



# LNG IUS

## Training Manual for Family Planning

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# Preface

This manual was developed by ICA Foundation to provide family planning service providers, clinic managers and clinical trainers with a concise source of up-to-date information on the new hormonal intrauterine contraceptive method, the Levonorgestrel Intrauterine System (LNG IUS) manufactured by Schering Oy. The purpose of this manual is to help clinicians (physicians, nurses and midwives) to discover contraceptive clients who would derive the most benefit from the use of the LNG IUS, the system that combines the benefits of oral contraceptives and IUDs.

The manual is partly based on the JHPIEGO reference manual “IUD Guidelines for Family Planning Service Programs”, but as it concerns a local hormonal contraceptive, the text has been revised according to common guidelines on progestin-only pills and the official Summary of Product Characteristics of the product. References are acknowledged at the end of each chapter.

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 events and other problems. The **key points are repeated** in several sections to emphasize their importance.

## Specific objectives of this manual:

- Highlight the importance of counseling clients about the LNG IUS, which looks like an IUD but in many ways acts as a hormonal progestin only method.
- Explain the indications and precautions for use of the LNG IUS
- Define the issues necessary to consider with every potential LNG IUS user.
- Detail necessary infection prevention practices
- Describe the step-by-step insertion instructions for the LNG IUS
- Provide a guide for the management of possible adverse effects and other problems

The information in this manual should be combined with competency-based training to build a successful family planning program, with staff competent in client assessment, counseling, and recognizing and managing potential problems. Comprehensive counseling has a positive impact on user satisfaction. Good counseling combined with a careful and skillful insertion technique will result in clients being pleased with family planning and enjoying the benefits of the LNG IUS, beyond contraception.

# Introduction

## BACKGROUND

Intrauterine contraceptive methods have been used for many decades. Women throughout the world have found intrauterine contraception to be effective, safe and convenient. Today it is the most commonly used reversible, long-acting contraceptive method in the world.

At present it is estimated that over 150 million women are using intrauterine contraceptive methods, of which 60% are in China. By contrast, in other areas of the world intrauterine contraceptive use is much less common, ranging from about 8% in some developed countries to 0.5% in Sub-Saharan Africa. (UN Population Division, World Contraceptive Use, 2003.)

## TYPES OF INTRAUTERINE CONTRACEPTIVES

Currently there are three types of intrauterine contraceptive methods available worldwide:

- Inert intrauterine devices (IUDs) made of plastic (Lippes Loop) or stainless steel (the Chinese ring)
- Copper bearing intrauterine devices (copper IUDs), which include e.g. TCu 380A, Multiload (ML Cu 250 and 375) and the NOVA T®.
- Medicated intrauterine devices with a steroid hormone such as the progesterone containing Progestasert and the levonorgestrel containing LNG IUS, which is the latest innovation in the field of intrauterine contraception. Because the characteristics of the levonorgestrel intrauterine contraceptive system in many respects are totally different from the copper IUDs, it is called “an intrauterine system” instead of “an intrauterine device”. Apart from the excellent contraceptive efficacy of the LNG IUS, it also has many health benefits for women. This manual is written to provide information on the special characteristics of the LNG IUS.

## DEVELOPMENT OF THE LNG IUS

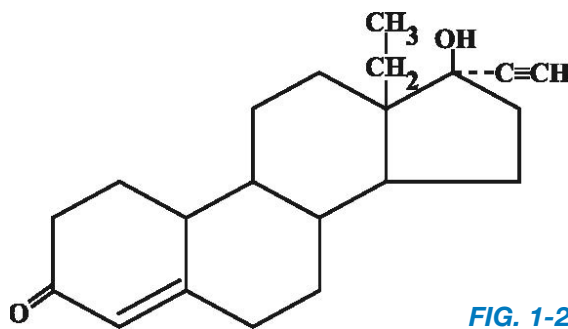
The development of the LNG IUS was started in the 1970's in Finland by Professor Tapani Luukkainen and his group, supported by the Population Council, an international contraceptive research organization. The first aim was to develop an IUD that would resist expulsion, and levonorgestrel (LNG) was added to decrease the contractile activity of the uterus. However, it soon became evident that the LNG IUS not only was an extremely effective contraceptive method, but also included important health effects by decreasing the amount of menstrual blood loss. Large clinical trials were conducted first in Europe, followed by South America, India and China, and the safety and effectiveness of the system were confirmed in clinical trials with more than 12,000 women-years of use. The LNG IUS was first launched in Finland in 1990, and today it has regulatory approval as contraception in more than 100 countries. In many countries it also has approved indications beyond contraception, such as its use for the treatment of excessive menstrual bleeding.

## DESCRIPTION

The LNG IUS consists of a plain plastic T-shaped frame with a hormone reservoir around the vertical stem (Fig. 1-1). The T-shaped frame is the same as in the copper IUD NOVA T®, and the design has been proven to be safe and adaptable during many decades of use. The steroid hormone reservoir consists of a cylinder, made of LNG and a special plastic (polydimethylsiloxane) mixture, containing a total of 52 mg of LNG (or 50% by weight). The reservoir forms a 19 mm-long ‘sleeve’ around the vertical arm of the plastic body and is covered by a polydimethylsiloxane membrane, which regulates the minimal intrauterine release of LNG. After insertion into the uterus, minute amounts of LNG (20 microg/day) are released from the cylinder at a constant rate into the uterine cavity.

The T-shaped frame is impregnated with barium sulphate, which makes it visible in X-ray pictures.

The active steroid in the LNG IUS is the progestin levonorgestrel, a chemical derivative of 19-nortestosterone. Levonorgestrel has potent progesterone-like activity, weak androgenic properties and no significant estrogen activity. With the LNG IUS, the effect of levonorgestrel is mainly local at the level of the endometrium, and the systemic serum concentration of the hormone is much lower than e.g. with oral contraceptive pills. The chemical structure of LNG is shown in Fig.1-2.



**FIG. 1-2**

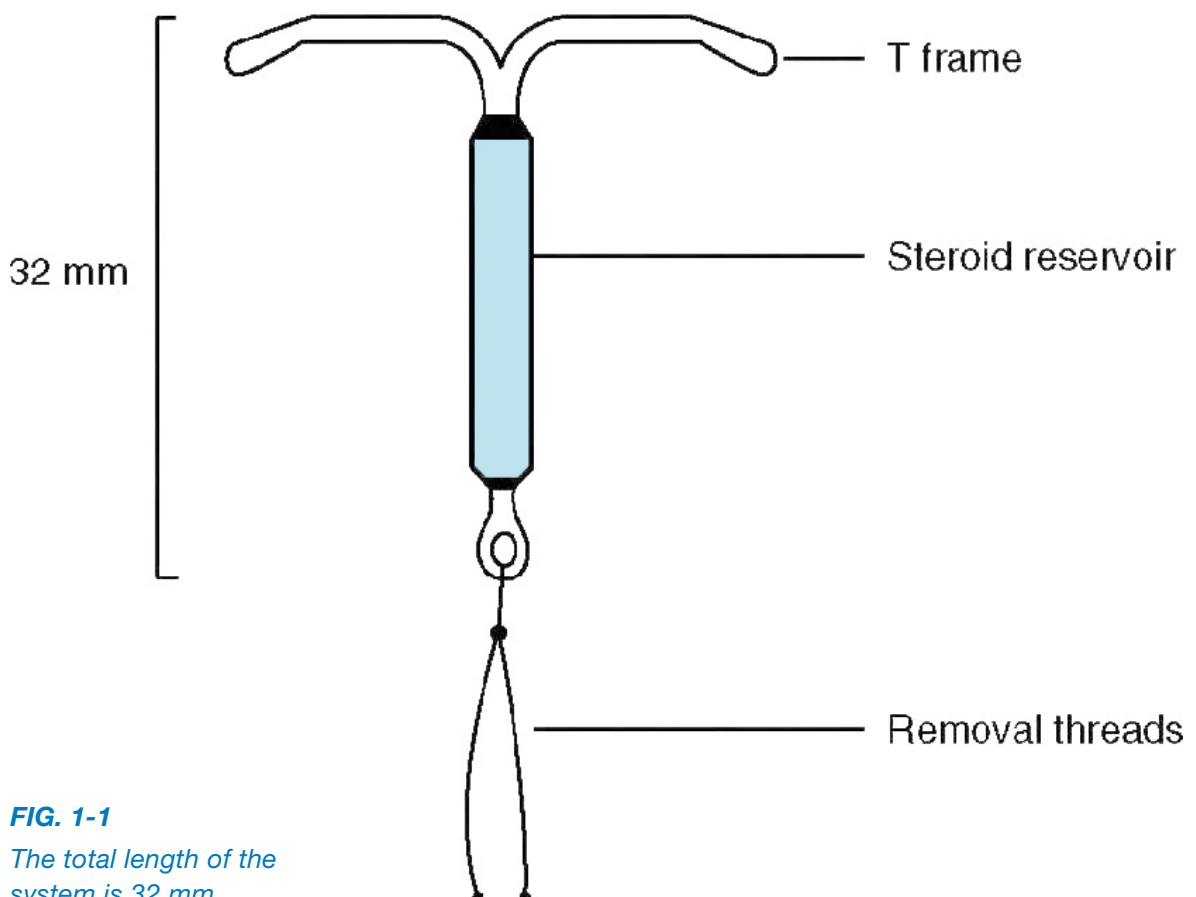
The materials used in the production of the LNG IUS are not new to medicine. Levonorgestrel has been used since the 1960s in combined (estrogen and progestin) oral contraceptives and in

progestin-only mini-pills. The silicone tubing used to cover the hormonal capsule 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.

### MECHANISM OF ACTION

The contraceptive action of the LNG IUS is based on the inhibition of fertilization. Therefore, the method cannot be regarded as an abortifacient. There is not a single mechanism; fertilization is prevented by various local effects of LNG in the uterine cavity:

- Uterine fluid is changed to contain a high amount of white blood cells and different cellular mediators that inhibit sperm motility and destroy the sperm. As the endometrial concentration of LNG is more than 200 times higher than that with oral contraceptive pills containing LNG, this probably is the most important contraceptive effect of the LNG IUS.
- The cervical mucus is thickened and sperm is blocked from passing through the cervix



**FIG. 1-1**

The total length of the system is 32 mm.

into the uterus and oviduct (Fallopian tube). The effect is the same as that seen with progestin-only mini-pills, contraceptive implants and injectables as well as combined oral contraceptive pills.

