *Pseudomonas species* have been known to multiply in iodophors. These chemicals should be used for disinfection **only** when the high-level disinfectants listed above are not available or appropriate.

Table C-3 provides guidelines for preparing and using these chemical disinfectants.

Note: Chemical HLD of needles and syringes is **not** recommended because chemical residues may remain even after repeated rinsing with sterile water. These residues may interfere with the actions of the medication being injected.

The major **advantages** and **disadvantages** of each disinfectant are described below.

- **Chlorine solutions** are fast acting, very effective against HBV and HIV, inexpensive and readily available.

A major disadvantage is that concentrated chlorine solutions ($\geq 0.5\%$) can discolor and corrode metals. Stainless steel instruments, however, can be soaked safely in a 0.1% chlorine solution (using a plastic container) for up to 20 minutes. Discoloration is only a problem where calcium (not sodium) hypochlorite powders are used. (Wiping instruments with vinegar, which is weakly acidic, will quickly remove the discoloration.) Also, corrosion will **not** be a problem if items are rinsed with boiled water and dried **promptly**.

Because chlorine solutions break down rapidly and can lose their effectiveness, fresh solutions should be made at least daily or more often if the solution is visibly cloudy.

- **Formaldehyde (8%)** can be used as a chemical sterilant and also is an effective high-level disinfectant, but the vapors are very irritating. Care must be taken to protect both staff and clients from the fumes when mixing and using formaldehyde solutions. (Wear gloves, protect eyes from splashes, limit exposure time and use only in well-ventilated areas.) **Do not dilute with chlorinated water as a dangerous gas (bis-chloromethyl-ether) can be produced.**
- **Glutaraldehydes**, which can be used for chemical sterilization, are effective high-level disinfectants as well. Although less irritating than formaldehyde, they too should be used in well-ventilated areas following recommended precautions.

Table C-3. Preparing and Using Chemical Disinfectants

Chemicals for Sterilization or High-Level Disinfection										
Disinfectant (common solution or brand)	Effective Concentration	How to Dilute	Skin Irritant	Eye Irritant	Respiratory Irritant	Corrosive	Leaves Residue	Time Needed for HLD	Time Needed for Sterilization	Activated Shelf Life ^{a,b}
Chlorine	0.1%	Dilution procedures vary ^c	Yes (with prolonged contact)	Yes	Yes	Yes ^d	Yes	20 minutes	Do not use	Change daily; sooner if cloudy
Formaldehyde (35-40%)	8%	1 part 35-40% solution to 4 parts boiled water	Yes	Yes	Yes	No	Yes	20 minutes	24 hours	Change every 14 days; sooner if cloudy
Glutaraldehyde (Cidex)	Varies (2-4%)	Varies: read instructions on container	Yes	Yes vapors	Yes	No	Yes	20 minutes at 25°C ^e	10 hours for Cidex	Change every 14 days; sooner if cloudy
Hydrogen Peroxide (30%)	6%	1 part 30% solution to 4 parts boiled water	Yes	Yes	No	Yes	No	30 minutes	Do not use	Change daily; sooner if cloudy
Chemicals for Disinfection (alcohols and iodophors are not high-level disinfectants)										
Alcohol (ethyl or isopropyl)	60-90%	Use full strength	Yes (can dry skin)	Yes	No	No	No	Do not use	Do not use	Change weekly; daily if heavily used; sooner if cloudy
Iodophors (10% povidone iodine/PVI)	Approximately 2.5%	1 part 10% PVI to 3 parts water	No	Yes	No	Yes	Yes	Do not use	Do not use	Change daily

^a All chemical disinfectants are heat and light sensitive and must be stored appropriately.

^b Always check manufacturer's instructions for when to discard.

^c See Tables C-1 and C-2 for instructions on preparing chlorine solutions.

^d Corrosive with prolonged (> 20 minutes) contact and/or concentrations $\geq 0.5\%$ if not immediately rinsed with boiled water.

^e Different commercial preparations of Cidex and other glutaraldehydes are effective at lower temperatures (20°C) and for a longer activated shelf life.

Adapted from: Rutala 1993.

Remember: Both glutaraldehyde and formaldehyde solutions leave a residue; therefore, instruments must be rinsed thoroughly with boiled water after HLD to remove any residue and prevent skin irritation.

- **Hydrogen Peroxide**, (H_2O_2), which must be diluted to a 6% solution, often is available locally and is less expensive than other chemical disinfectants. (The 3% H_2O_2 solutions used as antiseptics

should not be used as disinfectants.) The major disadvantage of H_2O_2 is that it is highly corrosive. It should not be used to disinfect copper, aluminum, zinc or brass. Because hydrogen peroxide loses potency rapidly when exposed to heat and light, it must be stored carefully.

WHO does **not** recommend using H_2O_2 in hot (tropical) climates because of its instability in the presence of heat and light.

Key Steps in Chemical High-Level Disinfection

- Decontaminate instruments that have been in contact with tissue beneath the skin which normally is sterile. Thoroughly clean and dry all instruments.
- Cover all items completely with correct dilution of high-level disinfectant which has been properly stored.
- Soak for 20 minutes.
- Remove using high-level disinfected forceps or wearing high-level disinfected gloves.
- Rinse well with boiled water and air dry.
- Use promptly or store for up to 1 week in a high-level disinfected, covered container.

To prepare a high-level disinfected container, boil if small or (if large) 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.

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).

Processing Used Chemical Containers

Glass containers may be washed with soap and water, rinsed, dried and reused. Alternatively, thoroughly rinse the container (at least two times) with water and dispose of by burying.

Plastic containers used for toxic substances such as glutaraldehydes or formaldehyde should be rinsed (at least two times) with water and disposed of by burning or burial.³

Note: Do not reuse plastic containers which originally held these chemicals.

