Jadelle®

Training Manual
for Family Planning

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Preface

This manual was developed to provide family planning trainers and service providers with a concise source for up-to-date information on the latest levonorgestrel implant system, Jadelle. The manual is partly based on the JHPIEGO's training manual "Jadelle two-rod levonorgestrel contraceptive implants" but has been revised by the company according to the official Summary of Product Characteristics (SmPC) text of the product. Throughout this manual, references to these and other documents are specifically cited within the text or acknowledged at the end of each chapter.

The purpose of this reference manual is to provide clinicians (physicians, nurses and midwives) with essential information on how to provide Jadelle 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 adverse 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.

Specific objectives of this manual:

- Describe the basic process of counseling clients about using Jadelle.
- Explain the indications and precautions for LNG implants use.
- Define the items necessary to include in the assessment of a potential Jadelle client.
- Detail easy-to-use, inexpensive infection prevention practices that minimize disease transmission to clients and health care staff.
- Describe a step-by-step procedure for insertion of Jadelle rods.
- Describe the important elements in the follow-up of LNG implants users.
- Provide a guide to the management of possible adverse effects and other problems associated with use the of LNG implants.
- Describe a step-by-step procedure for the removal of Jadelle rods.

Finally, it is the author's belief that if the information provided in this manual is combined with a competency-based training approach, clinicians will be better prepared to **competently** and **confidently** provide Jadelle services.

Remember: Successful programs are those in which the staff exhibit:

- good clinical judgment in selecting acceptors;
- care, sensitivity and thoroughness in informing the client about Jadelle and its common adverse effects;
- skill in inserting (and removing) the rods;
- 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

Chapter 1: Introduction

Background

Levonorgestrel (LNG) implants are the first new contraceptive to be made available since the 1960s when the oral contraceptive pill was developed, and IUDs were rediscovered. Jadelle, the latest second generation LNG implant system, has been found to be equally effective and acceptable as Norplant, the initial first generation sub-dermal implant system. Like Norplant, it provides safe, highly-effective reversible contraception. Because Jadelle consists of only two rods, rather than the six capsules in Norplant, insertion and removal are easier and take less time.

Compared to other methods of hormonal contraception Jadelle as an implant provides a different way to deliver the hormone LNG into the body: the LNG passes continuously into the bloodstream through the walls of the implants at a relatively constant rate. With Jadelle the LNG is maintained at an effective level for 5 years. Thus this method makes it possible for a single act of application acceptance to replace more than 1800 days of pill taking. After the Jadelle rods are removed LNG levels drop quickly and normal fertility returns promptly.

Levonorgestrel implants were developed by Bayer Schering Pharma AG under licence from the Population Council, an international contraceptive research organization.

Development of levonorgestrel implants

Implant development began in 1966 with the pioneering research of Segal and Croxatto. They showed that steroid hormones could be released continuously for more than a year from silicone (Silastic) capsules implanted just under the skin (Croxatto et al 1969; Segal and Croxatto 1967). These preliminary results formed the conceptual basis for the development of a long-acting implantable contraceptive. Their goal was to develop a contraceptive that would allow women to make a single decision resulting in effective contraception for several years (Croxatto et al 1975).

First phase of clinical trials

Based on encouraging early results, it was determined that:

- six capsules made of medical grade silicone (Silastic) tubing would be the drug-delivery system; and
- levonorgestrel was the best progestin to use because of its safety, effectiveness and rate of release through Silastic tubing (Segal 1982).

In 1975, the first long-term clinical trials were initiated in six countries (Brazil, Chile, Denmark, the Dominican Republic, Finland and Jamaica). Because the first year results showed a very low pregnancy rate (0.6 per 100 woman-years), good acceptability and continuation rates of 75-80%, the clinical studies were continued (Coutinho et al 1978). When the capsules were analyzed for the steroid remaining in them, only about 10% of the initial LNG load had been released during the first year (Nash et al 1978).

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Chapter 1

This indicated the effective life of the six capsule system could be several years.

Second phase of clinical trials
By 1980 results from the first five years of experience showed that the LNG implants were effective, well-accepted and had few adverse effects (Diaz et al 1982). At this time manufacture of the capsules, which until then had been done in the laboratory, was shifted to industrial production by Leiras Oy in Finland, and the second phase of LNG implant studies began.

The 1980s also marked the development and trial of a two-rod LNG implant. Unlike the capsules, which are filled with dry crystalline LNG and then sealed in silicone tubing, each rod consists of a core containing equal weights of silicone elastomer and LNG, covered with thin-walled silicone tubing (Sivin et al 1997a). Each rod is nearly 1 cm longer than a capsule and contains more than twice as much LNG, 75 versus 36 milligrams (mg). During this phase, further multinational clinical trials were conducted which included several clinics in the US. By 1983, basic research on Norplant capsules was essentially complete, but investigations of the two-rod implant system continued. Unfortunately, while these trials were underway, an elastomer used in making the rods became unavailable commercially. It took several years to identify another elastomer whose use approximated the LNG release rate of the original rods. Once these new rods, now called Jadelle, became available in mid-1990, new clinical trials began.

Current status
The first country to approve marketing of Norplant was Finland in 1983. The two-rod Jadelle has been introduced first in 1996 to replace the six capsules implant Norplant. Today Jadelle has been approved in more than 44 countries.

Since its approval in Finland, more than six million women worldwide have chosen Norplant as their contraceptive method. And with the introduction of Jadelle, the use of LNG implants has become even more popular.

Table 1-1. Development of contraceptive implants

1974	Development of the Norplant drug-delivery system (six LNG-releasing silicone capsules)
1977	Testing of a two-rod drug-delivery system (two LNG-releasing silicone rods) begins
1983	Norplant capsules first approved for marketing in Finland
1990	Testing of the reformulated two-rod system (Jadelle) begins
2002	Norplant approved in more than 60 countries
1996	Jadelle approved for marketing in the US
1997	Jadelle approved for marketing in Finland
2001	Jadelle approved for marketing in several European countries
2002	Jadelle approval process initiated in several African countries

Figure 1-1.
Jadelle rod, actual size

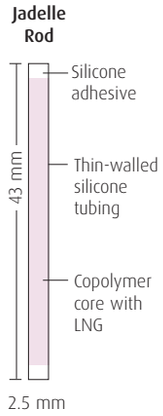
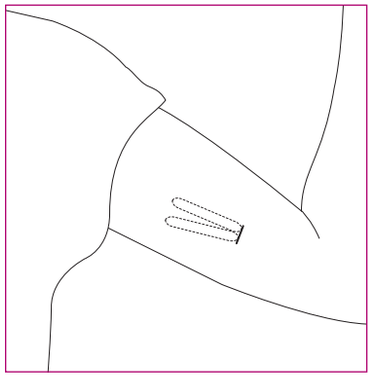


Figure 1-2.
Jadelle insertion site



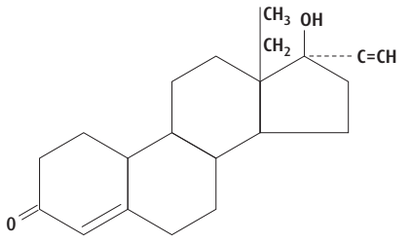
Description

Levonorgestrel implants are a progestin-only product; they contain no estrogen. A set of Jadelle implants consists of two small, flexible rods that have a core consisting of an equal mixture of levonorgestrel and silicone elastomer. The rods are covered with thin-walled silicone tubing and are sealed at the ends with Silastic medical grade adhesive. Each rod is 43 millimeters (mm) long, 2.5 mm in diameter and contains 75 mg LNG (Figure 1-1).