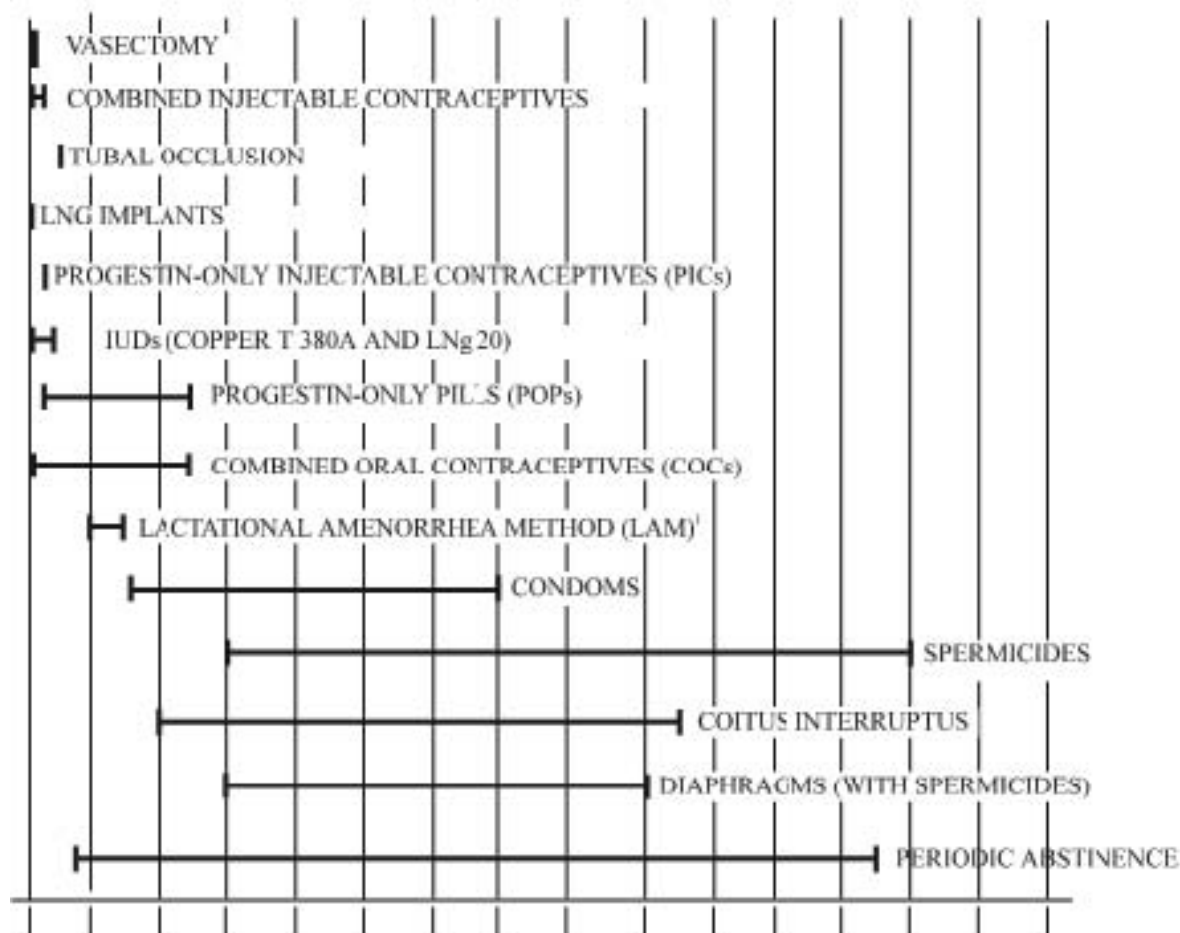
- The endometrium becomes thin and atrophic within 3 months after the insertion of an LNG IUS, as the endometrial estrogen receptors are suppressed by the strong effect of LNG in the uterus. The endometrium is in a resting phase after the insertion of the LNG IUS and for this reason menstrual bleeding is also greatly diminished, sometimes even stopped during the use of the LNG IUS. This is totally harmless, and in many cases even beneficial for the user.
- In some women ovulation is inhibited. A weak foreign body reaction is also present.

After the LNG IUS is removed from the uterus the endometrial changes and menstrual bleeding pattern revert to normal within one cycle.

## PHARMACOKINETICS

The pharmacokinetics of the synthetic steroid LNG have been extensively studied and reported in the literature. The bioavailability of orally administered LNG is about 90%. A half-life of 20 hours is most often presented, but there are marked differences in the metabolic clearance rate among individuals.

The LNG IUS releases LNG into the uterine cavity, from where it is quickly absorbed via the vessels of the endometrium into the systemic circulation. LNG can be detected in the plasma 15 minutes after insertion, and maximum plasma levels are reached within a few hours. Plasma LNG concentrations reach a plateau of 150–200 pg/ml (0.4–0.6 nmol/L) after the first few weeks. The plasma concentrations achieved by the LNG IUS are lower than those seen with the levonorgestrel implant Norplant®, the combined oral contraceptive and the mini-pill. Ovulation is usually not inhibited. As the plasma concentrations are so



**FIG.1-3**

<sup>1</sup>During first 6 months of use.

low, the risk for hormonal side effects is diminished. The contraceptive effectiveness does not depend on the plasma concentration, but on the local endometrial concentration of LNG. Although plasma LNG concentrations are fairly stable, there is a marked interindividual variation.

The local release of LNG results in very high concentrations of LNG in the endometrium (range 470–1500 ng/g tissue wet weight) within weeks of insertion. The high concentration of LNG is limited to the level of the endometrium, and LNG concentrations in myometrial and fallopian tube tissue are similar and very low, regardless of the duration of use.

### CONTRACEPTIVE EFFECTIVENESS

The effectiveness of a contraceptive method is usually the most important factor both for the client (or couple) trying to choose a method and for the family planning provider involved in counseling.

Presenting meaningful information regarding failure (pregnancy) rates for couples choosing a contraceptive method is difficult. For valid comparisons to be made among the methods, failure rates must be presented both for couples who use the method consistently and correctly and for typical users of the method. Data presented in this way for the first year of use for a number of contraceptive methods are shown in Fig.1-3.

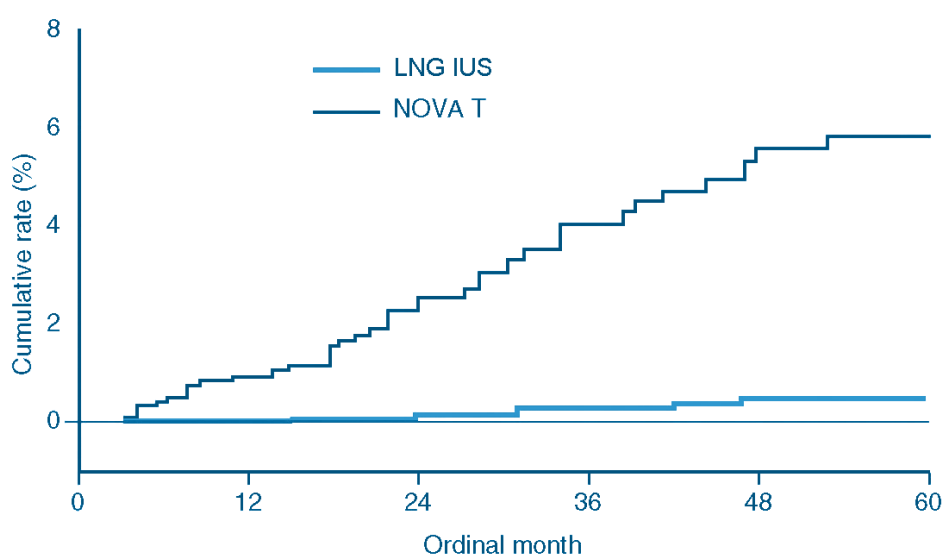
The contraceptive effectiveness of the LNG IUS is fully comparable to that of female sterilization,

but unlike sterilization, the LNG IUS is a reversible method of contraception. It has been said that the LNG IUS was developed to combine the benefits of oral and intrauterine contraceptives – reliability and simplicity. The LNG IUS is easy and convenient to use, and the effectiveness is not influenced by patient compliance.

The contraceptive effectiveness of the LNG IUS was initially assessed in comparative and non-comparative studies of up to 7 years of duration. The initial studies collectively report on more than 12 000 woman-years of use, with an overall Pearl rate of 0.14 (table I). In large, comparative multicenter trials the first-year pregnancy rate has been 0–0.2%, and the cumulative rate over 5 years has been 0.5–1.1%. These figures are lower than with any other reversible contraceptive method.

NOVA T® is a copper IUD with a T body frame that is identical to that of the LNG IUS. It is natural, that in many contraceptive trials with the LNG IUS, the NOVA T® has been the comparative method. There are two 5-year contraceptive studies comparing NOVA T® and the LNG IUS.

In a large, multicenter study conducted in Europe with 1821 users of the LNG IUS and 937 users of NOVA T®, the 1- and 5-year pregnancy rates with the LNG IUS (0.1% and 0.5%, respectively) were statistically significantly lower than the pregnancy rates with NOVA T® (1.0% and 5.9%, respectively) (Fig.1-4). The expulsion rates were comparable for the two meth-



**FIG.1-4**

5-year cumulative gross pregnancy rates for LNG IUS and NOVA T (Andersson et al. 1994).