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. **They do not destroy bacteria, viruses or endospores reliably.** For example, Savlon (chlorhexidine gluconate with or without cetrimide), 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)
- Cetrimide (e.g., Cetavlon[®])
- Chlorhexidine gluconate (e.g., Hibiscrub, Hibitane)
- Chlorhexidine gluconate and cetrimide in various concentrations (e.g., Savlon)
- Chlorinated lime and boric acid (e.g., Eusol[®])
- Chloroxyleneol (e.g., Dettol)
- Hexachlorophene (e.g., pHisoHex[®]) is not recommended for use as a disinfectant or antiseptic because it is readily absorbed through the skin and is neurotoxic.
- Mercury solutions (such as mercury laurel) cause birth defects and are too toxic to use as either disinfectants or antiseptics (Block 1991).

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 compound (e.g., Zephiran[®]). These are low-level disinfectants and should be used only to decontaminate environmental surfaces (e.g., examination tables) when chlorine compounds are not available.

³ To further prevent plastic containers from being reused, put a hole in each container before disposal so that it cannot be used to carry water or other liquids.

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APPENDIX D

PROCESSING SURGICAL GLOVES¹

The risk in reusing surgical gloves is that processed gloves contain more invisible tears than new ones and therefore provide less protection to the wearer. Sterilization (autoclaving) and high-level disinfection (steaming or boiling) of gloves, when correctly performed, can provide a high quality product. In addition, **double-gloving** for high-risk procedures can be done. Therefore, processing surgical gloves constitutes an **appropriate reuse of disposable items**.

HOW TO DECONTAMINATE AND CLEAN SURGICAL GLOVES BEFORE STERILIZATION OR HIGH-LEVEL DISINFECTION (HLD)

STEP 1: Before removing soiled gloves, immerse hands briefly in a container filled with 0.5% chlorine solution (or other locally available disinfectant).

STEP 2: Remove gloves by turning inside out and soak in the chlorine solution for 10 minutes.

(Performing **Steps 1 and 2** insures that both surfaces of the gloves are decontaminated.)

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

STEP 4: Rinse gloves in clean water until no soap or detergent remains. (Residual soap

or detergent can interfere with subsequent sterilization or HLD.)

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

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

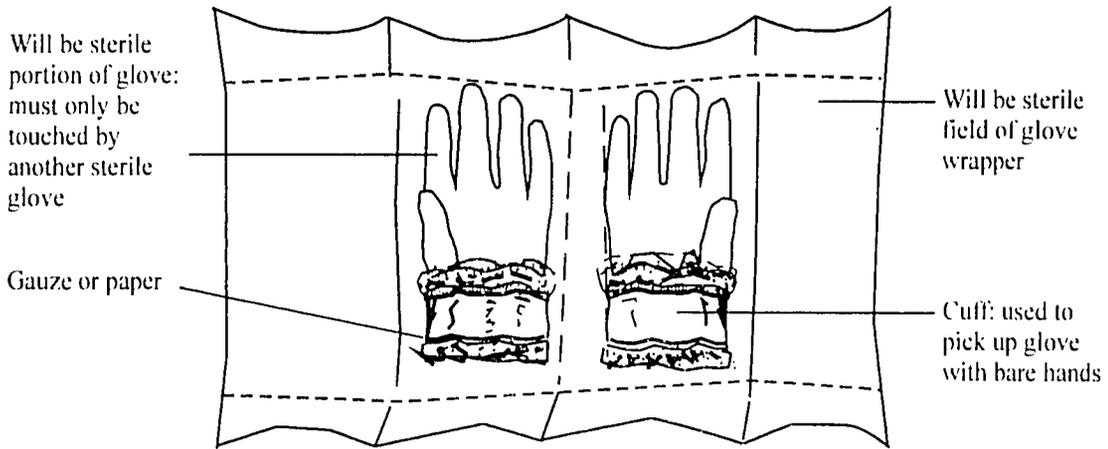
Note: Gloves should be discarded after processing three times because invisible tears may occur with additional processing (Bagg, Jenkins and Barker 1990; Martin et al 1988).

HOW TO STERILIZE SURGICAL GLOVES

After decontamination, cleaning and drying, gloves must be packaged prior to sterilizing by autoclaving. First, fold the cuffs of the gloves out towards the palm so that they can be put on easily and without contamination after sterilization. Next, put gauze or paper inside each glove and under the fold of the cuff and wrap the gloves as shown in **Figure D-1**. (Do not tie tightly or wrap glove packs with rubber bands.) Finally, place them in a wire basket on their sides to allow optimum steam penetration. (If gloves are stacked in

¹ Adapted from: Tietjen LG et al. 1995. *Infection Prevention for Family Planning Service Programs*, 2nd ed. JHPIEGO Corporation: Baltimore, Maryland.

Figure D-1. Preparing Gloves for Autoclaving (steam sterilization)



Source: South East Asia Office/ World Health Organization 1988.

plies, penetration of steam under the cuffs may be poor.) Autoclave at 121°C (250°F) for 30 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). (Table D-1)

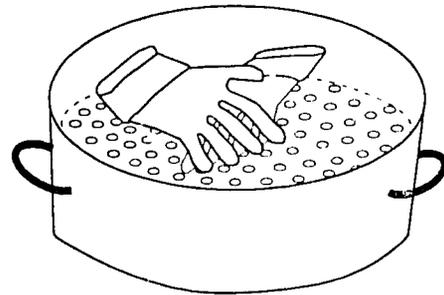
HOW TO HIGH-LEVEL DISINFECT SURGICAL GLOVES BY STEAMING

After gloves have been decontaminated and thoroughly washed, they are ready for HLD by steaming (McIntosh et al 1994). (See Appendix C for more information on steaming.)