The rods 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 with local anesthetic.

The active contraceptive steroid in Jadelle is the progestin levonorgestrel, a chemical derivative of 19-nortestosterone. Levonorgestrel has potent progesterone-like activity, weak androgenic properties and no significant estrogen activity. Its chemical structure is depicted in Figure 1-3.

Figure 1-3.
Structure of levonorgestrel



The materials used in the production of Jadelle rods are not new to medicine. Levonorgestrel has been used since the 1960s in combined (estrogen and progestin) oral contraceptives and in progestin-only minipills (Population Council 1990). The silicone tubing used to cover the rods has been used in humans (prosthetic valves and other surgical devices) since the 1950s, and the medical adhesive (Silicone Type A) has been used extensively in surgical implants such as cardiac pacemakers for many years (Croxatto 1993).

Packaging
The contraceptive is supplied

as a set. One sealed, sterile plastic pouch contains two rods, each filled with 75 mg of levonorgestrel, for use in one woman.

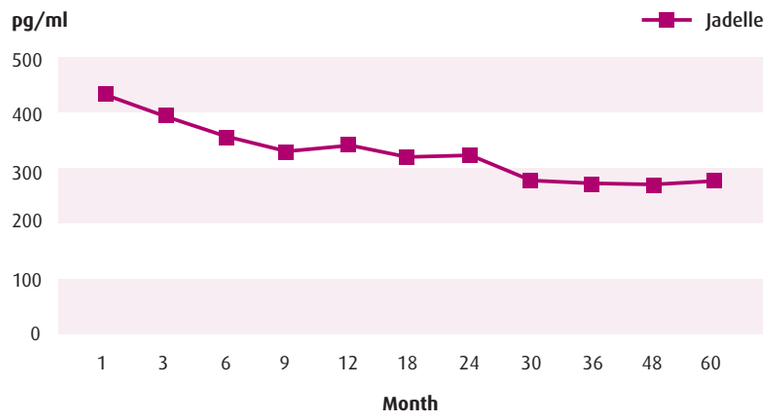
Storage and shelf life

The sterile packs of Jadelle rods should be stored away from excessive heat (temperatures higher than 30°C) and moisture. An unopened, undamaged sterile pack of Jadelle rods, if properly stored, has a shelf life of 5 years. The last date for insertion (expiration date) is stamped on each box.

Effective life

If inserted anytime before the expiration date (shelf life), a set of Jadelle rods is effective for 5 years. The rods should be removed by the end of the fifth year. If desired, a new set of rods may be inserted in the same location immediately following removal.

Figure 1-4. Mean levels of levonorgestrel



Pharmacokinetics

Absorption

As shown in Figure 1-4, one month after insertion of Jadelle rods the mean levels of LNG were 435 picograms/milliliter (pg/ml). During the first year, mean concentrations of levonorgestrel remained well above 300 pg/ml. Although by the end of the fifth year the LNG concentration in women using Jadelle rods had decreased to a mean of 279 pg/ml, this value was well above the suggested pregnancy threshold of 200 pg/ml (Sivin et al 1997b, Sivin et al 2001).

These results suggest that Jadelle rods are effective for 5 years

Distribution and excretion

In the blood, LNG is bound to sex hormone binding globulin (SHBG). Because LNG is weakly androgenic, within a few days after insertion SHBG levels are decreased, leading to lower concentrations of LNG (Affandi et al 1987; Fotherby 1994). The elimination half-life of LNG is about 13 to 18 hours (Sisenwine et al 1975). The majority (40-68%) of LNG and its metabolite are excreted in the urine and 16-48% in feces (Croxatto et al 1988; Hümpel et al 1977).

Mechanism of action

With LNG implants, pregnancy is prevented through a combination of mechanisms. The two primary means are:

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

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

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

Effect on cervical mucus

Perhaps the most important contraceptive effect of LNG implants is the change they cause in the composition of the cervical mucus. Within 48–72 hours after insertion the cervical mucus becomes thick, is decreased in amount and limits the ability of sperm to pass through it. For example, in postcoital tests with women using LNG implants, few sperm were able to reach the endocervical canal, and those that did had de-creased motion (Brache et al 1985; Croxatto et al 1987). This effect is the same as that seen with progestin-only minipills and injectables as well as combined oral contraceptive pills. This action has been confirmed in laboratory tests (Croxatto et al 1987).

Effect on ovulation

The amount of LNG released from implants is sufficient to activate feedback mechanisms in the hypothalamus and anterior pituitary gland. The decrease the secretion of follicle-stimulating hormone (FSH) and luteinising hormone (LH) and prevent or significantly reduce the LH surge that precedes ovulation (Alvarez et al 1986). However, serial measurements of circulating endogenous progesterone have indicated that individual women show a wide spectrum of ovarian responses to LNG implants, includ-

Table 1-2. Frequency of ovulation in women using LNG implants

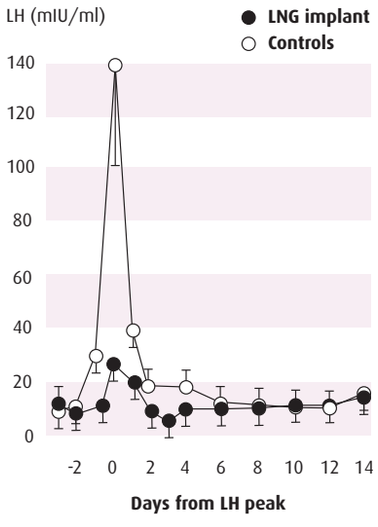
Years of LNG implants use	numer of woman	ovulatory (%)	anovulatory (%)	uncertain (%)
1	27	11	82	7
2	21	62	29	10
3	36	28	64	8
4	23	44	52	4
5	48	52	46	2
6	19	74	26	0
7	15	60	33	7
Average (1-7 years)	189	44	50	5

Source: Croxatto, Diaz and Pavez 1982.

[1] To be classified as "compatible with ovulation, progesterone level above 9.5 nanomoles 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.

ing absence of both follicular and luteal activity, cyclical follicular but no luteal activity, normal follicular but deficient luteal activity, and normal ovulation (Davies et al 1992). Only about 11% of cycles are ovulatory during the first year, rising to over 50% by the fifth year. Studies using ultrasonography as well as circulating progesterone levels have demonstrated that blocking ovulation is an important mechanism by which LNG implants prevent pregnacy, especially during the first years of use (Brache et al 1990). The effects of implants on ovulation are similar to those seen with progestin-only oral contraceptives, which inhibit ovulation in approxiamately 50% of cycles and produce a deficient luteal phase in others (Martinez-Manoutou et al 1966; Fotherby et al 1968; Landgren et al 1980).