Table II. Summary of comparative studies of LNG IUS

Reference	Duration of study (y)	No. of women	Contraceptive method	Cumulative gross rate <sup>a</sup> per 100 women		
				Pregnancy	Expulsion	Continuation
<b>Non-comparative</b>						
Bounds et al. (1993)	7	66	LNG IUS	0.0	—	—
Scholten et al. (1989c)	1	148	LNG IUS	0.0	0.0	83.1
Scholten et al. (1989c)	4 <sup>b</sup>	148	LNG IUS	0.0	0.0	65.6
Faúndes et al. (1993)	7	581	LNG IUS	0.0	—	37.7
Thiery et al. (1989)	1	131	LNG IUS	1.0	3.6	80.6
Thiery et al. (1989)	2 <sup>b</sup>	131	LNG IUS	2.8	4.8	62.9
<b>Comparative vs Cu T380 Ag</b>						
Sivin et al. (1984)	1	755	LNG IUS	0.3	6.4	75.0
		754	Cu T380 Ag	0.3	5.8	78.0
Sivin et al. (1987)	2 <sup>b</sup>	1124	LNG IUS	0.2	6.3	59.4***
		1120	Cu T380 Ag	0.9	5.7	67.5
Sivin et al. (1990)	5 <sup>b</sup>	1124	LNG IUS	1.1	11.8	33.0***
		1121	Cu T380 Ag	1.4	7.4	40.6
Sivin et al. (1991)	7 <sup>b</sup>	897	LNG IUS	1.1	11.7*	24.9
		896	Cu T380 Ag	1.4	8.4	29.4
ICMR (1989)	3 <sup>b</sup>	475 <sup>c</sup>	LNG IUS	0.0	10.6	38.8
		434	Cu T380 Ag	1.0	7.6	50.4 <sup>s</sup>
<b>Comparative vs Cu T200B &amp; T220C</b>						
ICMR (1989)	1	475 <sup>c</sup>	LNG IUS	0.0	6.5	75.5
		500	Cu T200B	0.9	4.9	82.4
		496	Cu T220C	0.0	4.8	84.4
	3 <sup>b</sup>		LNG IUS	0.0	10.6	38.8
			Cu T200B	1.6	8.5	45.4
			Cu T220C	0.3	8.3	45.4
<b>Comparative vs NOVA T</b>						
Nilsson et al. (1981)	1	164	LNG IUS	0.6	0.6	84.1
		156	NOVA T	2.6	4.5	87.5
Nilsson et al. (1983)	2 <sup>b</sup>	164	LNG IUS	0.6	0.6	66.6
		157	NOVA T	3.3	6.1	71.9
Luukkainen et al. (1986)	5 <sup>b</sup>	281	LNG IUS	0.8	2.0	53.0 <sup>d</sup>
		134	NOVA T	6.7	6.0	49.7
Luukkainen et al. (1987)	1	1821	LNG IUS	0.1†	3.7	79.7
		937	NOVA T	1.0	3.9	82.2
Toivonen et al. (1991)	3 <sup>b</sup>	1821	LNG IUS	0.3***	5.3	57.0
		937	NOVA T	3.7	5.4	59.0
Andersson et al. (1994)	5 <sup>b</sup>	1821	LNG IUS	0.5***	5.8	46.9
		937	NOVA T	5.9	6.7	44.5
<b>Comparative vs Norplant® II<sup>e</sup></b>						
Gao et al. (1990)	1	100	LNG IUS	1.0	3.0	90.0
		100	Norplant® II	0.0	0.0	96.0
Wang et al. (1992)	3 <sup>b</sup>	100	LNG IUS	1.1	4.2	75.0
		100	Norplant® II	0.0	0.0	69.0

a Gross rates are estimates of the cumulative probability of an event, such as pregnancy or expulsion, computed by life table or actuarial methods. Gross rates are unaffected by the rates at which competing events occur; net rates allow the presence of competing risks of termination of use, e.g. for bleeding/pain. Definitions from Tietze et. al. (1973).

b Extension to earlier study.

c The same 475 woman were used in the comparison with other copper IUDs studied.

d Net rates quoted.

e Subdermal implant releasing about 30 µg levonorgestrel/day.

Between-treatment differences: \* p<0.05; \*\*\* p<0.001; † p<0.006; s = significant, but level not stated.

ICMR = Indian Council of Medical Research.

## TABLE I

### Summary of comparative studies of LNG IUS.

ods. See Table II. The continuation rates after 5 years were 47% and 45% for the LNG IUS and NOVA T®, respectively.

The results in an earlier 5-year study with the LNG IUS and NOVA T® were similar: the 5 year pregnancy rate for the LNG IUS was 0.8% and for NOVA T® 6.7%.

The LNG IUS has been compared with Cu T380 for up to 7 years by Sivin and colleagues in a large multicenter study. The two methods had similar

contraceptive reliability, the pregnancy rates for each being 0.3% at 1 year, increasing to 1.1% (LNG IUS) and 1.4% (Cu T380 Ag) at 5 years.

The Indian Council of Medical Research conducted a 4-way comparison of the LNG IUS and Cu T380 Ag, Cu T220 C and Cu T200 B over 3 years. No pregnancies were reported with the LNG IUS, whereas the pregnancy rates with the copper IUDs ranged from 0.3 to 1.0%.

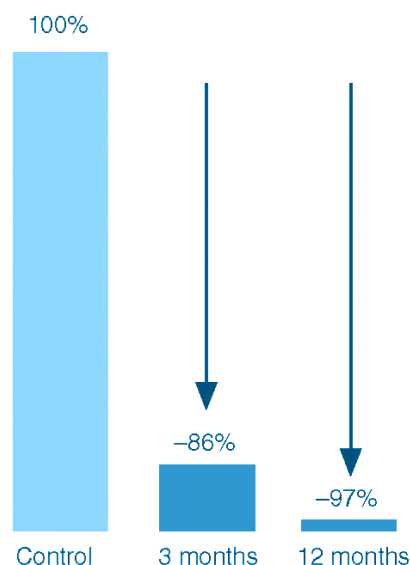
The pregnancy rate for the LNG IUS in everyday



use has been studied in a postmarketing study involving over 17 000 women during 58 600 woman-years of use. The study was started as the LNG IUS first came to the market in Finland in 1990. A total of 108 unplanned pregnancies were reported, giving a 5-year Pearl Index of 0.11. Thus, the contraceptive effectiveness of the LNG IUS in normal clinical practice is similar to that of clinical trials.

### MENSTRUAL BLEEDING CHANGES WITH THE LNG IUS

After a LNG IUS is inserted into the uterus, the menstrual bleeding pattern greatly changes in all users, as levonorgestrel is dispersed throughout the inner lining of the uterus. Unlike with copper-IUDs, the amount of menstrual bleeding is strongly diminished with the LNG IUS. However, during the first 3 months the number of bleeding days is usually increased because of longer periods, some intermenstrual spotting and, indeed, some women may have spotting and light bleeding almost every day. As the amount of blood loss is small, this spotting does not interfere with the health of the woman. However, after 3–6 months the number of bleeding days and the volume of menstrual blood loss decrease. The amount of blood loss is reduced by 50–85% after three months of use. There is in consequence an increase in hemoglobin levels. In some women the reduction in menstrual blood flow may be such that their periods stop altogether. Counseling regarding the possibility



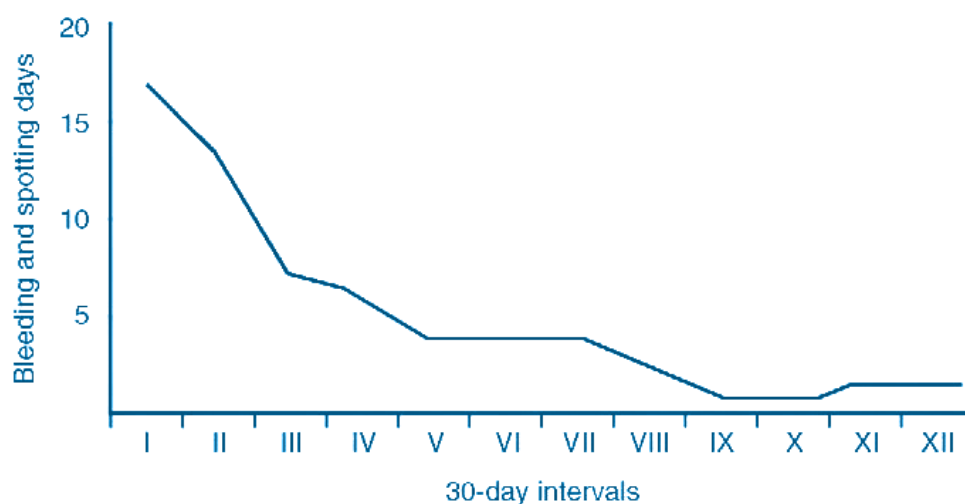
**FIG.1-6**

*Reduction in menstrual blood loss in menorrhagic women after 3 and 12 months of LNG IUS use (from Andersson & Rybo 1990).*

of absence of bleeding is important in order to avoid unnecessary removals of a LNG IUS.

The effect of the LNG IUS on menstrual bleeding is totally different from that of copper-IUDs, as with copper-IUDs the amount of bleeding usually increases by 50%.

The amount of menstrual bleeding is reduced continuously the longer the LNG IUS is in the



**FIG.1-5**

*Mean days of bleeding and spotting during 12 months of LNG IUS use by women with normal menstrual periods (Nilsson et al. 1980).*

**Table II.** Comparison of LNG IUS: 1- and 5-year net cumulative discontinuation rates per 100 women for NOVA T (n=937) or LNG IUS (n=1821) (Study A; Andersson et al. 1994) and 1- and 5-year gross annual rates per 100 women for Cu T380 Ag (n=1121) or LNG IUS (n=1124) (Study B; Sivin et al. 1990) during two separate 5-year studies

Event	Study	1 Year			5 Years		
		NOVA T	LNG IUS	Cu T	NOVA T	LNG IUS	Cu T
Pregnancy	A	0.9	0.1		4.2	0.3	
	B		0.2	0.3		1.1	1.4
Expulsion	A	3.4	3.4		5.5	4.9	
	B		6.3	5.6		11.8	7.4
Amenorrhoea	A	0.0	1.5		0.0	4.3	
	B		4.5	0.2		19.7	0.4
Bleeding problems	A	5.7	5.8		16.2	10.9	
	B		6.1	6.7			
Other menstrual/pain						15.4	23.3
Pain	A	1.6	1.6		4.2	4.2	
Hormonal	A	0.1	2.3		1.1	8.4	
PID	A	0.4	0.3		1.6	0.6	
Other medical	A	2.4	2.7		7.6	5.8	
	B		4.5	3.9		16.9	16.2
Planning pregnancy	A	1.9	1.9		11.8	10.8	
	B		2.6	1.6		25.9	23.5
Other personal	A	0.6	0.6		3.3	2.9	
	B		2.2	1.3		9.5	9.4
Continuation	A	83.0	79.9		44.5	46.9	
	B		76.3	81.8		33.0	40.6

Abbreviation: PID = pelvic inflammatory disease.

**TABLE II**

uterus. After one year about 20% of women do not have any bleeding at all, and still more women have only scanty spotting every now and then. As heavy menstrual bleeding is the most important reason for anemia, the LNG IUS is especially good for women who have excessive menstruation. In women with heavy bleeding without any organic cause hemoglobin values have been considerably improved after the insertion of the LNG IUS. Iron stores of the body are also recovered. This is especially important for women in poor nutritional conditions.