STEP 1: Fold up the cuffs of the gloves so that they can be put on easily and without contamination after HLD.

STEP 2: Place gloves into one of the steamer pans with holes in its bottom. To make removal from the pan easier, the cuffs should be facing outward toward the edge of the pan (Figure D-2). Five to fifteen pairs can be put in each pan depending on the size (diameter) of the pans.

Figure D-2. Gloves in Steamer Pan



STEP 3: Repeat this process until up to three steamer pans have been filled with gloves. Stack the filled steamer pans on top of a bottom pan containing water for boiling. A second (empty) pan without holes should be placed on the counter next to the heat source (see Step 9).

Table D-1. Tips to Help Avoid Glove Problems

PROBLEM: TACKY OR STICKY GLOVES	
Probable Cause	Recommended Solution
Residual liquid soap or detergent	Reduce amount of liquid soap or detergent used when washing gloves. Rinse gloves at least three times in clean water.
Heated to high temperature for too long	Use 30 minutes sterilizing time at 121°C (250°F) and remove gloves from sterilizer as soon as cycle is completed.
Gloves sterilized with other goods	Sterilize gloves separately.
Gloves not allowed to dry completely after steaming	Wear "wet" within 30 minutes or allow to dry for 4 to 6 hours before using.
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	Gauze or paper wicks should be inserted between the palm and back of hand of each glove and between the hand of the glove and the turned-back cuff. This allows steam to contact all surfaces during sterilization and prevents surfaces from adhering to each other.
Breakdown (deterioration) of rubber (latex) (Rubber gloves deteriorate while stored even though they have not been used. They become soft, sticky and unusable.)	Store in a dry, cool area. Do not store in direct sunlight.
PROBLEM: EXCESSIVE TEARING OR RUPTURING	
Gloves used too soon following sterilization	Do not use gloves for 24 to 48 hours after sterilization. This allows gloves to regain their elasticity before use.

Source: Tomlinson 1991.

STEP 4: Place lid on top pan and bring water to a full **rolling** boil. (When water only simmers, very little steam is formed and the temperature may not get high enough to kill microorganisms.)

STEP 5: Reduce heat so that water continues to boil at a rolling boil. (When water boils too violently, it evaporates quickly and wastes fuel.)

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Remember: Be sure there is sufficient water in the bottom pan for the **entire** 20 minutes of steaming.

STEP 6: When steam begins to come out between pans, start timer or note time on clock and record time in the HLD log.

STEP 7: Steam gloves for 20 minutes.

STEP 8: Remove top steamer pan and place cover on top pan remaining on the stack. Gently shake excess water from the gloves in the pan just removed.

STEP 9: Place pan containing gloves on the second (empty) pan (see **Step 3**). Repeat until all pans containing gloves are restacked on this empty pan. (This step allows the gloves to cool and dry without becoming contaminated.)

Remember: Do **not** place pans containing gloves down on a table top, counter or other surface as gloves will be contaminated.

STEP 10: Allow gloves to air dry in the steamer pans (4 to 6 hours) before using.²

² Alternatively, allow gloves to cool for 5 to 10 minutes before wearing "wet." Gloves should be used within 30 minutes, if possible. After this time, the fingers of the gloves stick together and the gloves are hard to put on despite being damp. Gloves which have been removed from the steamer pan(s) to be worn "wet" but were not used during the clinic session should be reprocessed before using.

³ To prepare a high-level disinfected 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.

STEP 11: Using a high-level disinfected forceps, transfer the dry gloves to a dry, high-level disinfected container³ with a tight-fitting lid. Store for up to 1 week. (Gloves also can be stored in the stacked and covered steamer pans.)

HOW TO HIGH-LEVEL DISINFECT SURGICAL GLOVES BY BOILING

Although boiling effectively high-level disinfects gloves, it is difficult to dry them without contaminating them. Therefore, boiling surgical gloves should be done **only** if the gloves are to be used immediately (i.e., worn "wet" after they have been allowed to cool).

After surgical gloves have been decontaminated and thoroughly washed they are ready for HLD.

STEP 1: Place gloves in a bag made of plastic or nylon netting.

STEP 2: Place a weight in the bag so that all gloves and the bag will be at least 2.5 cm (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.)

Remember: Be sure there is sufficient water in the pan to cover items for the entire 20 minutes of boiling.

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: When rolling boil begins, start timer or note time on clock and record in HLD log. (**No objects or water should be added after timing starts.**)

STEP 6: Boil gloves for **20 minutes**.

STEP 7: After boiling for 20 minutes, remove bag of gloves with **high-level disinfected**, dry forceps. (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 [Perkins 1983].)

STEP 8: Allow excess water to drip off gloves (shake the bag gently). Place the bag in a high-level disinfected container, cover and allow to cool (about 5 to 10 minutes) before using.

STEP 9: Wear high-level disinfected gloves to untie the bag. Remove gloves from the container using a high-level disinfected forceps. Gloves which are worn "wet" may be weakened and less stretchy (elastic). Therefore, put on "wet" gloves very carefully.

STEP 10: Gloves remaining in the bag at the end of the clinic session should be reprocessed. (They will not dry completely inside and outside.)

Note: After boiling, gloves should be used within 30 minutes, if possible. After this time, the fingers of the gloves stick together and the gloves are hard to put on despite being damp.

ACCIDENTAL CONTAMINATION OF STERILE OR HIGH-LEVEL DISINFECTED GLOVES

There are several ways to contaminate sterile or high-level disinfected surgical gloves:

- tearing or puncturing the glove,
- touching any nonsterile object with the glove, or
- touching the outside of a glove with an ungloved hand.