Figure 1-5. Mean LH Levels in LNG implant users



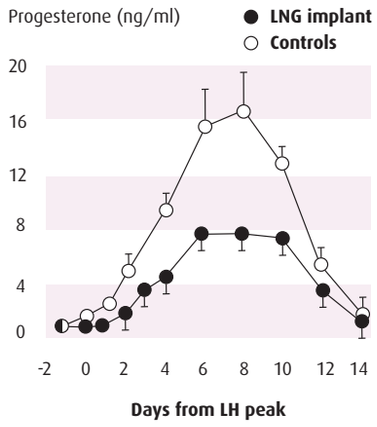
How ovulation is prevented

The small amount of LNG that is continuously released from the implants acts on specific 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).

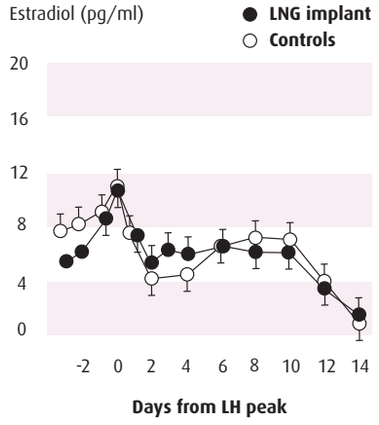
Thus in LNG implant users, ovulation is either prevented (no LH surge) or, if ovulation does occur, progesterone levels are reduced (Li, Davies and Newton 1992). As depicted in Figure 1-6, mean natural progesterone levels even in "ovulatory" cycles of LNG implant users **(•) are significantly** less than those in women (controls) not using a hormonal contraceptive (○).

Figure 1-6. Mean progesterone levels in LNG implant users during ovulatory cycles



This lower level of progesterone is due to the action of LNG, which limits secretion of progesterone but **not** estrogen (Figure 1-7), from the corpus luteum that forms in the ovary following ovulation. As a consequence, even in presumed 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). Whether ovulation is prevented, or just impaired due to decreased function of the corpus luteum, varies from cycle to cycle.

Figure 1-7. Mean estrogen levels in LNG implant users



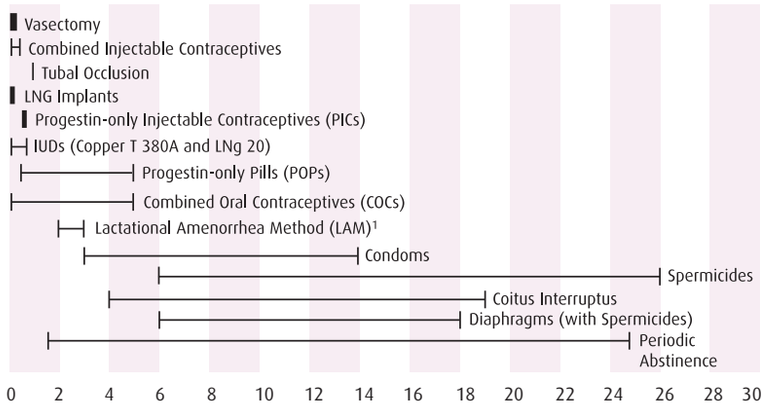
Effect on endometrium

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 glands and these function poorly (i.e., they do not have as much secretory activity). This added effect of LNG is thought to further reduce the likelihood of successful implantation and may contribute to the contraceptive action of LNG implants.

Clinical experience

Clinical experience with LNG 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 US, had participated in Norplant clinical trials. Based on study results, the Pearl index (i.e. the Pearl Index indicates the number of pregnancies occuring if 100 sexually acrtive women use a specific method of contracep-

Figure 1-8. Range of theoretical and typical use pregnancy rates per 100 women during first year of use



Adapted from: Labbok, Cooney and Coly 1994; Trussell 1998

[1] During first 6 month of use

tion for one year. The lower the Pearl Index is the safer is the method) was 0.2. for the first 2 years and 0.9, 0.5 and 1.1 per 100 woman-years for the third through fifth years (Darney et al 1990b.) The first- and second-year failure rates compare favorably with the lowest expected failure rates even for male and female voluntary sterilization (Trussell et al 1990b). The **effectiveness** of a contraceptive method is an important factor, both for the individual (or couple) trying to choose a method and the service provider. 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.** With methods such as Jadelle that do not require action by the user, there is essentially no difference between typical and theoretical use. Data presented in this way for the **first year of use** for most contraceptive methods are illustrated in **Figure 1-8.**

In a multicenter clinical trial (Sivin et al 1997a, Sivin et al 1998a), no pregnancies were reported during the first 4 years, and at 5 years, the cumulative pregnancy rate was 1 per 100 users or less for each regimen **(Table 1-3).** Summarizing all the published studies, the cumulative pregnancy rates with Jadelle were 0.1 at 1 year, 0.3 at 3 years, and 1.1 at 5 years (Sivin et al 1998 a, 1998b). Thus Jadelle is as effective as Norplant during 5 years of use.

Table 1-3.
Gross cumulative pregnancy and continuation rates for Jadelle (per 100 women, by year)

	Year 1	Year 2	Year 3	Year 4	Year 5
Pregnancy	0.0	0.0	0.0	0.0	1.0
Continuation	93.8	81.3	71.3	63.0	55.1
No. Started Year	600	560	473	410	353

Source: adopted from Croxatto, Diaz and Pavez 1982.

Effect of other medications

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

- **anti-epilepsy (seizure disorder) drugs** such as barbiturates (phenobarbital), phenytoin and carbamazepine but **not** valproic acid; and
- **antibiotics** (only rifampin and griseofulvin[2]).

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

Compliance

As mentioned above, a major stumbling block to the effective use of some 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 Jadelle is that one act of contraceptive acceptance by a woman will provide up to 5 years (1800 days) of continuous pregnancy protection without the need to remember to take a pill, use a condom or check that a device is still in place.

Table 1-4.
First-year continuation rates of selected contraceptive methods

Method	Continuation Rate at one Year (%)
Jadelle	**94**
Norplant	93
Levonorgestrel IUS	93
Oral Contraceptive Pills	73
IUD	73
Condom	64
Cervical Cap	63
Vaginal Sponge	
Nulliparous	60
Parous	53
Diaphragm	57
Spermicide	43

Source: Sivin et al 1997a; Trussell et al 1990a; Backman et al 2002

Note: Because Jadelle does not protect women from hepatitis B, AIDS and other sexually transmitted diseases (STDs), women may wish to use a barrier contraceptive method in addition to Jadelle to protect themselves from STDs.

Continuation

As shown in **Table 1-3**, the 5-year cumulative continuation rate for Jadelle is very favorable. Moreover, as shown in **Table 1-4**, the first-year continuation rate for Jadelle is better than for most of other reversible methods.

Pregnancy

The use of LNG implants does not increase the frequency of **ectopic pregnancy**. In a study involving 600 women who used Jadelle for 5 years, there was one ectopic pregnancy yielding an ectopic pregnancy rate of 0.4 per 1000 (Sivin 1998a). This rate is significantly below the ectopic pregnancy rate of 2.7 to 3.0 per 1,000 woman-years reported for non-contracepting women aged 15 to 44 (Franks et al 1990).