The absence of bleeding with the LNG IUS does not mean that the hormonal balance of the woman is abnormal. It has been shown that in most women ovulation takes place normally with the LNG IUS, and the secretion of estrogen and progestin from the ovaries remains normal. As the contraceptive effectiveness of the LNG IUS is so good, it is also unlikely that the absence of bleeding would be caused by an unnoticed pregnancy. However, if menstrual bleeding ceases altogether very soon after the insertion of the LNG IUS, a pregnancy test can be done.

The bleeding changes are fully reversible, and after removal of the LNG IUS both menstrual bleeding and fertility return to normal. Conception may occur already during the first month after removal. The 12 and 24-month cumulative conception rates according to Andersson, 1992 being 79/100 and 87/100 respectively.

### CONTINUATION WITH LNG IUS

The percentages of women still using the LNG IUS after 1 year and after 5 years vary markedly between different populations and centers. According to two large multicenter trials, from 76 to 80% of women were still using the LNG IUS one year after insertion. The continuation rate through 5 years was 33–47%. 11–26% of discontinuations were due to desire for pregnancy. The reasons for removal because of adverse events and complications, such as bleeding, pain, perforation, ectopic pregnancy and infection, are also shown in table II.

The most important reason for the removal of a copper-IUD is excessive uterine bleeding and pain. With the LNG IUS, the bleeding disturbanc-

es are different, and there are few removals for excessive bleeding. However, the percentage of women who discontinue the method because of absence of bleeding varies between individual studies. Unless women receive method-related counseling regarding the typical bleeding pattern with the LNG IUS the discontinuation rate will be higher. The initial period of spotting and the continuously diminishing amount of bleeding, possibly even a total absence of bleeding during the following months have to be explained to the women.

The impact of such counseling is demonstrated by a large postmarketing study involving over 17 000 LNG IUS users, in which continuation rates were 93% at 1 year and 65% at 5 years. The women who received pre-insertion information about the characteristics and possible side effects of the LNG IUS were more likely to continue use of the system. The authors point out that once women have been reassured that infrequent or absent bleeding are benign, they regard it as an advantage. Hence, amenorrhea-related discontinuation rates are lower in studies that incorporate counseling.

During the first few months after insertion of the LNG IUS, women may experience transient hormonal side effects including edema, headache, breast tenderness and acne or other skin problems. Generally these are mild, and do not lead to discontinuation in most cases. Hormonal side effects tend to be more pronounced in the beginning and subside by time. Lower abdominal or back pain, vaginal discharge and nausea have been described and functional ovarian cysts may occur, as with other progestogen-only methods of contraception. Other side effects, apart from spotting in the first few months, are rare.

It is important to remember that with all intra-uterine contraceptive methods, abnormal bleeding and pain may not be due to the IUD or IUS itself, but to pelvic inflammatory disease (PID), an ectopic pregnancy or other conditions. Therefore, the health care provider should consider all conditions that might cause bleeding and pain before attributing them to the IUS.

Other reasons for removal are **spontaneous expulsion**, pregnancy and infection. After the IUS insertion, uterine contractions can push the device downward, causing partial or complete expulsion. The expulsion rate of the LNG IUS varies in different studies from 3 to 6 percent in

the first year of use. (See Table II). The number of expulsions can be diminished through correct insertion technique, with the IUS placed high in the fundus. Most expulsions occur during the first three months after insertion. Because undetected partial or complete expulsion can lead to an unplanned pregnancy, IUS users should know how to check for the IUS strings to make sure that the system is still in place.

The contraceptive effectiveness of the LNG IUS is high, and **pregnancies** are quite uncommon. However, the discontinuation rate for pregnancy, intrauterine or ectopic, is 0.1–1.0 per 100 women during the first year. (See Table I) Spontaneous abortion is the most frequent complication of pregnancy with any IUD in place. Some 50–60% of uterine pregnancies spontaneously abort if the IUD is not removed. Furthermore, regarding the LNG IUS, the consequences of the high local levonorgestrel concentration in the uterus near the developing fetus are not known, since the experience of pregnancies with the LNG IUS in situ is limited. However, so far no malformations are known to be caused by the LNG IUS among the children born with a LNG IUS in place during pregnancy. Still another serious complication regarding any IUD in the uterus during pregnancy is a septic (infected) second trimester spontaneous abortion in women whose IUDs are left in place. This event is rare but life threatening.

Based on all these reasons, as soon as an accidental pregnancy is detected, the IUS should be removed. If the removal is not successful, a termination of pregnancy should be considered.

Regarding an **ectopic pregnancy**, the risk with the LNG IUS is the lowest of all intrauterine contraceptive methods. In one study, the 5-year rate (0.02 per 100 woman-years) compared favorably with both the rate for women using NOVA T® (0.25 per 100 woman-years) and, more importantly, the rate for a control population of sexually active women not using contraception (1.2–1.6 per 100 woman-years). However, of all pregnancies with the LNG IUS a higher proportion is ectopic as the LNG IUS more effectively prevents intrauterine pregnancies. The rate differs from 20% of pregnancies to 53% in one recent survey. Thus, if a woman becomes pregnant with the LNG IUS, the possibility of an extra uterine location must be kept in mind.

In general, women using IUDs have an increased risk of **pelvic inflammatory disease** (PID) dur-

ing the first weeks after insertion. This increase is strongly related to the insertion process (i.e., lack of good infection prevention practices) and background risks of sexually transmitted infections (STIs). Thereafter, the risk of contracting PID is greater only among women exposed to STIs. This latter finding is based on a study by Family Health International, which involved 10 000 women in 23 countries. In this study no significant link was observed between the use of IUDs and PID for women not exposed to STIs or other genital infections. In some studies there have been less genital tract infections with the LNG IUS than with Copper-IUD as the thick cervical mucus inhibits not only sperms but also to some extent infectious agents from getting up to inner genitalia. However, everything should be done to minimize the risk of inserting a LNG IUS in a woman with risk for STIs such as gonorrhea, chlamydia or syphilis.

**IUS use and the risk of AIDS.** While the increased risk for PID in IUD users exposed to STIs is well established, there is at present no evidence that IUS or IUD users may be at increased risk for contracting HIV (AIDS), i.e., the possibility that the IUS itself could be considered a risk factor for transmitting HIV to the woman. Because an IUS does not protect women who are at risk for STIs, including AIDS, IUS users should use a barrier method (condoms) to minimize the risk of infection.

**Uterine perforation** is a rare (less than 1 per 1000 insertions), but potentially serious complication of IUS use. The risk of perforation is inversely related to the skill and experience of the health provider inserting the IUS. Therefore, new providers should be properly trained before performing live insertions. Insertion instructions should be carefully followed during the insertion procedure to ensure a successful insertion of the LNG IUS.

### STORAGE, SHELF LIFE AND EFFECTIVE LIFE

The contraceptive is prescribed as a set consisting of a LNG IUS and an insertion tube. They are packed in a sealed, sterile plastic pouch. The sterile packs of LNG IUSs should be stored away from excessive heat (temperatures higher than 30 degrees centigrade/ 86 degrees Fahrenheit) and moisture.

An unopened, undamaged sterile pack of a LNG IUS, if properly stored, has a **shelf life of**

**3 years.** The last date for insertion (expiration date) is stamped on each package. After the shelf life has expired, the system should be discarded.

LNG is released into the uterine cavity at a constant rate for 5 years. The recommended duration of use for the LNG IUS in contraception is 5 years.

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### REFERENCES:

- Andersson K, Rybo G. Levonorgestrel-releasing intrauterine device in the treatment of menorrhagia. *British Journal of Obstetrics and Gynaecology* 97: 690–694, 1990
- Andersson K, Batar I, Rybo G. Return to fertility after removal of a levonorgestrel releasing intrauterine device and Nova T. *Contraception* 45: 575–584, 1992b
- Andersson K, Odland V, Rybo G. Levonorgestrel-releasing and copper-releasing (Nova T) IUDs during five years of use: a randomised comparative trial. *Contraception* 49: 56–72, 1994
- Backman et al. Sixty thousand woman-years of experience on the levonorgestrel intrauterine system: an epidemiological survey in Finland. *European Journal of Contraception and Reproductive Health Care* 6 (Suppl 1): 23–26, 2001
- Backman T, Huhtala S, Luoto R, et al. Advance information improves user satisfaction with the levonorgestrel intrauterine system. *Obstetrics and Gynecology* 99: 608–613, 2002
- Backman et al. Pregnancy during the use of levonorgestrel intrauterine system. *American Journal of Obstetrics and Gynecology* 190: 50–4, 2004
- Barbosa I, Bakos O, Olsson SE, et al. Ovarian function during use of a levonorgestrel-releasing IUD. *Contraception* 42: 51–66, 1990
- Belhadji H, Sivin I, Diaz S, et al. Recovery of fertility after use of the levonorgestrel 20 mcg/d or copper T 380Ag intrauterine device. *Contraception* 34: 261–267, 1986
- Family Health International: Use of IUDs in developing countries: a comparative study. *Network* 12(2), 1991
- Faúndes A, Alvarez F, Díaz J. A Latin American experience with levonorgestrel IUD. *Annals of Medicine* 25: 149–153, 1993
- Gao J, Wang S-I, Wu S-c, et al. Comparison of the clinical performance, contraceptive efficacy and acceptability of levonorgestrel-releasing IUD and Norplant®-II implants in China. *Contraception* 41: 485–494, 1990
- Haukkamaa M, Holma P. Five-year clinical performance of the new formulation of the levonorgestrel intrauterine system and serum levonorgestrel concentration with the new formulation compared to that with the original one. *Leiras Clinical Study Report* 1 No. 02–89532–07, 1996
- Indian Council of Medical Research. Task force on IUD. Randomized clinical trial with intrauterine devices (levonorgestrel intrauterine device (LNG), CuT 380Ag, CuT 220C and CuT 200B). A 36-month study. *Contraception* 39: 37–52, 1989