Service providers wearing sterile or high-level disinfected gloves should be careful **not** to contaminate gloved hands inadvertently by touching nonsterile objects, unprepped skin or mucous membranes.

REGLOVING AFTER CONTAMINATION

To reglove after contaminating a glove during a procedure:

- Remove contaminated glove by the cuff, and place in chlorine solution for decontamination, if reusing, or in waste container.

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Sterile Glove:

- Have circulating nurse or technician open sterile glove pack, laying the glove package on a clean surface.
- Put on replacement glove in the usual manner.

Alternatively:

- Have circulating nurse or technician open the sterile glove package, remove a sterile glove and hold the glove open by the cuff. Put hand into the glove without touching the outside of the glove.
- Adjust the glove after the nurse or technician lets go of the cuff (Sorensen and Luckman 1979)

High-Level Disinfected Glove:

- Have circulating nurse or technician pick up replacement glove with high-level disinfected forceps.
- Grasp replacement glove by turned-down cuff and put on glove in the usual manner.

Alternatively:

- Have circulating nurse or technician remove a replacement glove from the high-level disinfected container with forceps and hold the glove open by the cuff. Put hand into the glove without touching the outside of the glove.

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APPENDIX E

DECONTAMINATING AND CLEANING INSTRUMENTS, HYPODERMIC NEEDLES AND SYRINGES AND LINENS¹

HOW TO DECONTAMINATE AND CLEAN SURGICAL (METAL) INSTRUMENTS

Decontamination

STEP 1: After use, immerse all soiled instruments in a plastic container filled with 0.5% chlorine solution or other locally available disinfectant for at least 10 minutes. (This step is necessary to help prevent transmission of HBV or HIV/AIDS to clinic staff.)

STEP 2: If the instruments and other items cannot be washed immediately, rinse the objects with water and towel dry to minimize possible corrosion (rusting) due to chlorine.

Cleaning

Remember: If available, wear utility gloves, eyewear and mask. Do not use hot water because it coagulates protein, making blood and body fluids hard to remove.

STEP 3: Scrub instruments under surface of water to prevent splashing of infectious materials. Use a soft brush and liquid soap or detergent and water (be sure to clean the teeth, joints and screws—an old toothbrush works well).

STEP 4: Rinse again with clean water until no soap or detergent remains. (Soap or 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 HLD, making them ineffective.) Drying is not necessary for instruments which are to be boiled or steamed.

STEP 6: Proceed with sterilization (if available) or HLD by steaming, boiling or soaking in a chemical disinfectant (see **Appendix C**).

HOW TO DECONTAMINATE, CLEAN AND DISPOSE OF NEEDLES AND SYRINGES

The processing and disposal of **needles** and **syringes** constitute a special problem. Clearly, to minimize the risk of needle-stick injuries to staff and because they are difficult to satisfactorily clean and either sterilize or high-level disinfect, they (especially needles) should not be reused.

The use, and especially the disposal of both needles and syringes, however, creates logistical and infection prevention problems. For example, a clinic or health care facility using disposable needles and syringes must ensure that adequate supplies are available at all times. Without a continuous supply of

¹ Adapted from: Tietjen LG et al. 1995. *Infection Prevention for Family Planning Service Programs*, 2nd ed. JHPIEGO Corporation: Baltimore, Maryland.

Decontaminating and Cleaning

needles and syringes, services for Norplant implants and other surgical contraceptive methods, as well as other activities, will be disrupted.

An even larger problem is **how to** safely dispose of used needles and syringes if they cannot be burned or buried. In many countries, boxes of used disposable needles can be found lying discarded outside health care facilities and hospitals. These used needles and syringes constitute an increasing health risk, especially to children and adults seeking items to play with, sell or use.

An alternative to disposing of both needles and syringes would be to reprocess **only** syringes but **not** needles. The rationale for this is the following:

- Contaminated needles primarily are responsible for injuries and the potential risk of acquiring a life-threatening disease.
- Needles are difficult to decontaminate, clean and either sterilize or high-level disinfect; syringes are not.
- Plastic syringes, many of which are made of polyvinyl chloride (PVC), contribute heavily to environmental pollution when burned at high temperatures.

Although processing used needles represents an **inappropriate reuse of disposables** and is responsible for numerous infections (Phillips et al 1971), in some circumstances it is the only available option.

Instructions

When available and affordable, **disposable** (plastic) sterile syringes and needles are

recommended for all client care and surgical procedures. If disposables are being used, it is important to:

- Maintain adequate supplies.
- Decontaminate needles and syringes and discard them in a puncture-proof container immediately after use.
- Dispose of these containers after they are filled by burning or burying them.

As mentioned above, if disposable needles and syringes will be reused, the safest approach is to process **only** syringes but **not** needles.

For those situations where **both needles and syringes** must be reused, care must be taken to avoid accidental needle sticks to cleaning staff during processing.

Instructions for processing needles (and for their disposal) and syringes for **each** of these options are given below.

Disposal of Needle and Syringe

STEP 1: Do **not** recap needle or disassemble needle and syringe.

STEP 2: Immediately after use, decontaminate needle and syringe:

- hold the needle under the surface of a 0.5% chlorine solution, fill with solution and push out (flush) three times, **or**
- draw a small amount of 0.5% chlorine solution into the syringe through the needle and soak in chlorine solution for 10 minutes.

STEP 3: Place assembled needle and syringe into a puncture-proof container such as a heavy cardboard box, plastic bottle or tin can with lid. (Old intravenous fluid bottles also may be used, but they can break.)

Remember: Do not recap needles prior to disposal.