If a woman **does** become pregnant with LNG implants in place, however, it may more likely be an ectopic pregnancy. Any woman using LNG

[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 LNG implants, either Jadelle or Norplant. They should use a backup method while taking griseofulvin and until the start of the next menstrual period after stopping the antibiotic.

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

Table 1-5. Cumulative pregnancy rates after removal (per 100 users)

Time after removal (months)	Jadelle (%)
3	-
6	63
12	80
24	88
Subjects (n)627	96

Source: adapted from Buckshee et al 1995; Sivin 1988.

implants who presents with symptoms of pregnancy, especially if she has lower abdominal pain, should be carefully evaluated to rule out the possibility of ectopic pregnancy (Croxatto 1993).[3] With the passage of time, the risk of both intrauterine and ectopic pregnancy in women using LNG implants increases. The rate of ectopic pregnancy also increases. Thus, if clients using Jadelle want to continue the method, they should have them removed and replaced by or before the end of their effective life. Finally, in the clinical trials of Norplant, no birth defects or pregnancy-related problems other than ectopic pregnancy were reported (Population Council 1995). During the post-marketing period, however, there have been rare reports of congenital abnormalities in infants born to women who were using it when they became pregnant. No cause and effect relationship has been established.

Return of fertility

Once LNG implants are removed, serum levels of LNG become undetectable within a few days (Croxatto et al 1988). This results in a prompt return of fertility. In addition, several studies have reported no long-term effects on future fertility, regardless of age or parity (Buckshee et al 1995; Sivin et al 1992). In fact pregnancy rates for women who have used LNG implants compare favorably with those not using any contraception (Sivin 1988). For example, as shown in Table 1-5, over 60% of women wanting to become pregnant did so within 6 months after removal of Jadelle; 80% within 12 months and 88% within 24 months.

Advantages of Jadelle

A major advantage of Jadelle is that insertion and removal are easier and take less time because there are only two rods instead of the six Norplant capsules. As shown in Table 1-6, the mean (±SD) time required for removal of Jadelle was 4.9 (± 3.5) minutes, but for Norplant it was 10.4 (± 7.9) minutes. In this study, which involved removal of 165 sets of Jadelle rods and 162 sets of Norplant capsules, the time interval measured began with the skin incision and ended with removal of the last rod or capsule respectively. By contrast, because removal of either type of implant involves making a skin incision and varying amounts of soft tissue (blunt) dissection, no differences in bruising, pain or superficial tissue trauma were reported. In this study all removals were done by the Standard Technique (Appendix F) which involves using Crile or Mosquito forceps to grasp the end of the rods. The clinicians were all well trained and experienced.

Adverse effects

Although nearly all LNG implant users will experience one or more adverse effects, serious problems are very rare (Darney et al 1990b). Unfortunately, despite the fact that most adverse effects are minor, they may be bothersome enough to prompt some users to stop using LNG implants. 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. Careful explanation of the adverse effects before inserting Jadelle rods, as well as reassurance that rarely do they represent a risk to the client's health, helps in decreasing any concerns.

The most common adverse effect with LNG implants is a change in the menstrual bleeding pattern. Unlike oral contraceptives which provide a predictable and adequate amount of estrogen, natural estradiol levels in LNG implant users are quite variable. As a consequence, the excellent cycle control (e.g., lack of breakthrough bleeding and spotting) typical for pill users does not occur with LNG implants. Instead, prolonged bleeding and irregular bleeding and spotting are common, especially during the first 6 to 9 months of use. Studies have shown that these types of bleeding patterns are more often seen in cycles where estrogen levels are low (i.e., anovulatory cycles or cycles where ovulation is impaired) (Kaewrudee and Taneepanichskul 2000). By contrast, bleeding irregularities were rarely observed when cycles were ovulatory (Faundes et al 1991). Although initially many women report an increase in the number of bleeding and spotting days while using LNG 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, and only rarely has heavy vaginal bleeding caused a significant decrease (Sivin 1988).

Table 1-6. Removal times

Type of implant	N	Time (Mean ± SD)
Jadelle	165	4.9 ± 3.5 minutes
Norplant	162	10.4 ± 7.9 minutes

Source: Sivin et al 1997a.

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

Table 1-7. 5-Year discontinuation rates for changes in menstrual bleeding patterns

Type of change	Jadelle (%)
Irregular Bleeding	4.2
Heavy Flow	3.0
Prolonged Flow (> 8 days)	5.3
Delayed Menses (> 6 weeks)	0.5
Spotting	0.5
Other Bleeding	0.0
Total	13.7
Subjects (n)	600

Source: adapted from Sivin et al 1998a.

Table 1-8. 5-year gross cumulative discontinuation rates for menstrual problems (per 100 users)

Time after placement (year)	Jadelle (n=600)
1	9.7
2	7.2
3	11.4
4	14.5
5	16.4

Source: adapted from Sivin et al 1997a; Sivin et al 1998a

Type of menstrual bleeding changes

As shown in **Table 1-7**, in a randomized study the percentage of women with reported changes in their menstrual bleeding patterns was rather low. **(Table 1-8)**. Type and frequency of these changes are similar to those known to occur with progestin-only pills and injectables.

Typically the frequency of these bleeding changes, especially irregular and prolonged flow, decreases with time and is less of a problem by the end of the first year. 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 first year but increased in subsequent years.

Women's reaction to menstrual changes

Although most women experience some change in their menstrual bleeding pattern, studies show that the majority are willing to tolerate such changes. For example, as shown in one US clinical trial, while 86% of LNG implant users reported menstrual changes, 69% were not, or were only slightly, bothered by them (Darney et al 1990a). And in the study reported by Sivin et al **(Table 1-8)**, the 5-year cumulative discontinuation rates for all types of menstrual problems were only 16.4 per 100 users for Jadelle.

Table 1-9.
Ten most frequently reported adverse events

Condition[a]	Cumulative percentage of women
	Jadelle (n=600)
Vaginal Dischargea	24.3
Headache	23.5
Pelvic Pain	16.7
Weight Increase	12.0
Dizziness	10.7
Breast Pain	8.3
Genital Itching	8.2
Nervousness	7.7
Cervicitis	7.5
Nausea	6.7

[a] Women reported more than one condition.
Source: Sivin et al 1997a.

Thorough pre-insertion counseling about possible changes in menstrual bleeding patterns can improve continuation. For example, in a study of two groups of LNG implant users, the group that received more counseling regarding this adverse effect had much higher continuation rates (Alvarez-Sanchez, Brache and Faundes 1988). And data from user satisfaction studies have shown that staff attitudes and knowledge about the method, positive clinic management practices and the availability of "user friendly" client information also help to improve continuation (Darney 1990a).

Other adverse effects

In addition to menstrual bleeding pattern changes, several other conditions have been reported. Most of these are similar to those seen with other progestin-only methods and are bothersome but not serious. Although some of these conditions may be linked directly to use of LNG implants, others may not. Table 1-9 lists the 10 most frequently reported conditions associated with use of Jadelle during a 3-year period.