- Jones RL, Critchley HO. Morphological and functional changes in human endometrium following intrauterine levonorgestrel delivery. *Human Reproduction* 15 (Suppl. 3): 162–172, 2000
- Jonsson B, Landgren B-M, Eneroth P. Effects of various IUDs on the composition of cervical mucus. *Contraception* 43: 447–458, 1991
- Kuhn W, Al-Yacoub G, Fuhrmeister A. Pharmacokinetics of levonorgestrel and ethinylestradiol in 9 women who received a low-dose oral contraceptive over a treatment period of 3 months and, after a washout phase, a single oral administration of the same contraceptive formulation. *Contraception* 46: 455–469, 1992
- Lähteenmäki P. Serum levonorgestrel concentration during 78 month use of LNG IUD. *Leiras Clinical Study Report No. 1207*, 1991
- Luukkainen T, Allonen H, Haukkamaa M, et al. Five years' experience with levonorgestrel-releasing IUDs. *Contraception* 33: 139–148, 1986
- Luukkainen T. Levonorgestrel-releasing intrauterine device. *Annals New York Academy of Sciences* 626: 43–49, 1991
- Luukkainen T. Contraception after thirty-five. *Acta Obstetrica et Gynecologica Scandinavica* 71: 169–174, 1992
- Luukkainen T, Lähteenmäki P. Treatment of menorrhagia by levonorgestrel-releasing intrauterine device. *Immunology* 36: 261–267, 1992
- Luukkainen T, Lähteenmäki P, Toivonen J. Levonorgestrel-releasing intrauterine device. *Annals of Medicine* 22: 85–90, 1990
- Mati JKG et al. AIDS and contraceptive practice. National Center for Research in Reproduction. Abstract No 48, 1991.
- Nilsson CG, Lähteenmäki P. Recovery of ovarian function after the use of a d-norgestrel-releasing IUD. *Contraception* 15: 389–400, 1977
- Nilsson CG, Lähteenmäki PLA, Luukkainen T, et al. Sustained intrauterine release of levonorgestrel over five years. *Fertility and Sterility* 45: 805–807, 1986
- Robinson GE, Bounds W, Kubba AA, et al. Functional ovarian cysts associated with the levonorgestrel releasing intrauterine device. *British Journal of Family Planning* 14: 131–132, 1989
- Scholten PC, van Eykeren MA, Christiaens GCML, et al. Menstrual blood loss with levonorgestrel Nova T and Multiload CU 250 intrauterine devices. In Scholten PC (Ed.). Thesis. The levonorgestrel IUD: clinical performance and impact on menstruation, pp. 35–45, University Hospital, Utrecht, 1989a
- Scholten PC, Christiaens GCML, Haspels AA. Treatment of menorrhagia by intrauterine administration of levonorgestrel. In Scholten PC (Ed.). Thesis. The Levonorgestrel IUD: clinical performance and impact on menstruation, pp. 47–55, University Hospital, Utrecht, 1989b
- Silverberg SG, Haukkamaa M, Arko H, et al. Endometrial morphology during long-term use of levonorgestrel-releasing intrauterine devices. *International Journal of Gynecological Pathology* 5: 235–241, 1986
- Sivin I, El-Mahgoub S, McCarthy T, et al. Long-term contraception with the levonorgestrel 20 mcg/day (LNg 20) and the copper T 380Ag intrauterine devices: a five-year randomized study. *Contraception* 42: 361–378, 1990
- Sivin I, Stern J, Coutinho E, et al. Prolonged intrauterine contraception: a seven-year randomized study of the levonorgestrel 20 mcg/day (LNg 20) and the copper T 380Ag IUDs. *Contraception* 44: 473–480, 1991
- Tang GWK, Lo SST. Levonorgestrel intrauterine device in the treatment of menorrhagia in Chinese women: efficacy versus acceptability. *Contraception* 51: 231–235, 1995
- Toivonen J, Luukkainen T, Allonen H. Protective effect of intrauterine release of levonorgestrel on pelvic infection: three years' comparative experience of levonorgestrel- and copper releasing intrauterine devices. *Obstetrics & Gynecology* 77: 261–264, 1991
- Videla-Rivero L, Etchepareborda JJ, Kesseru E. Early chorionic activity in women bearing inert IUD, copper IUD and levonorgestrel-releasing IUD. *Contraception* 36: 217–226, 1987
- Zhu P, Hongzhi L, Ruhua X, et al. The effect of intrauterine devices, the stainless steel ring, the copper T220, and releasing levonorgestrel, on the bleeding profile and the morphological structure of the human endometrium – a comparative study of three IUDs. *Contraception* 40: 425–438, 1989
- Zhu P, Liu X, Luo H, et al. The effect of a levonorgestrel-releasing intra-uterine device on human endometrial oestrogen and progesterone receptors after one year of use. *Human Reproduction* 14: 970–975, 1999

# Counseling

## BACKGROUND

Experience suggests that good, thorough counseling improves user satisfaction and increases the successful use of any contraceptive method. This has clearly been shown with the LNG IUS as well. Effective counseling also allows the client (or couple) to arrive at an informed choice after having carefully considered the benefits and limitations of all the methods available.

This chapter focuses on the following key components related to effective counseling for the LNG IUS; namely

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

Information regarding rumors and facts about the LNG IUS is also provided. Finally, guidelines for family planning counseling are presented in **Appendix A**. They 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 the needs of each client.

## CLIENT RIGHTS<sup>1</sup>

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 the 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 preg-

nancy, but for other reasons that include planning pregnancy or protecting their reproductive and sexual health.

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

1. All individuals of reproductive age have the right to information about family planning for themselves and their families, regardless of their ethnic origin, socioeconomic status, religion, marital status or political beliefs.
2. All persons have the right to decide freely whether or not to practice family planning.
3. 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.
4. Clients should be able to obtain the method they have decided to use, provided the method is available and there are no reasons why they should not use it.
5. It is natural that the client's concepts of acceptability and appropriateness change with their circumstances. Therefore, the client has the right to decide when to start, stop or switch methods.
6. Clients 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.
7. 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 right to privacy also includes

<sup>1</sup>Adapted from: Huezo and Briggs 1992.



the following aspects related to the 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 that is going to be done and has the right to refuse any particular type of examination if she does not feel comfortable with it.
8. 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 waiting to be seen and receiving requested services should be reasonable.
  9. 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.
  10. Finally, clients have the right to express their views about the services received. Opinions on the quality of services, either thanks or complaints, together with suggestions for changes in service provision, should be viewed positively in an effort to monitor, evaluate and improve the quality of a program.

## BENEFITS OF COUNSELING

Counseling is an ongoing process integrated into all aspects of family planning services. Clients who have been well counseled are able to make an informed choice about their contraceptive method, they are more likely to be satisfied with it, and by talking about their positive experience become the most effective means of promoting it. Remember that it is important to repeat and reinforce important information on how to use the method, side effects, STI prevention etc.

### Benefits for the Woman

- Counseling results in the woman arriving at a free and informed decision. She feels in control

of her choice of the LNG IUS 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 from the LNG IUS. She understands all the advantages it offers and will 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 system removed at any time she wishes.
- She knows where she can go to have the system removed.

### Benefits 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 the LNG IUS.

## 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 woman/couple has had the opportunity to discuss contraceptive options fully. At this time the client can:

- be helped to choose a suitable method;
- receive further information about how to use the method safely, effectively and with satisfaction; and
- discuss personal issues and needs.
- If the woman is interested in the LNG IUS, counseling should provide specific information about
- basic health to ensure there are no reasons (e.g., suspected pregnancy, uterine malformation, STI risk) the woman should avoid using this contraceptive;

- how the LNG IUS prevents pregnancy;
- advantages and disadvantages including side effects (particularly those related to changes in menstrual bleeding) and other problems
- insertion / removal procedure and the 5-year effective life of the LNG IUS; If the woman is interested, the insertion procedure should be explained with a demo and a uterus model
- the timing of the insertion and which method to use if the insertion is delayed
- the freedom of the client to discontinue the method whenever desired
- there being no delay in the return of fertility after removal of the system
- the need to use condoms to protect from STIs

**Post-insertion counseling** is usually given right after IUD insertion and it should focus on the need for follow-up and on the potential warning signs prompting a quick return to the clinic.

**Follow-up counseling** should reinforce information given post-insertion. Counselors should listen and be prepared to answer any questions the client has encountered. Answering questions helps a client to cope with any problems and side effects.

## RUMORS AND FACTS

Correcting false rumors and misinformation is an important part of the work of healthcare providers. 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:** The IUS might travel through the woman's body.

**Response:** Show the client a picture or a model of a uterus, and explain that the IUS usually stays in the uterus until it is removed. If it comes out by itself, it comes out through the vagina. It is very rare that IUS perforates the wall of the uterus and remains in the abdomen.

**False rumor:** The IUS prevents pregnancy by causing an abortion.

**Response:** Explain that the mechanism of action of the LNG IUS is the inhibition of sperm motility and transfer through the cervix, thereby preventing the sperm from fertilizing the egg.

**False rumor:** Absence of bleeding with the IUS means that her ovaries stopped functioning and the woman is no longer fertile.

**Response:** Absence of bleeding that occurs in some women with the LNG IUS, is caused by the local action of LNG at the level of the uterus. The functioning of the ovaries is not affected. When the system is removed, menstrual bleeding will reappear and fertility is restored.

**False rumor:** Absence of bleeding is unhealthy, because it means that the dirty blood remains in the body.

**Response:** Normally, menstrual bleeding consists of the inner lining of the uterus, the endometrium, and its vessels, that bleed away once a month as the hormones from the ovary regulate the cycle. Explain to the woman that with the LNG IUS bleeding is scanty or remains totally absent, because the local levonorgestrel in the uterus keeps the inner lining of the uterus in the resting phase, very thin. There simply is nothing to bleed away, and no dirty blood remains in the uterus. Instead, this may be beneficial as anemia is prevented and the iron stores are restored.

**False rumor:** the IUS causes discomfort in coitus.

**Response:** The LNG IUS is inside the uterus and it does not interfere with coitus. It is not possible for the partner to feel the IUS itself. However, sometimes the partner may feel the strings during intercourse. This is fully harmless, but if it causes discomfort for the partner, the strings can be cut shorter.

## IMPORTANT FACTS ABOUT THE LNG IUS

The LNG IUS is a new hormonal method of contraception. The contraceptive effectiveness is as good as that of female sterilization, yet the LNG IUS is a fully reversible method of contraception. It looks like a T-model IUD, but instead of a copper wire, there is a hormone capsule around the vertical stem of the T body. The insertion should be performed during menstruation in order to ensure that the client is not pregnant. The hormone is released at a steady rate into the uterus and the system in-

hibits fertilization by affecting the motility and function of the sperm. A sterile, single packed LNG IUS, is inserted into the uterine cavity by a trained healthcare provider. The effective life of the LNG IUS is 5 years. After the initial few months of spotting and intermenstrual bleeding, use of the IUS makes menstruation lighter and less painful. The LNG IUS does not protect from sexually transmitted infections.