Place the container close to the area where it will be used so that health care staff do not have to carry sharp items a long distance.

STEP 4: When the container is three quarters full, seal and either burn or bury.

Disposal of Needle but Syringe Reused

STEP 1: Do not recap needle or disassemble needle and syringe.

STEP 2: Immediately after use draw a small amount of 0.5% chlorine solution into the syringe through the needle.

STEP 3: Decontaminate assembled needle and syringe by placing in a 0.5% chlorine solution for 10 minutes.

STEP 4: Wearing utility gloves, remove from decontamination solution, push out (flush) solution from assembled needle and syringe and **remove the needle** from the syringe.

STEP 5: **Dispose of needle** in puncture-proof container. When the container is three quarters full, seal and either burn or bury.

STEP 6: Wash syringe in soapy water and rinse at least three times with clean water.

STEP 7: Sterilize or high-level disinfect syringe (see **Appendix C**).

Reuse of Both Needle and Syringe

STEP 1: Do not recap needle or disassemble needle and syringe.

STEP 2: Immediately after use, draw a small amount of 0.5% chlorine solution into the syringe through the needle.

STEP 3: Decontaminate assembled needle and syringe by placing in a 0.5% chlorine solution for 10 minutes.

STEP 4: Wearing utility gloves, remove from decontamination solution and push out (flush) solution from assembled needle and syringe.

STEP 5: Take needle and syringe apart and clean with soapy water. (Be sure to clean hub area of the needle.) Insert stylet or needle wire through hub of needle to be sure it is not blocked.

STEP 6: Put syringe and needle back together. Rinse at least three times by filling with clean water and pushing out (flushing) water into another container so as not to contaminate the rinse water.

STEP 7: Detach needle from syringe.

STEP 8: Examine needle and syringe for:

- bent needle tip or other damage,
- needle hub fit to syringe, and
- readable syringe markers (lines indicating volume, cc or ml).

Decontaminating and Cleaning

STEP 9: Dispose of damaged needles in a puncture-proof container. When container is three quarters full, seal and either burn or bury.

STEP 10: Sterilize or high-level disinfect needle and syringe (see **Appendix C**).

Recapping Needles

If needles must be recapped, use the “one-handed” recap method:

- First, place cap on a hard, flat surface, then remove hand.
- Next, with one hand, hold syringe and use needle to “scoop up” cap.
- Finally, when cap covers needle completely, hold cap at base with other hand and secure cap on needle hub.

HOW TO CLEAN LINENS AND SURGICAL DRAPES

All linen items used in the direct care of a client must be thoroughly washed in water with liquid soap or detergent before reuse. Decontamination prior to washing is **not necessary**.

STEP 1: At the end of the insertion or removal procedure, and while still wearing gloves, lift and remove the surgical drape and carefully place in a container or plastic bag.

STEP 2: Wash the **entire item** in water with liquid soap or detergent to remove all contamination, even if invisible.

STEP 3: Rinse with clean water.

Remember: Never just wash bloody or wet areas of linen.

STEP 4: Completely air or machine dry before further processing. (Air dry in direct sunlight, if possible, keeping the fabric off the ground, away from dust and moisture.)

STEP 5: After linens are totally dry, they should be checked for holes and very threadbare areas. If these are present, the item must be discarded or repaired before reuse. (If there are any holes or many repaired areas, the item should not be used as a drape. It can be cut into pieces to be used as cleaning rags.)

Note: If surgical drapes or surgical gowns are to be sterilized, do not iron. (Ironing dries out the material making autoclaving more difficult.)

If a **clean drape** is acceptable, the air-dried drape can be ironed before placing it on a shelf or in a container for storage. A clean drape should be used for procedures when sterile drapes are not available or necessary (e.g., Norplant implants insertion and removal).

Clean gowns and drapes should be stored in a clean, dry space which is mold-, dust- and insect-free, preferably in a closed cabinet and not near areas that are frequently mopped or near sinks. (Air should circulate between the items in the storage area and the supply should be rotated.)

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APPENDIX F

**CONTENTS OF NORPLANT
IMPLANTS INSERTION/REMOVAL KIT
PROVIDED BY USAID**

ITEM	QUANTITY
Pan	1 each
Pan Cover	1 each
Trocar	5 each
Syringe, Control, 10 ml	3 each
Syringe, Hypodermic, 10 ml	3 each
Needle, Hypodermic, 22 Gauge x 1-1/2"	12 (2 packages)
Handle, Surgical Knife, Size #3	3 each
Blade, Surgical, Size #11	24
Forceps, Crile, Curved, 5-1/2"	1 each
Forceps, Mosquito, Halsted, Straight, 5"	1 each
Forceps, Mosquito, Delicate, Curved, 5"	1 each

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APPENDIX G

FORECASTING REQUIREMENTS FOR NORPLANT IMPLANTS PROGRAMS¹

There are three stages for Norplant implants programs for which the materials and services requirements will need to be forecast:

- pre-introduction, when training and service delivery resources are being established;
- startup, when implants are being incorporated into the family planning program; and
- mature program, when implants services are fully available.

In the **pre-introduction stage**, the object of forecasting is to estimate initial and long-term requirements. The initial national experience and training program should start slowly to ensure that an adequate infrastructure is in place. Therefore, the pre-introduction stage requires few implants sets (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- or over-supply are 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 implants sets.

The following example (**Table G-1**) can be used to estimate requirements for implants sets and the potential demand on service delivery requirements over time. This model assumes that 1,000 women per year choose to use implants. That 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). At the end of the 5-year effective life of Norplant implants, some women (line 3) will have to choose to have a second set of capsules inserted. In this example, 50% of the women choose to use implants again (line 4). The total insertions per year (shown in line 5) obviously dictate the requirements shown in line 13. A certain loss of implants during storage and distribution must be anticipated. Here, a 5% loss from inventory is assumed (line 14). The annual and cumulative requirements are given in lines 15 and 16.