Adverse conditions

Persistent ovarian follicles

Enlarged ovarian follicles sometimes have been reported in women using LNG implants as well as those using other progestin-only contraceptives. These are thought to be caused by delayed regression (atresia) of follicles. In some women these persistent follicles, which cannot be distinguished from other types of ovarian cysts, 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).

Benign Idiopathic Intracranial Hypertension (Pseudotumor Cerebri)
Women of all ages, but especially those in the childbearing years who are overweight (> 20% of their ideal body weight), may in rare instances develop benign intracranial hypertension (pseudotumor cerebri). According to post-marketing surveys, this problem has been reported in fewer than 20 LNG implant users in the US (Deitch 1994). This corresponds to a rate of 2-3 cases per 100,000 users. The cause is unknown. Swelling of the retina (papilledema) is the key physical finding. Other early symptoms may include headaches, especially those that persist or are severe, and visual disturbances (e.g., blurred or double vision). Because no cause and effect relationship has been demonstrated, removal of LNG implants may or may not improve the symptoms. Removal is recommended, however, because of the seriousness of the disorder.

Reactions at the insertion site
If recommended infection prevention practices are followed, problems with healing of the insertion site are infrequent and usually occur only in the first few weeks of use. In a study involving more than 2,000 women, problems at the site of placement were rare and the infection rate for LNG implant users was 1.6% during the first year (Population Council 1990). Therefore with adequate attention to pre-insertion skin preparation, use of aseptic technique and correct placement of the rods, the risk of infection should be very low (see Chapter 5 for details).
Expulsion of Jadelle rods is also uncommon. This problem occurs most often when the implants are inserted too shallow, the ends 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. Correct positioning of the rods subdermally makes them barely visible. In some women, however, darkening of the skin over the insertion site occurs. This disappears when the implants are removed. Once inserted, they will **not** move around or break inside the arm.

Metabolic effects

A wide range of studies has been conducted to determine the metabolic effects of LNG implants.
To date no clinically important changes in carbohydrate metabolism; liver, kidney, adrenal or thyroid function; blood clotting factors or iron metabolism have been demonstrated (Population Council 1990; Dorflinger 2002). Although about 30% of LNG implant users have reported changes in body weight, in many the weight gain was associated with an increase in appetite after insertion of the implants (Darney et al 1990a). In addition, longitudinal studies of bone mineral density of the lumbar spine and distal forearm have shown an in-crease at 1 and 2 years after insertion of Norplant in adolescents and women aged 20-45 (Cromer et al 1996; Naessen, Olsson and Gudmundssom 1995).

Lipoproteins
Studies investigating the effect of LNG on serum lipoproteins have produced variable results. Most studies demonstrated a decrease in total cholesterol, triglycerides and low-density lipoproteins in LNG implant users, while HDL was only slightly diminished or even increased (Darney et al 1990b). Results of a longitudinal study involving 99 women using the LNG implants showed similar initial changes in lipoproteins, but by the end of the study, all serum levels had returned to pre-insertion (control) levels (Singh et al 1992). In this study, the LDL cholesterol/HDL cholesterol ratio was also determined. After an initial decrease, it rose to slightly above the pre-insertion ratio during the next 2 years but then returned to the control ratio by the end of the study. Of greater importance are the findings from epidemiologic studies that no increased risk of blood clotting problems (thromboembolism), respiratory disorders or cancer (including breast or genital) have been reported in LNG implant users (Population Council 1990; Meirik et al 2001).

Endocrine changes
Serum levels of estradiol have shown non-cyclic, irregular changes. Baseline values for women using LNG implant are usually 30 to 70 pg/ml, with occasional peaks from 200 to 400. Infrequently, peaks of up to 600 pg/ml have been measured (Population Council 1990).
In those women having ovulatory cycles, however, estradiol levels are similar to the control values ob-served in women not using hormonal contraception (Figure 1-7).
By contrast progesterone levels (Table 1-4 and Figure 1-6) range from undetectable to normal luteal phase values depending on whether the woman is anovulatory, ovulatory or has a luteal phase deficiency (Li, Davies and Newton 1992).
Significant decreases in circulating androstenedione, a weak androgen, and total testosterone have been reported in LNG implants users. These findings are accompanied by slight decreases in 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 LNG on androgens is clinically important (Population Council 1990).

Endometrium
LNG blocks progesterone receptors in endometrial cells, resulting in a decrease in the number and activity of endometrial glands. This furtherreduces the likelihoodof sucessful implantation of any fertilised eggs. Endometrial biopsies obtained during clinical trials of

LNG implants usually showed a mixedsecretory and proliferative pattern, with many exhibiting considerable hypoplasia or atrophy (The Population Council 1990). This is similar to the pattern produced by progestin-only oral contraceptives (Johannsisson et al 1980). Importantly, no progessive changes were observed, and there were no clinically important pathological changes, indicating that long-term implant does not appear to result in hazardous effects on the endometrium.

Summary

Jadelle is the newest long-acting LNG implant. While Norplant consists of six capsules, Jadelle has only two LNG-releasing rods. The contraceptive action of Jadelle, as well as the mechanism of action, effectiveness, safety, continuation, reversibility and adverse effects differ very little from those reported for Norplant. A major advantage of Jadelle is that it is easier to insert and remove than Norplant and both procedures take less time.

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Chapter 2: Counseling

Background

Experience suggests that good, thorough counseling improves user satisfaction and increases the successful use of any contraceptive method (Darney et al 1990). This is particularly important in the case of Jadelle because the woman depends entirely on the service provider for both insertion and removal. Effective counseling also allows the client (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 Jadelle use:

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

Information regarding rumors and facts about Jadelle is also provided. Finally, in **Appendix A** guidelines for conducting family planning counseling are presented which fully describe the following:

- How to help clients get the most out of counseling
- The counseling process
- The GATHER counseling technique
- How to hold group discussions

Using the information in this chapter and **Appendix A**, a healthcare worker will be better able to counsel clients and adjust her/his counseling to each client's needs.

Clients rights[1]

There are various reasons why individuals and couples decide to start, continue or stop practicing family planning. Some 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. And some people 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 protecting their reproductive and sexual health.

In helping couples achieve their reproductive goals, the healthcare worker must be sensitive to the client's needs and must treat her/him with dignity and respect. Over the years, the following aspects of quality care have come to be known as client rights.

- All individuals of reproductive age have a right to information about family planning for themselves and their families, regardless of their ethnic origin, socioeconomic status, religion, marital status or political beliefs.

- 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.

- A client should be able to obtain the method s/he has decided to use, provided the method is available and there are no reasons why s/he should not use it (WHO 1996).

- Because a client's concept of acceptability and appropriateness changes with circum-stances, s/he has the right to decide when to start, stop or switch methods.

- Clients have the right to discuss their concerns in an environment in which they feel confident. This includes being sure that conversations with counselors or service providers 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 the 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, individ als under-going training, supervisors, instructors, researchers, etc.).*
  - *A client should know in advance the type of physical examination that is going to be done and s/he has the right to refuse any particular type of examination if s/he does not feel comfortable with it.*

- Clients 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). In addition, the time clients spend receiving 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.

- Finally, clients have the right to express their views about the services received. Opinions on the quality of services, either thanks or complaint, together with 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 Jadelle and does not feel she has been pressured into accepting a method of contraception with which she is not comfortable.