### WHO CAN USE AN LNG IUS

#### The LNG IUS is indicated for women who

- do not want a child for several years but may want to have a child later
- do not want any more children but do not want to have sterilization
- need contraception and have heavy menstrual bleeding
- are troubled by the estrogenic side effects of contraceptive pills
- who can accept menstrual changes, including the possibility of absence of bleeding
- who are breastfeeding, starting from 6 weeks post delivery
- who want long-term contraception immediately after a first trimester abortion

#### The LNG IUS is not indicated for women who

- wish to have children soon
- have uterine anomalies
- are at risk for STIs – except if using a male or female condom
- cannot tolerate absence of bleeding
- express serious concern about the insertion procedure

In addition, the LNG IUS may not be the first method of choice for women who have not been pregnant and who have a small uterine cavity.

The LNG IUS is not intended for postcoital contraception.

### BENEFITS AND LIMITATIONS OF THE LNG IUS

#### Benefits:

- Highly effective (0.1 pregnancies per 100 women in the first year)
- A long-term reversible method (effective for

5 years)

- No daily action required
- Comfortable to use
- Insertion easy without need for local anesthesia
- The lowest dose hormonal contraceptive, with no estrogen
- Makes menstrual bleeding lighter and less painful
- Few serious adverse events

#### Limitations:

- Spotting and intermenstrual bleeding in the first months
- Possibility of hormonal side effects
- Absence of bleeding hard to accept by some women
- Insertion and removal need to be done by trained providers
- If a pregnancy occurs it can have a higher likelihood of being ectopic

### THE IMPORTANCE OF COMPREHENSIVE COUNSELING

The LNG IUS is a novel system, and few providers or clients have any former experience about its special characteristics. As an intra-uterine system, it may be confused with copper IUDs, and as the clinical performances of these methods are in many respects different, this may give rise to unnecessary misunderstandings. Counseling is especially important in all family planning programs before the LNG IUS is inserted. Firstly, the staff has to be trained to understand the local hormonal effects of the LNG IUS; secondly the counselors have to use their sound knowledge and good communication skills in discussions with the clients. Particularly the negative aspects, such as the initial period of irregular bleeding, should be described honestly. Furthermore, an effective client screening is of vital importance to avoid adverse events such as PIDs. It is also well

known that in some cultures the acceptance of missing periods and irregular uterine bleeding is low. Considering these aspects in advance will probably inhibit unnecessary discontinuations of the method.

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#### REFERENCES:

Backman T, Huhtala S, Luoto R, et al. Advance information improves user satisfaction with the levonorgestrel intrauterine system. *Obstetrics and Gynecology* 99: 608–613, 2002

Darney P et al. Acceptance and perceptions of Norplant among users in San Francisco, USA. *Studies in Family Planning* 21(3): 152–160, 1990

Gallen M, Lettenmaier C, Green CP. Counseling makes a difference. *Population Report Series J* (35): 1–31, 1987

Huezo C, Briggs C. Medical and service delivery guidelines. International Planned Parenthood federation Medical department; London, 1992

Lettenmaier C, Gallen M. Why counseling counts! *Population Reports Series J* (36): 1–28, 1987

World Health Organization (WHO). Improving Access to Quality Care in Family Planning: Medical Eligibility Criteria for Initiating and Continuing Use of Contraceptive Methods. 2nd edn, WHO, Geneva, 2000

# Indications and Conditions Requiring Precautions

## BACKGROUND

A contraindication, also termed a precaution, 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 were 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 may be 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 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.

## CONTRACEPTIVE CHOICE AND REPRODUCTIVE HEALTH CARE FOR WOMEN

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. For example, for a woman with many children, the importance of her future fertility may be of less concern than access to a highly effective long-acting contraceptive method such as the LNG IUS – even if it entails some risks or side effects.

In some countries, women who do not want any more children are denied voluntary sterilization for a number of reasons (e.g. they are too young or do not have many children, or the system cannot accommodate all requests). For such women, a copper IUD or the LNG IUS can be a good alternative. In addition to being highly effective, they are long-acting and require limited follow-up unless there is a problem.

Under most circumstances, the risk of dying from pregnancy is many times greater than the risk of dying from using the LNG IUS or any other modern contraceptive method. In fact, the higher the maternal mortality rate, the more important it is to offer women the widest choice of effective methods. Thus, in order to maximize access to quality family planning services, protocols that list the indications and precautions for use of the LNG IUS should be flexible. They should be designed to help the service provider consider not only the individual history and living conditions of a woman, but also the local maternal health situation.

## INDICATIONS FOR USE

The LNG IUS is an appropriate method for a woman who:

Condition	Rationale
<b>Prefers a long-term method</b> 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 an LNG IUS is inserted, it is effective for five years. Periodic check-ups according to local clinic protocols are recommended after insertion. The woman should be advised how to check the strings.
<b>Has the number of children she wants</b> but does not want a permanent method (voluntary sterilization) at this time.	Consecutive LNG IUS's can be used, provided the client develops no serious medical problems and replaces it on schedule every 5 years.
<b>Has one or more children</b>	All IUDs and the LNG IUS are better tolerated by women who have borne a child, probably because the uterine cavity is larger and accommodates the system better. The recommended time for insertion after delivery is 6 weeks.
<b>Has been breastfeeding</b> for 6 weeks or more postpartum and wants contraception.	Breastfeeding is not negatively affected by the use of progestins. The level of LNG in breast milk has not been shown to cause any clinically important effects on infant health or growth. Progestin only methods such as the LNG IUS may be safely used after 6 weeks postpartum. The LNG IUS can be safely inserted after six weeks from the delivery. In addition, if a client is fully breastfeeding, insertion can be delayed for six months provided she remains amenorrheic (no vaginal bleeding) and gives no supplementary feeding.
<b>Is postabortal</b>	The LNG IUS may be inserted safely directly after a first trimester surgical abortion or during the next menstrual bleeding.
<b>Has moderate to severe menstrual pain</b>	Progestins, such as LNG, reduce the frequency and intensity of menstrual pain. Users of the LNG IUS have reported decrease of dysmenorrhea
<b>Has heavy menstrual bleeding</b>	The LNG IUS effectively decreases menstrual bleeding
<b>Women for whom estrogen containing contraceptives are contraindicated. e.g. heavy smokers</b>	The LNG IUS does not have marked effects on the cardiovascular system or blood clotting
<b>Has stopped using a copper IUD because of heavy menstrual bleeding or cramping</b>	The LNG IUS may be well tolerated by these women because it diminishes bleeding and pain
<b>Is at low risk of contracting sexually transmitted infections (STIs)</b> (i.e. is in a mutually monogamous sexual relation)	The LNG IUS does not protect women against hepatitis B, AIDS or STIs, such as gonorrhea and chlamydia, which can cause pelvic infection (PID) and lead to infertility.



**CONDITIONS REQUIRING PRECAUTION**

For women with any of the following conditions, healthcare workers need to assess with the client the appropriateness of the LNG IUS for **each client**, not only in terms of her special needs but also in relation to the healthcare climate in which she lives. Because the LNG IUS releases minimal

doses of progestin into the uterine cavity, the rationales for the precautions listed in this section are based on the most recent epidemiologic and clinical data regarding the medical criteria for POPs. In addition, because it is an intrauterine contraceptive system, some precautions are identical with those of copper IUDs.

Condition	Precaution	Rationale
<b>Pregnancy</b> (known or suspected)	If the possibility of pregnancy <b>cannot</b> be excluded by history, examination or pregnancy testing, insertion of an LNG IUS should be delayed until the next menstrual period. In the interim, help the client choose another method (e.g., condoms).	If a woman is pregnant at the time when an LNG IUS is inserted, she is at an increased risk for spontaneous abortion (miscarriage) as well as for serious uterine infection. Because of the local exposure to levonorgestrel, teratogenicity cannot be completely excluded. However, to date there is no evidence of birth defects caused by the LNG IUS in cases where pregnancy continues to term with the LNG IUS in place.
<b>Current, recent or recurrent PID</b> (or post-abortal/post partum endometritis within the past three Months).	She should use another contraceptive method. An LNG IUS should not be the first choice for a woman who has had a post-abortal or postpartum endometritis.	A history of recent /recurrent PID not associated with pregnancy or abortion strongly suggests the woman is at risk for STIs.
<b>Acute purulent discharge from the cervical canal, gonorrheal or chlamydial cervicitis</b>	If, following treatment, the woman chooses to have an LNG IUS inserted, she should be followed closely for signs of re-infection and should use a condom.	Sexually transmitted infections may increase the risk for PID and subsequent infertility.
<b>Undiagnosed abnormal vaginal bleeding</b> (irregular bleeding between the periods or postcoital bleeding during the last 3 months)	The cause of any vaginal bleeding should be determined and treated before an LNG IUS is inserted	Because the LNG IUS often causes irregular bleeding during the first months, the symptoms of an underlying problem, such as normal or ectopic pregnancy or cervicitis may be masked. Rarely, there may be a genital tract cancer.
<b>High risk for STIs</b>	A woman who has more than one sexual partner or whose partner has more than one sexual partner should be counseled about this. If she wants to use an LNG IUS, the couple should also use a condom for infection prevention.	The LNG IUS does not protect against STIs.

<b>Uterine anomaly, large fibroids</b>	The LNG IUS is effective in a uterine cavity of normal size and shape. Never force an LNG IUS into the uterine cavity	Distortions of the uterine cavity (caused by uterine anomalies e.g. double uterus or submucous or large fibroids) may cause difficulties in insertion, increase the risk for IUS expulsion and decrease effectiveness.
<b>Severe cervical stenosis</b>	Counsel the client, and if needed, refer the client to a center where cervical dilatation with local anesthesia is available.	Severe narrowing of the cervical canal (entrance to the uterus) may make any IUD insertion more difficult and painful.
<b>Acute liver disease or liver tumor</b>	In acute liver disease other, non-hormonal methods should be considered. However, the serum concentration of hormone with the LNG IUS is lower than with any other hormonal contraceptive method.	There is no evidence that the LNG causes liver disease (e.g., benign or malignant tumors or cirrhosis), hepatitis or gall bladder problems. LNG is metabolized in the liver; it is not likely to clinically worsen liver disease and its use is safer than pregnancy in women with active hepatitis
<b>History of an ectopic pregnancy</b>	Women should be counseled about the warning signs for ectopic pregnancy.	Women who have had prior ectopics are at an increased risk for another ectopic pregnancy. However, with the LNG IUS the risk for an ectopic pregnancy is very low, and in clinical trials it has been 0.06 per 100 women per year.
<b>Symptomatic rheumatic or congenital valvular heart disease.</b>	Women with symptomatic valvular disease should receive antibiotic prophylaxis at the time of insertion and removal of the LNG IUS. (Amoxicillin 3.0 g orally one hour before the insertion, and 1.5 g six hours after the first dose OR Erythromycin 1.0 g orally two hours before the insertion, and 500 mg six hours after the first dose, if the patient is allergic to amoxicillin).	Prevent remote possibility of endocarditis based upon possible transient bacteremia associated with IUD insertion or removal in women with symptomatic congenital or rheumatic valvular disease.
<b>Breast cancer</b>	The LNG IUS should not be the first choice contraceptive for a woman with breast cancer.	Breast cancer is a hormonally sensitive tumor. Hormonal contraceptives are generally not recommended to women with a history of breast cancer. The safety of the LNG IUS in women suffering or recovered from breast cancer has not been demonstrated. However, because of the low systemic dose of LNG, concerns about progression of the disease may be less with the LNG IUS than with other forms of hormonal contraception.