¹ Adapted from: World Health Organization (WHO). 1990. *Norplant Contraceptive Subdermal Implants: Managerial and Technical Guidelines*. WHO: Geneva.

Forecasting Requirements for Norplant Implants Programs

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 implants will begin to need removal services (line 9).

The total removals per year are 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 acceptors per year, the demand for procedures will double in about 8 years.

The number of women using implants at the end of each year, for whom followup clinical or counseling services may be needed, obviously increases with time, as shown in line 12. The service delivery requirements for implants are discussed in **Chapter 11**.

Table G-1. Estimating Requirements for Norplant Implants

	Years From Start of Program									
	1	2	3	4	5	6	7	8	9	10
1. Insertions in current year	1000	1000	1000	1000	1000	1000	1000	1000	1000	1000
2. Users from previous years	0	898	1616	2191	2651	3019	3198	3341	3455	3547
3. Users remaining who entered 5 years ago	0	0	0	0	0	328	328	328	328	328
4. Second insertions	0	0	0	0	0	164	164	164	164	164
5. Total insertions—current year	1000	1000	1000	1000	1000	1164	1164	1164	1164	1164
6. Removals from current acceptors	102	102	102	102	102	102	102	102	102	102
7. Removals—acceptors 1 to 4 years earlier	0	180	323	438	530	538	574	603	625	644
8. Removals—women who entered 5 years ago	0	0	0	0	0	328	328	328	328	328
9. Removals—second set of implants	0	0	0	0	0	17	17	17	17	17
10. Total removals—in current year	102	282	425	540	632	985	1021	1050	1072	1091
11. Insertion and removal procedures in year	1102	1282	1425	1540	1632	2149	2185	2214	2236	2255
12. Users at end of year	898	1616	2191	2651	3019	3198	3341	3455	3547	3620
13. Implants needed during year	1000	1000	1000	1000	1000	1164	1164	1164	1164	1164
14. Inventory loss	50	50	50	50	50	58	58	58	58	58
15. Annual implant requirements	1050	1050	1050	1050	1050	1222	1222	1222	1222	1222
16. Cumulative total	1050	2100	3150	4200	5250	6472	7694	8916	10138	11360

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JHPIEGO Educational Materials and Training Packages

Described below are current and upcoming JHPIEGO educational materials and training packages. See page 5 for information on ordering.

Family Planning

PocketGuide for Family Planning Service Providers. This pocketguide is designed to provide clinicians with easily accessible, clinically-oriented information about contraceptive methods and family planning clients. It is intended for use by clinicians when they need immediate answers to questions about a client's condition or a contraceptive method. The easy-to-find information is organized into sections on providing services (e.g., client assessment, infection prevention), specific contraceptive methods (e.g., natural family planning, oral contraceptives, voluntary sterilization) and contraception for clients with special needs (e.g., adolescents, clients with chronic medical problems). Available in English, French, Portuguese and Spanish (1995).

Genital Tract Infections (GTIs)

Managing Genital Tract Infections in Family Planning Service Programs. This monograph describes a problem-oriented approach for the management of sexually transmitted GTIs. Problem-solving flowcharts, which are based on clinical findings and use of microscopy and other simple tests, are used to support the clinical diagnosis. Using the information provided allows the clinician to determine the diagnosis while the client is still in the office or clinic. This improves the likelihood of providing the correct diagnosis and treatment at the first presentation of the problem, minimizing treatment failures and improving compliance. Available in English (1993).

Genital Tract Infection Guidelines for Family Planning Service Programs. This reference manual is designed to serve as a primary reference for clinicians (physicians, nurses and midwives) learning to manage and diagnose those GTIs frequently encountered in the family planning setting. Because the problem-oriented approach more closely approximates clinical practice, the material in the guidelines is organized by client problem (e.g., vaginal discharge, genital ulcer or abdominal pain) rather than by causative agent (microorganism). Flowcharts are used wherever applicable as step-by-step guides for diagnosis, and tables summarize the chief clinical features of the GTIs. The appendices contain detailed descriptions of how to perform the diagnostic tests and interpret the results, and a comprehensive treatment guide. Available in English and French (1991). (Second edition due in 1995.)

GTI Training Slide Set—Managing Sexually Transmitted Genital Tract Infections. This annotated slide set consists of 104 slides which are divided into three sections: gross and microscopic lesions; diagnosis of trichomoniasis, candidiasis and bacterial vaginosis; and diagnosis of gonorrhea. Available in English and French (1991).

Infection Prevention (IP)

Infection Prevention for Family Planning Service Programs. This international reference standard is designed to enable clinic administrators, managers and health care professionals develop uniform IP standards for use in any type or size of family planning service program. The goal of IP is twofold: preventing infection in the client, and providing protection to both clients and health care workers. The three sections of the manual cover basic IP principles, practical and easy-to-do IP practices for each surgical contraceptive method and "how to" instructions for using the recommended procedures. Available in English, French, Portuguese, Russian and Spanish (1992). (Second edition due in 1995.)

Infection Prevention Course Handbook and Notebook. The **participant handbook** outlines a model one-week (five-day) training course in recommended IP practices for the safe delivery of all types of surgical contraceptive

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procedures. The learning objectives and pre- and midcourse questionnaires are keyed to the *Infection Prevention for Family Planning Service Programs* manual. Participants measure their progress using detailed IP learning guides. An eight-hour refresher module is included for use in short, inservice surgical contraceptive courses. The handbook contains information about how the course is taught, the precourse questionnaire, learning guides and supplemental training materials. The **trainer's notebook** contains the precourse questionnaire and answer key, midcourse questionnaire answer key, competency-based (qualification) checklists and a section on tips for conducting the training course, in addition to all participant material. Handbooks and notebooks are provided in a ratio of one trainer's notebook for every five participant handbooks. Available in English, French and Russian (1994).