- The woman knows exactly what to expect with Jadelle. She understands all the advantages it offers and will be prepared for any

[1] Adapted from: Huezo and Briggs 1992

adverse 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 rods removed at any time she wishes and when she should have them removed.
- She knows where she can go to have the rods removed.

For the clinician

- Although counseling may appear to be time-consuming, it is cost-effective and saves time in the long run. For example, it has been shown that women who receive counseling are more likely to continue using LNG implants and have fewer return visits (Darney et al 1990).

Steps in counseling

Initial counseling or education prior to a decision about contraceptive use is intended to familiarize the client with **all** contraceptive methods and other healthcare services provided by the clinic. **Education** about all methods can be done effectively in a group setting prior to individual counseling. It provides the client with an opportunity to ask questions about specific contraceptives in which she is interested.

Individual counseling, which should take place in private, is important 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 Jadelle, let her examine the sterile package containing the rods and provide general information about their use and insertion. Or, using a model training arm, demonstrate how the rods are inserted. Tell her that they must be inserted and removed by a trained healthcare provider (physician, nurse or midwife).

Subsequent counseling about Jadelle should cover the following points:

- basic health information to ensure there are no reasons (e.g., suspected pregnancy) why the woman should not use this contraceptive;
- how Jadelle prevents pregnancy;
- method characteristics (benefits and limitations), including the 5-year effective life of Jadelle;
- common adverse effects, particularly those related to changes in the menstrual bleeding pattern;
- how the rods are inserted and removed, how long each procedure takes and what discomfort, if any, to expect;
- the importance of having the rods inserted when it is reasonably certain the client is not pregnant (e.g., days 1 to 7 of her menstrual cycle – see **Chapter 4**) and which backup contraceptive method to use if insertion is delayed;
- freedom of the client to discontinue the method whenever desired;
- where she can go for removal;
- that there is no delay in return of fertility after removal of the rods; and
- that this method does not provide protections against STDs.

Note: In countries where Norplant has been available, women may need additional counseling to assure them that the two Jadelle rods are as effective as the six Norplant capsules.

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

- Any questions the woman may have regarding the insertion procedure and what she can expect (e.g., post-insertion 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).

Post-insertion counseling usually is provided immediately after insertion. This is a good time to reinforce information given earlier (e.g., care of the insertion site). Post-insertion counseling should focus on those problems (continued pain, redness or bleeding at the insertion site, fever immediately after insertion, or expulsion of a rod) that indicate the need for a quick return to the clinic. In addition, the client should be:

- told that bruising is common and is part of the healing process; it does not require a return to the clinic;
- 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 should have the rods removed and where she can go for removal.

Follow-up counseling should reinforce information given post-insertion. Counselors need to listen attentively and be prepared to answer questions about any problems the client has had. Answering questions helps clients cope with any problems or adverse effects. At each follow-up visit, the following points should be covered:

- The woman should be asked if she is satisfied with the method and if there have been any problems since her last visit.
- She should be reminded that Jadelle rods need to be removed after 5 years but can be removed at anytime before that time if she desires.
- The warning signs (e.g., missed menstrual period or blurred vision) that indicate the need to return to the clinic should be reviewed (see **Chapter 7**).

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

Figure 2-1.
Steps in counseling for Jadelle

Initial counseling

Client reception

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

Individual counseling

Counseling area

- 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 Jadelle:

- Make sure there is no medical condition that would be a problem or require more frequent follow-up.
- 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 Jadelle does not provide protection against GTIs and other STDs, including HBV and HIV/AIDS. If the client is at risk for STDs, she should also use a condom.
- Explain common adverse effects, especially changes in the menstrual bleeding pattern, and be sure they are understood fully.
- Describe the insertion and removal procedures and what the woman should expect during and afterwards.

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 the implants are in place.

(Insert the two rods.)

- Give post-insertion counseling, including how she should care for the insertion site and what to do if she experiences any problems or adverse 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 rods removed.
- Tell the client where she should go to have the rods removed.
- Have the client repeat all instructions back to you.
- Answer any remaining client questions.

Follow-up/Return Visit counseling

Counseling/Examination area

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

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

As Jadelle is introduced into a country, women with Norplant may come in requesting replacement of Norplant with Jadelle. If this occurs before the 5-year effective life of Norplant has passed, the woman should be reassured that Norplant remains effective for at least 5 years. She should be counseled that:

- there is no medical reason to switch,
- switching would require an unnecessary medical procedure as well as additional expense, and
- the major benefit of Jadelle is related to easier insertion and removal.

A few women may still want to switch because two rods are likely to be less visible than six capsules. The response to this situation will depend on the individual circumstances and clinic policy.

Table 2-1. Important facts about Jadelle

Who can use Jadelle?	
Jadelle is appropriate for women who:	Jadelle is not appropriate for women who:
• Want highly effective, reversible contraception that does not require daily action • Are delaying the start of their family, have completed their family or do not want children • Have a history of ectopic pregnancy • Cannot remember to take a pill every day	• 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 Jadelle	
Benefits:	Limitations:
• Highly effective (0.1 pregnancies per 100 women in the first year of use) • Long-term method (5 years of protection) • No daily action required • Easy to use and requires no further action other than follow-up visits and return for removal; does not interfere with normal daily activities • Comfortable – once the insertion site has fully healed (about 1 week), the rods should not cause any pain and are not noticeable in most women • One of the lowest doses of any hormonal contraceptive and contains no estrogen • Few serious adverse effects	• Changes in the menstrual bleeding pattern are common (counseling should prepare the woman adequately for this). • Insertion and removal are minor surgical procedures and may therefore be associated with bruising (discoloration of the arm), infection or bleeding. • A woman cannot discontinue the method on her own (counseling should, however, prepare her for this). • The outline of the rods may be visible under the skin of some women, especially when the skin is stretched. • Jadelle does not protect a woman from GTIs and other STDs, including HBV and HIV/AIDS.

Rumors and facts

Correcting false rumors and misinformation is an important job of healthcare workers. When talking to the client about rumors and misinformation, do not just say that what she has heard is not true. Always politely explain or show her 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: Jadelle is less effective than Norplant because there are only two rods.
Response: Jadelle is equally effective as Norplant for 5 years.
False Rumor: Jadelle weakens the woman because it increases menstrual bleeding.
Response: Although bleeding may occur more frequently, the amount of blood loss actually decreases. In several studies, hemoglobin levels have increased with continued use.
False Rumor: The rods can move around within her body.
Response: No, they remain under the skin in her arm, where they were placed, until they are removed. Each rod is surrounded by a small sheath of fibrous tissue that prevents it from moving.
False Rumor: The procedure for inserting the rods 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 first injected. While there may be some pain after the anesthetic wears off, this is usually easily managed with aspirin or other analgesics.
False Rumor: The rods are implanted permanently.
Response: No, they can be removed at any time and should be removed after 5 years.
False Rumor: The rods never need to be replaced.
Response: No, they should be replaced every 5 years if the client wishes to continue using Jadelle.