<b>Severe arterial disease such as stroke or myocardial infarction</b>	The LNG IUS should not be the first choice contraceptive for a woman with these conditions.	There is theoretical concern, because of possible aggravation of the condition.
<b>HIV positivity</b>	Risk assessment and testing for STIs prior to insertion are recommended.	HIV positive women are at increased risk for STIs. These women may still choose to use the LNG IUS provided that a condom is used in addition.

## REFERENCES:

- Abdalla MY et al. Contraception after heart surgery. *Contraception* 45: 73, 1992
- Angle MA et al. Guidelines for clinical procedures in Family Planning, 2nd edn, INTRAH, 1993
- Andersson JK, Rybo G. Levonorgestrel-releasing intrauterine device in the treatment of menorrhagia. *British Journal of Obstetrics and Gynaecology* 97: 690–694, 1990
- Backman T, Rauramo I, Huhtala S et al. Pregnancy during the use of levonorgestrel intrauterine system. *American Journal of Obstetrics and Gynecology* 190: 50–54, 2004
- Dajani AS et al. Prevention of bacterial endocarditis: recommendations by the American Heart Association. *Journal of American Medical Association* 264: 2919, 1990
- Heikkilä M, Luukkainen T. Duration of breast-feeding and development of children after insertion of a levonorgestrel releasing intrauterine contraceptive device. *Contraception* 25: 279–292, 1982
- Heikkilä M, Haukkamaa M, Luukkainen T. Levonorgestrel in milk and plasma of breast-feeding women with a levonorgestrel-releasing IUD. *Contraception* 25: 41–49, 1982b
- Heikkilä M, Lähteenmäki P, Luukkainen T. Immediate postabortal insertion of a levonorgestrel-releasing IUD. *Contraception* 26: 245–259, 1982
- Indian Council of Medical Research. Task force on IUD. Randomized clinical trial with intrauterine devices (levonorgestrel intrauterine device (LNG), CuT 380Ag, CuT 220C and CuT 200B). A 36-month study. *Contraception* 39: 37–52, 1989
- Labbok M, K Cooney and S Coly. Guidelines for Breastfeeding and the Lactational Amenorrhea Method. Institute for Reproductive Health: Washington, D.C., 1994
- McCann MF and LS Potter. Progestin-only oral contraception: a comprehensive review. *Contraception* 50(6): 1–195, 1994
- McEwan J. Contraception for women with liver disease. *British Journal of Family Planning* 9(2): 53–57, 1983
- Petersen KR et al. Intrauterine devices in nulliparous women. *Advances in Contraception* 7(4): 333–338, 1991
- Royal College of General Practitioners (RCGP) Oral Contraceptives Study. Oral contraceptives and gall bladder disease. *Lancet* 2(8305): 957–959, 1982
- Scarselli G, Tantini C, Colafranceschi M, et al. Levonorgestrel-Nova T and precancerous lesions of the endometrium. *European Journal of Gynaecological Oncology* IX: 284–286, 1988
- Shikary K et al. Transfer of levonorgestrel (LNG) administered through different drug delivery systems from the maternal circulation into the newborn infant's circulation via breast milk. *Contraception* 35: 477–486, 1987
- Sivin I, Stern J, Coutinho E, et al. Prolonged intrauterine contraception: a seven-year randomized study of the levonorgestrel 20 mcg/day (LNg 20) and the copper T 380Ag IUDs. *Contraception* 44: 473–480, 1991
- Speroff L, RH Glass and NG Kase. Clinical Gynecologic Endocrinology and Infertility, Fourth edition. Williams & Wilkins: Baltimore, Maryland, 1989
- Toivonen J, Luukkainen T, Allonen H. Protective effect of intrauterine release of levonorgestrel on pelvic infection: three years' comparative experience of levonorgestrel- and copper releasing intrauterine devices. *Obstetrics & Gynecology* 77: 261–264, 1991
- World Health Organization (WHO). Improving Access to Quality Care in Family Planning: Medical Eligibility Criteria for Initiating and Continuing Use of Contraceptive Methods. 2nd edn, WHO: Geneva, 2000
- World Health Organization (WHO) Task Force for Epidemiological Research on Reproductive Health. Progestogen-only contraceptives during lactation: I. Infant growth. *Contraception* 50: 35–53, 1994a
- World Health Organization (WHO) Task Force for Epidemiological Research on Reproductive Health. Progestogen-only contraceptives during lactation: II. Infant development. *Contraception* 50:55–68, 1994b

# Client Assessment

## BACKGROUND

The medical assessment of potential LNG IUS users should include a brief history, a limited general examination and a complete pelvic examination. Sometimes, when warranted and available, simple diagnostic tests may be done (e.g. pregnancy test, testing for STIs such as chlamydia and gonorrhea). The aim of the medical assessment is to distinguish those women who will be more likely to use the LNG IUS successfully. (See list of precautions).

First of all, make sure that potential clients have been counseled about the method; its benefits, limitations and side effects (especially changes in the menstrual bleeding pattern); as well as about other contraceptives. Make sure that they understand what to expect during the insertion and where, when and why the LNG IUS should be removed.

## MEDICAL HISTORY

The following specific information should be obtained:

### General

- Diabetes, HIV positivity, AIDS or other immunological disorders
- Symptomatic valvular or rheumatic heart disease, a history of bacterial endocarditis, artificial heart valves.

### Reproductive

- Menstrual history (pain, the amount and duration of bleeding, the length of the menstrual cycle) and the date of the last menstrual period (LMP)
- Parity, pregnancy outcomes and dates, desire for more children
- Previous use of contraception
- PID or ectopic pregnancy

- Lower abdominal pain, which may be worse during special time of the cycle, while walking or after intercourse.
- Postpartum or postabortal endometritis
- Multiples sexual partners for either partner
- Cervical or uterine malignancy
- Breast cancer

## PHYSICAL EXAMINATION

- General examination
- Blood pressure and pulse
- Auscultation of the heart (listen for murmurs)

### Breast examination

(Not essential for the safe provision of an LNG IUS and may be omitted)

Check for masses and other abnormalities (should include teaching the client self breast examination as part of general health care)

### Abdominal examination

Check for:

- Suprapubic or pelvic tenderness
- Masses or gross abnormalities

### Pelvic examination

(Make sure the client has voided before the examination)

- External genitalia and speculum
- Inspect external genitalia for ulcers and bubo (enlarged lymph nodes)
- Check for vaginal discharge and other signs of lower genital tract infections
- Check cervix for purulent cervicitis or narrowing of cervical canal (stenosis)

- If indicated by history or physical signs, obtain necessary specimens of vaginal and cervical secretions for diagnostic studies
- Bimanual
- Determine the size, shape and position of uterus
- Check for enlargement or tenderness of the adnexa, active PID, etc.
- Check for pregnancy
- Check for uterine abnormalities
- Rectovaginal ( if needed for complete understanding of the pelvic status)
- Determine size of retroverted (posterior-directed) uterus
- Check for cul-de-sac mass or tenderness

### LABORATORY STUDIES

The following simple laboratory tests should be done only when the history or physical findings warrant further investigation:

- Saline and KOH wet mounts and pH test of vaginal discharge for trichomoniasis, monilia (yeast) and gardnerella (bacterial vaginosis)
- Gram stain of cervical or urethral discharge
- Urine pregnancy test
- Urine test for sugar and protein

When conducting the medical assessment, it may be helpful for the service provider to use a checklist so that no important information is left out. A sample Client assessment checklist is presented in **Appendix B**.

### REFERENCES:

Center for Communications Programs (Population Information Program): IUDs-a new look. Population Report Series B (5) 1988.

Hatcher et al. Contraceptive Technology: 1990–21. New York, Irvington Publishers, Inc., 1990

Technical Guidance Working Group (TGWG). Recommendations for Updating Selected Practices in Contraceptive Use: Results of a Technical Meeting, Vol 1. Program for International Training in Health: Chapel Hill, North Carolina, 1994.

## LNG IUS and Genital Tract Infections

### BACKGROUND

Sexually transmitted infections (STIs) are caused by small number of micro-organisms which usually are transmitted through sexual contact. STIs have been around for thousands of years or more. By contrast, HIV (AIDS) was not discovered until 1981. STIs constitute enormous health problems both in developing and developed countries, as their occurrence is increasing.

Inserting any intrauterine contraceptive into a woman who has an STI or other genital tract infections increases her risk for getting PID (pelvic inflammatory disease) with potential tubal damage and infertility. During the insertion process, bacteria and other infectious agents are easily led through the cervical canal into the uterine cavity and oviducts. Like oral contraceptives, the LNG IUS, according to some studies, is also associated with reduced rates of PID, because the thick, tacky cervical mucus and decreased menstrual bleeding are thought to reduce the risk of upward ascent of pathogens. However, the LNG IUS is not a method that protects against STIs or other infections of the genital tract. To avoid carrying infection from the vagina upward at the time of insertion, meticulous adherence to aseptic insertion is required. The best way to do this would be to perform a thorough investigation, including microbiologic and serologic studies in all clients. In most countries, this is not possible but a thorough medical history and examination are quite effective in ruling out infections.

In practice, the first step in screening a potential LNG IUS acceptor is to do a screening history for genital tract infections. It should include at least the following questions:

- Are you having vaginal discharge?
- Have you had increased or irregular vaginal bleeding during the last few menstrual cycles?