Infection Prevention Training Slide Set—*Infection Prevention Overview*. This annotated slide set is designed to accompany JHPIEGO's *Infection Prevention Guidelines* for use in the training course and provides an overview of the basic principles of infection prevention, guidelines for processing instruments and other items, and outlines the recommended IP practices for use in family planning service programs. Available in English, French, Portuguese and Spanish (1993).

Infection Prevention Training Video and Trainer's Notes—*Infection Prevention for Family Planning Service Programs*. Produced in collaboration with AVSC International, this video emphasizes the dual role of infection prevention in minimizing postoperative infections in clients and preventing serious disease transmission (hepatitis B and HIV/AIDS) to both clients and health care staff. It also documents practical, easy-to-do infection prevention practices that minimize costs and the need for expensive technology and/or fragile equipment. In addition, the video includes a series of short training demonstration segments (TDS) which can be used during a training course to demonstrate recommended infection prevention practices for selected processes and procedures. TDS topics include: processing instruments and other items (decontamination, cleaning and either high-level disinfection or sterilization), using multi-dose vials and special processing for manual vacuum aspiration (MVA) equipment and laparoscopes. The **trainer's notes**, included with the video, are intended to help trainers use the TDS more effectively. Available in English, French, Portuguese, Russian and Spanish (1994).

IUD (Copper T 380A)

IUD Guidelines for Family Planning Service Programs. This reference manual provides clinicians (physicians, nurses and midwives) with essential information on how to provide IUD (specifically the Copper T 380A IUD) services safely. The material is arranged sequentially, according to the usual way in which clients are cared for—beginning with counseling and ending with management of side effects and other health problems. Available in Portuguese and Spanish (1995); English and Russian (1993); French (1992).

IUD Course Handbook and Notebook. The **participant handbook** outlines a model two-week (10- to 12-day) competency-based training course for clinicians covering all aspects of IUD service delivery. The learning objectives and pre- and midcourse questionnaires are keyed to the *IUD Guidelines*. Participants measure their progress using detailed counseling and clinical skills learning guides. The handbook contains information on how the course is taught, the precourse questionnaire, learning guides and supplemental training materials. The **trainer's notebook** contains the precourse skills assessment, precourse questionnaire answer key, midcourse questionnaire and answer key, competency-based (qualification) checklists and a section on tips for conducting the training course, in addition to all participant material. Handbooks and notebooks are provided in a ratio of one trainer's notebook for every five participant handbooks. Available in English, Portuguese and Spanish (1995); French and Russian (1994).

IUD Training Slide Set—*Copper T 380A IUD Insertion and Removal*. This annotated slide set is designed to supplement JHPIEGO's *IUD Guidelines* for use in the training course. Using the Zoe® and hand-held uterine models, the slides provide step-by-step instructions for performing the screening pelvic exam, loading the Copper T 380A IUD in the sterile package, inserting and removing the Copper T 380A IUD and managing problems. Available in English, French, Portuguese and Spanish (1993).

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 for insertion, IUD removal and management of side effects and other health problems. Available in English, French and Spanish (1990).

Norplant® Implants

Norplant® Implants Guidelines for Family Planning Service Programs. This reference manual provides clinicians (physicians, nurses and midwives) with essential information on how to safely insert and remove Norplant implants. The material is arranged sequentially, according to the usual way in which clients are cared for—beginning with counseling and ending with management of side effects and other health problems. Available in English (1995); French and Spanish (1993).

Norplant® Implants Course Handbook and Notebook. The **participant handbook** outlines a model three-day competency-based training course covering all aspects of service provision using a team approach. The learning objectives and pre- and midcourse questionnaires are keyed to the *Norplant Implants Guidelines*. Participants measure their progress using detailed counseling and clinical skills learning guides. The handbook contains information about how the course is taught, the precourse questionnaire, learning guides and supplemental training materials. The **trainer's notebook** contains the precourse questionnaire answer key, midcourse questionnaire and answer key, competency-based (qualification) checklists and a section on tips for conducting the training course, in addition to all participant material. Handbooks and notebooks are provided in a ratio of one trainer's notebook for every five participant handbooks. Available in English (1995); French and Spanish (1993).

Norplant® Implants Training Slide Set (Norplant Implants Insertion and Removal). This annotated slide set is designed to supplement JHPIEGO's *Norplant Implants Guidelines* in the training course, and provides step-by-step instructions and trouble-shooting hints for Norplant implants insertion and removal. Available in English, French and Spanish (1993). (Second edition due in 1995.)

Postabortion Care

Postabortion Care: A Reference Manual for Improving the Quality of Care. This **manual**, produced by the Postabortion Care Consortium, provides clinicians with essential information on the safe and effective management of incomplete abortion and the life-threatening complications of unsafe abortion. The manual outlines the full range of activities needed to provide appropriate, high-quality postabortion care, including family planning and referral to health care services needed after emergency treatment. The material in this manual is arranged sequentially according to the usual way in which patients are cared for—starting with the initial assessment of their condition and ending with the provision of followup care, including family planning and other reproductive health services. Available in English and French (1995).