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 best interest of the client before any other concerns. It is both ethically and programmatically important that providers pay close attention to the needs of clients. Over the long term, programs are more likely to attract and keep clients when they offer services that meet clients' needs (Gallen, Lettenmaier and Green 1987).

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Chapter 3: 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.

In addition, 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 may not be appropriate when applied to a setting that has different reproductive health characteristics. Finally, in many countries new information is slow in arriving and the **contraindication** list remains the standard for many years, despite being outdated and inaccurate.
In this manual we have chosen to replace **contraindications** with **conditions requiring precaution.** Making this change, however, does not solve the problem of "lists" entirely. Therefore, in addition to listing the indications and those **conditions requiring precaution**, a brief statement is included explaining the rationale for categorizing the condition as such.

WHO classification system

During 1994-95, a series of working group meetings was held by the World Health Organization (WHO) to review medical criteria for initiation and continuation of all commonly available methods of contraception. In the resulting classification system, the suitability of different contraceptive methods is deter-mined 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 generally be used.)
Class 3: A condition where the theoretical or proven **risks usually outweigh the benefits** of using the method. (Method is usually 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.)

This manual complements the WHO classification system. For example, like the WHO system, this manual

includes a brief rationale for why a particular condition is assigned to one of the four categories. (For the reader's convenience, the WHO classification for each condition is included for each precaution.) The rationales included in this manual are adapted not only from those presented in *Improving Access to Quality Care in Family Planning: Medical Eligibility Criteria for Initiating and Continuing Use of Contraceptive Methods* (WHO 1996) but also from those provided in the manual *Recommendations for Updating Selected Practices in Contraceptive Use* (Vol 1), produced by the USAID Technical Guidance Working Group (1994), and selected references from the international literature on contraceptive technology.
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 Jadelle. Based on the WHO classification system, these conditions are no longer restrictions.

Contraceptive choice and women's reproductive healthcare

When a woman selects a contraceptive method, she and the healthcare worker should consider the degree to which she values her future fertility as well as the degree to which she is willing to risk a potential health problem.

In some countries women who want no more children are denied voluntary sterilization for a number of reasons (e.g., they are too young, they do not have many children). For such women, Jadelle can be a good alternative. In addition to being highly effective, it is long-acting and requires limited follow-up unless there is a problem.

Under most circumstances a woman's risk of dying from pregnancy is many times greater than her risk of dying from using Jadelle 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. Thus, in order to maximize the client's access to quality family planning services, protocols that list the indications and precautions for use of Jadelle should be flexible. 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.

Indication for use

Jadelle is an appropriate method for a woman who:

Condition	Rationale
Prefers a long-term method that 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 Jadelle is inserted, the client does not need to do anything except return to the clinic for follow-up visits and have the rods removed or replaced in 5 years.
Has the number of children she wants but does not want a permanent method (voluntary sterilization) at this time.	Jadelle can be used indefinitely, provided the client develops no serious medical problems and replaces it on schedule every 5 years.
Has been breastfeeding for 6 weeks or more post-partum and wants contraception.[1]	Breastfeeding is not negatively affected by the use of progestins, and their use may increase the volume and quality of breast milk (WHO 1988). The level of LNG in breast milk has not been shown to cause any clinically important effects on infant health or growth through adolescence (WHO 1988, WHO 1994a, 1994b). Because

[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).

Condition	Rationale
	Jadelle is a hormonal contraceptive, it is not considered the first choice for breastfeeding women. (At present, there are no data available about possible adverse effects when used before 6 weeks post-partum.)
Is post-partum and not breastfeeding.	Jadelle may be used safely by non-breastfeeding women immediately post-partum (WHO 1996).
Is post-abortal.	Jadelle may be used safely immediate post-abortion (WHO 1996).
Has moderate to severe menstrual cramping.	Progestins, such as LNG, reduce the frequency and intensity of menstrual cramping.
Smokes (any age, any amount).	Because small amounts of progestins such as LNG have no effect on cardiovascular or blood clotting problems, Jadelle can be used by women who smoke.

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 POCs (McCann and Potter 1994; TGWG 1994; WHO 1996). For women with any of the following conditions, health-care workers need to assess the appropriateness of Jadelle for **each client**, not only in terms of her special needs but also in relation to the healthcare climate in which she lives.

Condition	Precaution	Rationale
Pregnancy (known or suspected)	Jadelle should **not** be inserted during pregnancy and should be removed if intrauterine pregnancy is confirmed and will be carried to term. (WHO class 4) If the possibility of pregnancy **cannot** be excluded by history, examination or pregnancy testing, insertion of Jadelle should be delayed until the next menstrual period. In the interim, help the client choose another method (e.g., condoms and spermicide).	Current data show that the low dose of LNG released from implants does **not** cause any significantly increased risk of birth defects, spontaneous abortions or stillbirths (Population Council 1990; TGWG 1994; WHO 1996). Although the amount of hormone re-leased is small, it is unwise for a woman to take **any drugs** during pregnancy unless absolutely necessary.
Breastfeeding (< 6 weeks post-partum)	During the first 6 weeks post-partum, breastfeeding mothers should avoid using Jadelle unless other more appropriate methods are not available or acceptable. (WHO class 3)	There is **only** theoretical concern that the newborn may be at risk due to exposure to progestins during the first 6 weeks post-partum. **After** 6 weeks, studies have detected no clinically significant effects on the health or growth of breastfeeding babies whose mothers are using Jadelle. (WHO class 1)

Condition	Precaution	Rationale
Unexplained vaginal bleeding (only if a serious problem is suspected)	Until the cause of the unexplained bleeding (between menses or after intercourse) is determined and any serious, problem treated, the client should not use Jadelle.[2] (WHO class 4)	Because progestin can cause intermenstrual spotting or bleeding, an underlying condition (e.g., normal or ectopic pregnancy, cervicitis, other pelvic pathology and, **rarely**, cancer of the genital tract) may be masked (McCann and Potter 1994; WHO 1996). **None** of these underlying conditions, however, are worsened – and some are prevented – by use of implants (Herbst et al 1992; Parazzini et al 1991; Parkin et al 1988; Pike 1987; Sadan et al 1989; Speroff, Glass and Kase 1989). It is only because the effect of LNG implants cannot be easily stopped once the rods have been inserted that WHO recommends not starting Jadelle if a serious problem is suspected.
Jaundice (symptomatic viral hepatitis or cirrhosis)	Use of Jadelle should be avoided unless other more appropriate methods are not available or acceptable. (WHO class 3)	There is **no** evidence that LNG causes liver disease (e.g., benign or malignant tumors or cirrhosis), hepatitis or gall bladder problems (RCGP 1982; WHO 1996). Although the hormone may be poorly metabolized in women with impaired liver function, it is not likely to worsen the liver disease clinically (McEwan 1983; Speroff, Glass and Kase 1989) and its use is safer than pregnancy in women with active hepatitis.
	Note: For women who are asymptomatic (fully recovered or carriers), there is no restriction on the use of Jadelle. (WHO class 1)	
Breast cancer	Women with breast cancer should not use Jadelle. (WHO class 4) Women with a history of breast cancer and no current evidence of disease should avoid using Jadelle unless other more appropriate methods are not available or acceptable. (WHO class 3)	There is no evidence that low-dose progestins, including LNG, cause breast cancer. Because it is a hormonally-sensitive tumor, however, there is concern that the risk of progression may be in-creased among women with a past history of or current breast cancer (Population Council 1990; WHO 1996; WHO 1989). Note: Clients with suspicious breast lumps (firm, nontender or fixed and which do not change during menstrual cycle) need to he evaluated before Jadelle insertion.
Thromboembolic disorders (e.g., blood clots in the legs, lungs or eyes)	Women with past thromboembolic disorders (venous thrombosis or pulmonary embolism) should only use Jadelle after careful risk/benefit	Even if most experts now believe it is estrogens, not progestins, that cause blood clotting (Mc-Cann and Potter 1994; WHO 1996), because

[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 15B35) (TGWG 1994). Therefore, insertion should be restricted only if a serious condition is suspected (WHO 1996).

Condition	Precaution	Rationale
	assessment of the risk-benefit ratio. Women who develop thrombotic or embolic disease while using Jadelle should have the rods removed.	of seriousness of these conditions, cautiousness is recommended.
Taking drugs for **epilepsy** (phenytoin and barbiturates) or **tuberculosis** (rifampin) or taking antibiotic [3]	These women should avoid using Jadelle unless other more appropriate methods are not available or acceptable. (WHO class 3) Clients taking drugs for these disorders should be counseled about the potential reduction in the effectiveness of Jadelle.	**Long-term** use of drugs for epilepsy (**except** valproic acid) and tuberculosis causes the liver to metabolize progestins more rapidly and may decrease the effectiveness of Jadelle. Overall, neither estrogens nor progestins appear to alter seizure activity and both can be provided with caution. Women with Jadelle rods who use any of these drugs may develop intermenstrual spotting or bleeding, which may indicate a decreased level of progestin and possibly reduced effectiveness. Therefore, women using Jadelle may require more frequent follow-up or a backup method (see **Chapter 1**) (Angle, Huff and Lea 1991).

[3] At present, griseofulvin is the only antibiotic known to decrease the effectiveness of LNG implants. 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 Jadelle. They should also use a backup contraceptive method while taking griseofulvin and until the start of their first menstrual period after stopping the antibiotic.

Condition	Precaution	Rationale
Women who **cannot tolerate changes in their menstrual** bleeding pattern	Women who express strong concern regarding changes in their menstrual pattern (irregular or more frequent bleeding) may want to consider a trial use of progestin-only pills (POPs) for 3 months before Jadelle insertion.	Changes in the menstrual pattern are the most frequent reason for stopping Jadelle) POPs cause similar changes in the menstrual bleeding pattern. Using them first will give the woman an opportunity to see if she is comfortable with an altered bleeding pattern.

Conditions requiring more frequent follow-up care

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

Condition	Action	Rationale
Diabetes	Diabetics who choose Jadelle should be followed to be sure the disease is controlled. (WHO class 2)	Jadelle affects carbohydrate metabolism only slightly if at all, and does not pose an additional risk of thrombosis (estrogen effect) in noninsulin- or insulin-dependent diabetics. Its use may, however,

Condition	Action	Rationale
		require more medication or insulin to maintain control of diabetes.
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 Jadelle. (WHO class 2)	Little or no information is available on changes in severe headaches when LNG implants are used (Population Council 1990; WHO 1990).
Hypertension	Women with increased blood pressure should be followed to be sure their hypertension does not worsen. (WHP class 2)	If headaches worsen (e.g., are more frequent, last longer or cause blurred vision), consideration should be given to removing the rods (Deitch 1994).
Depression	Women with a history of depression should be followed when using Jadelle. Removal of rods should be considered if depression worsens or recurs to a serious degree.	There have been no statistically significant trends of in-creased blood pressure in women using Jadelle. Depression may be related to the use of progestins (Population Council 1990; WHO 1990).

Conditions for which there are no restrictions for use

In the past, precautions for use of POCs, such as progestin-only pills and implants, were based primarily on experience with combined oral contraceptives (COCs). Although some rare but potentially serious vascular problems have been associated with use of COCs, it is now known that progestin-only contraceptives only minimally increase the risk of cardiovascular problems (heart attack or stroke) or thromboembolic disorders (blood clots) in healthy women. While COCs containing the new progestins, desogestrel and gestodene, are associated with a higher risk of nonfatal blood clotting problems (UNDP 1996), there is no increased risk with Jadelle because it contains only the progestin, levonorgestrel (WHO 1996). The conditions for which there are no restrictions (i.e., WHO class 1) for the use of Jadelle, as well as other POCs, include:

Condition	Rationale
Ectopic pregnancy	Jadelle provides more protection against ectopic pregnancy than most other methods of contraception.
Pre-eclampsia (history)	In the absence of any pre-existing vascular disease, Jadelle may be used (WHO 1996).
Sickle cell disease and trait	Jadelle, like other POCs, may have a beneficial effect on sickle cell crises (WHO 1996).
Smoking (any age, any amount)	Because progestins like LNG do not increase the risk of cardiovascular disease, women (of any age) who smoke and have no other risk factors can use Jadelle (WHO 1996).

Condition	Rationale
Surgery (with or without prolonged bed rest)	Because progestin does not increase the risk of blood clotting problems, there is no restriction for use (McCann and Potter 1994; WHO 1996).
Valvular heart disease (symptomatic or asymptomatic)	Because progestin only minimally increases the risk of blood clotting problems, including embolism (McCann and Potter 1994; WH0 1996), even women with complications such as pulmonary hypertension, irregular heart rhythms (arrhythmia) or history of subacute bacterial endocarditis can use Jadelle.

In summary, the eligibility criteria for use of Jadelle 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.

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Chapter 4: Client assessment

Background

Because Jadelle contains only a progestin (levonorgestrel), one of the two steroid hormones present in COCs, it does not have estrogen-related adverse effects. As a consequence there are fewer precautions for its use. While Jadelle may be an appropriate contraceptive for nearly all women, clinic staff need to know how to assess potential users who:

- may need additional evaluation before they can use Jadelle, or
- have medical conditions which may require more frequent follow-up care.

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

Client assessment

In assessing potential clients, clinic staff should:

- Ask about the client's reproductive goals.
- Check clients for any condition that may be a precaution for Jadelle use.
- Evaluate clients by medical history and, if there are special problems, examine them.
- Make sure that potential clients have been counseled about the method; its benefits, limitations and adverse effects (especially changes in the menstrual bleeding pattern); as well as about other contraceptives **before** selecting Jadelle.
- Make sure that they understand what to expect during the insertion.
- Make sure they understand when, where and why Jadelle rods should be removed.

Conditions clients should be asked about and which may limit or delay starting use of Jadelle include:

- pregnancy (known or suspected);
- breastfeeding a baby less than 6 weeks old;
- unexplained vaginal bleeding (i.e., between menses or after intercourse);
- jaundice (i.e., symptomatic viral hepatitis or cirrhosis);
- diabetes,
- current thromboembolic disease;
- severe headaches or blurred vision;
- cancer of the breast (current or past) or suspicious breast lumps; or
- taking drugs for epilepsy or tuberculosis.

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

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**.