Postabortion Care Course Handbook and Notebook. The **participant handbook** outlines a model one-week (six-day) training course for clinicians covering all aspects of providing postabortion care. The learning objectives and pre- and midcourse questionnaires are keyed to the *Postabortion Care Reference Manual*. Participants measure their progress using detailed counseling and clinical skills learning guides. The handbook contains information on how the course is taught, the precourse questionnaire, learning guides and supplemental training materials. The **trainer's notebook** contains the precourse skills assessment checklist, precourse questionnaire answer key, midcourse questionnaires and answer key, competency-based (qualification) checklists, and a section on tips for conducting the training course, in addition to all participant material. Handbooks and notebooks are provided in a ratio of one trainer's notebook for every five participant handbooks. Available in English (1995).

Postabortion Care Educational Kit. This kit is intended for use in educating health administrators, clinic managers and all health professionals about postabortion care issues and practical solutions. It contains a complete set of materials that enables a user to present the concept of postabortion care and the rationale for treatment by manual vacuum aspiration. In addition, these materials can be used to begin a general discussion of the issue, introduce the key elements of postabortion care or serve as the initial session in a training course. The kit includes: a videotape, *Postabortion Care: A Global Health Issue*; annotated slide and transparency master sets; a handout, "Postabortion Care Services;" and "Postabortion Care: A Women's Initiative to Combat Unsafe Abortion," a report published in *Advances in Abortion Care*, IPAS (1994). The materials are packaged together in a binder and can be used individually or jointly depending on the audience. Available in English, French and Russian (1994).

Postabortion Care Video—*Postabortion Care: A Global Health Issue*. Produced by the Postabortion Care Consortium, the video provides an overview of the problem of unsafe abortion and the need for good postabortion care. Also covered are the three elements of postabortion care: emergency treatment of incomplete abortion and potentially life-threatening complications; postabortion family planning counseling and services; and links between postabortion emergency services and the reproductive health care system. It is designed to introduce the concept of postabortion care to policymakers as well as to clinicians. Available in English, French, Portuguese, Russian and Spanish (1994).

Training Skills

Clinical Training Skills for Reproductive Health Professionals. This reference manual is designed for the expert service provider who wishes to become a clinical trainer. It focuses on the essential areas of clinical skills training including creating a positive training climate, coaching in the clinical setting, conducting classroom and clinical demonstrations, training with models, using competency-based knowledge and skills assessments, presenting illustrated lectures and conducting a clinical training course. Available in English, French, Portuguese, Russian and Spanish (1995).

Clinical Training Skills Course Handbook and Notebook. The **participant handbook** outlines a two-week (10- to 12-day) model course which includes a clinical skill standardization component, instruction in clinical training skills and practice training experiences. It is designed to be used with JHPIEGO's *Clinical Training Skills* manual. The handbook contains detailed information about how the course is taught, the precourse questionnaire, learning guides and supplemental training materials. The **trainer's notebook** contains the precourse questionnaire answer key, midcourse questionnaire and answer key and competency-based (qualification) checklists, in addition to all participant material. Handbooks and notebooks are provided in a ratio of one trainer's notebook for every five participant handbooks. Available in English, French, Portuguese and Spanish (1995).

Advanced Training Skills for Reproductive Health Professionals. This reference manual is intended for use by medical, nursing and other health professional faculty and family planning trainers who are responsible for assessing training needs and designing, teaching and evaluating reproductive health training courses. It emphasizes a participatory training approach, and is based on adult learning principles and the use of competency-based knowledge and skill assessments. Available in English (due 1995).

Training Skills Course Handbook and Notebook. The **participant handbook** outlines a model course to give expert reproductive health trainers the essential information and skills they need to design and conduct training skills courses for reproductive health professionals. It is intended to be used with JHPIEGO's manual *Advanced Training Skills*. The handbook contains information about how the course is taught, the precourse questionnaire, learning guides and supplemental training materials. The **trainer's notebook** contains the precourse questionnaire answer key, midcourse questionnaire and answer key and competency-based (qualification) checklists, in addition to all participant material. Handbooks and notebooks are provided in a ratio of one trainer's notebook for every five participant handbooks. Available in English (due 1995).



Order Form

JHPIEGO Educational Materials

Please indicate language and quantity desired for each publication. Please complete the shipping information on pages 6 and 7. See page 8 to order videotapes.

Pricing Information	Language Abbreviations
All reference manuals, course handbooks for participants, trainers notebooks and <i>PocketGuide</i> = \$6 each.	En=English
All slide sets = \$28.50 each.	Fr=French
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TOPIC AND PUBLICATION

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Genital Tract Infections (GTI)

GTI Monograph En _____

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Infection Prevention (IP)

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IUD

IUD Reference Manual En _____ Fr _____ Po _____ Ru _____ Sp _____

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Norplant® Implants

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ASSESSMENT OF NORPLANT IMPLANTS REFERENCE MANUAL

Please indicate on a 1-5 scale your opinion of the following chapters

5-Excellent 4-Very Good 3-Satisfactory 2-Needs Improvement[†] 1-Unsatisfactory[†]

CONTENTS	Easy to read	Contains need to know information	Figures and tables helpful	Useful in problem solving
Overall Evaluation of Manual: Norplant Implants Guidelines for Family Planning Service Programs				
CHAPTER				
1. Introduction				
2. Counseling				
3. Indications and Precautions				
4. Client Assessment				
5. Infection Prevention				
6. Insertion				
7. Postinsertion and Followup Care				
8. Management of Side Effects and Other Health Problems				
9. Removal				
10. Providing Quality Services				
11. Organizing and Managing a Norplant Implants Service				

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[†] Please comment on the back if you rated any chapters less than satisfactory (2 or 1).

ADDITIONAL COMMENTS

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3. What topics (if any) should be **added** (and why) to improve the manual?
4. What topics (if any) should be **deleted** (and why) to improve the manual?
5. Did you receive this manual by attending a training course? if not, how?

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