- In the past year, have you had a genital tract problem such as a vaginal discharge, ulcers or skin lesions in your genital area?
- Has your sex partner (husband) been treated for a genital tract problem, such as discharge (drip) from the penis, an ulcer in the genital area, or swollen groin glands in the last three months?
- Does your sex partner have other sex partners that you know of?
- Have you had more than one sex partner in the last two months?
- Do you think that you might have a genital infection?

If the client answers “yes” to any of the above questions, she should undergo further evaluation for a possible STI. Remember that confidentiality must be assured for all clients.

The second step in screening a potential IUD acceptor for possible STIs or other infections of the genital tract is to perform a careful abdominal and pelvic examination to check for:

- Lower abdominal pain or tenderness
- Genital ulcers, sores or swellings in the groin
- Presence of purulent discharge, easily bleeding cervix or unreported vaginal discharge
- Suprapubic, adnexal or pelvic mass

If any of the above mentioned findings exist, an LNG IUS should not be inserted until the client has been further evaluated and treated.

Regarding the LNG IUS and specific diagnoses, the following considerations should be taken:

### Vulvovaginitis

- Women with trichomonal vaginitis are at increased risk of getting other types of STIs, and an LNG IUS should not be their first choice contraceptive method



- An LNG IUS can be safely inserted after the treatment of simple (yeast or bacterial vaginosis) vulvovaginitis and in women with increased vaginal discharge without pathogens

#### Cervicitis and urethritis

- The LNG IUS should not be inserted in women with evidence of cervical infection or PID, at risk of, or with a documented recent history of gonorrhea, chlamydial cervicitis or urethritis, septic abortion, postpartum uterine infection or PID.

#### Genital ulcers and buboes

- The LNG IUS should not be the first choice of contraception in clients with genital ulcers because of the risk of exposure to infection.

#### Pelvic inflammatory disease

- The LNG IUS should not be the first choice contraceptive method for women who have (or whose partners have) multiple sexual partners
- Women with documented PID are at a greater risk of an ectopic pregnancy because of potential damage in the oviducts
- PID can cause infertility, as the oviducts may be obliterated because of the infection
- Barrier methods (condoms) used consistently and properly are the best methods for prevention of PID

#### REFERENCES:

- Dixon-Mueller R, Wasserheit JN. The Culture of Silence: Reproductive Tract Infections Among Women in the Third World. New York, International Women's Health Coalition, 1991
- Grimes D. Intrauterine device and upper-genital tract infection. *Lancet* 356: 1013–1019, 2000
- JHPIEGO: Genital Tract Infection Guidelines for Family Planning Service Programs. Baltimore, Maryland, JHPIEGO Corporation, 1991
- JHPIEGO: IUD Guidelines for Family Planning Service Programs. A Problem-Solving Reference Manual. Baltimore, Maryland, JHPIEGO Corporation, 1993
- Judson FN. Does OC use affect the risk of HIV infection. *Outlook* 8:2, 1991
- Osoba AO. Microscopic techniques for the diagnosis of pelvic inflammatory disease in developing countries. *American Journal of Obstetrics and Gynecology* 138: 1091, 1980
- Toivonen J, Luukkainen T, Allonen H. Protective effect of intrauterine release of levonorgestrel on pelvic infection: three years' comparative experience of levonorgestrel- and copper releasing intrauterine devices. *Obstetrics & Gynecology* 77: 261–264, 1991
- Westrom L, Mardh PA. Acute pelvic inflammatory disease (PID). In: Holmes KK et al (eds), *Sexually Transmitted Diseases*, 2nd ed., New York, McGraw-Hill 1984
- World Health Organization (WHO). Guidelines for the management of sexually transmitted infections. Geneva, WHO, 2001

# LNG IUS Insertion and Removal

## BACKGROUND

Insertion of an LNG IUS has to be done carefully and gently, and the insertion instructions must be followed step-by-step. It ensures that the system will be placed in the proper position in the uterus, and diminishes the risk for post-insertion infection, perforation or expulsion of the system. When the LNG IUS is located at the fundus of the uterus, levonorgestrel is uniformly dispersed all over the endometrium.

## GUIDELINES FOR INSERTION OF THE LNG IUS

### Timing of insertion

The LNG IUS should preferably be inserted during or towards the end of menstruation, because

- there is little likelihood that the woman is pregnant
- bleeding and cramping may be less noticeable at this time.

However, an LNG IUS can be inserted also at the following times:

- At any time of the cycle if it is certain that the woman is not pregnant (e.g. if the woman has been using an effective modern contraceptive method correctly prior to insertion)
- Postpartum 6 weeks or more after delivery
- Immediately after menstrual regulation or first trimester spontaneous or induced abortion, provided there are no signs of infection (no fever, tenderness of the uterus, purulent or foul-smelling vaginal or cervical discharge)

## PREPARATION FOR INSERTION

Have the instruments required for the insertion readily available during the screening pelvic examination, but do not open the sterile packets until the pelvic examination has been done and a final decision to insert an LNG IUS has been

made. Detailed information regarding infection prevention is presented in **Appendix C**.

## INSTRUMENTS AND EQUIPMENT FOR LNG IUS INSERTION

The IUD insertion/removal kit supplied by USAID (Medical Kit no. 2) or Family Planning Equipment kit by UNFPA (IUD Insertion and removal kit) contains all the instruments needed to insert or remove an LNG IUS.

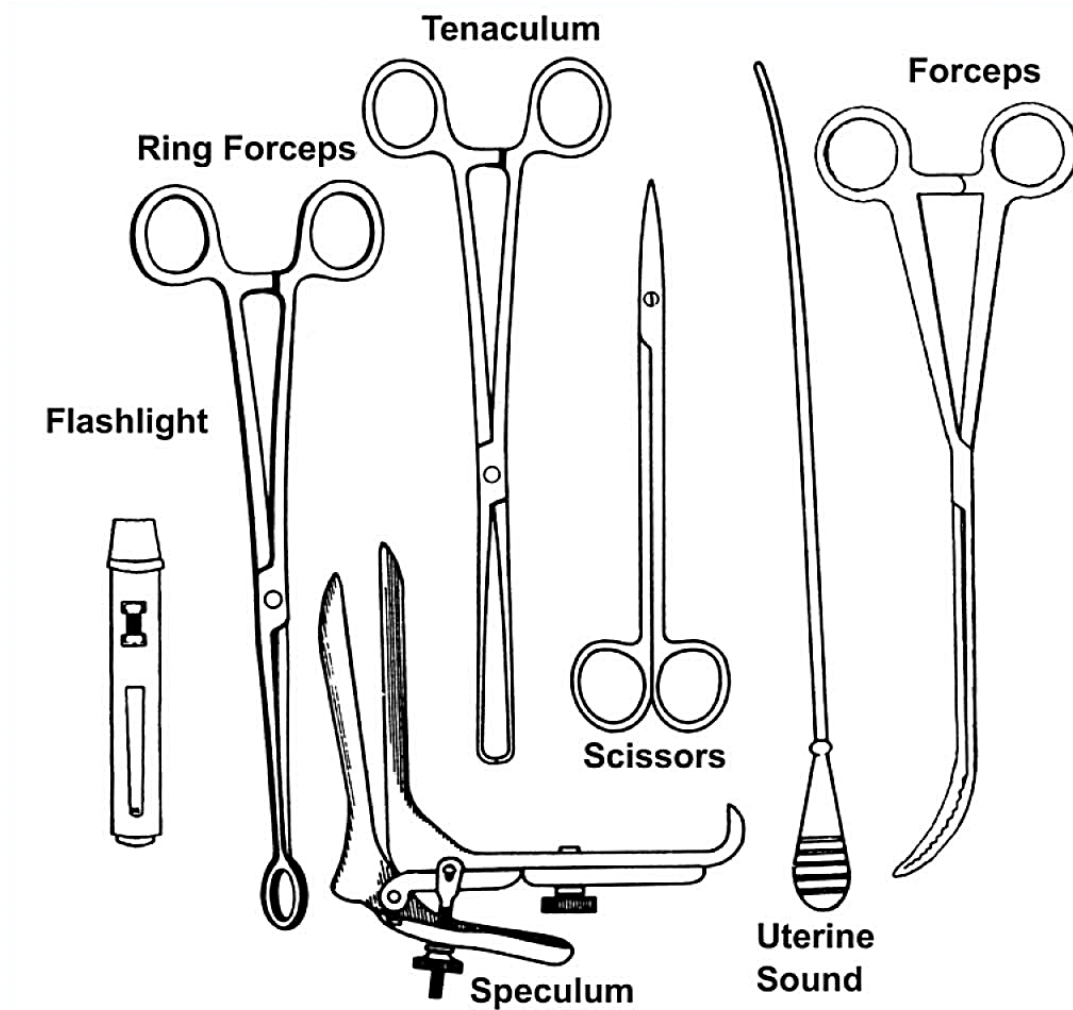
### For insertion, the following equipment is needed

- Bivalve speculum (small, medium or large)
- Uterine tenaculum
- Uterine sound
- Forceps
- Scissors
- Bowl for antiseptic solution

### Additionally, the following items are required:

- Gloves (reusable high-level disinfected or new disposable examination gloves)
- Antiseptic solution for cleaning the cervix (e.g. povidone iodine)
- Gauze or cotton balls
- Light source sufficient to visualize cervix (flash-light will suffice)
- An LNG IUS in an unopened, undamaged sterile package

Due to the hormonal capsule, the diameter of the LNG IUS inserter is slightly broader than that of a copper IUD. The diameter of the inserter is 4.8 mm. Sometimes a dilatation of the cervix up to 5 mm is needed, to enable the inserter to pass through the cervix. However, in women who have had vaginal deliveries, this is very rare. Thus, the package of the LNG IUS should not be opened until you have successfully sounded



**FIG. 6-1**

*Instruments and Equipment for IUD Insertion. Adapted from Hatcher et al: Family Planning Methods and Practice: Africa. Atlanta, Georgia, Centers for Disease Control, 1983.*

the uterus, because while sounding you can rule out severe stenosis and get an image of the size of the cervical canal. If it is probable that dilatation of the cervix is needed, the client should be remitted to a place where dilatation of the cervical canal is possible, if there are no dilators in the present clinic. Dilatation is a simple process, which is often done under local anesthesia to minimize discomfort.

If the LNG IUS is inserted during the first clinical visit, the client must first be thoroughly counseled. It is important to make sure she knows how her bleeding pattern will change during the next few months with the LNG IUS in the uterus. Secondly, she must be screened carefully to assure that she is at low risk for STIs (mutual, monogamous relationship, normal im-

munological condition with no history of PID or STIs). Thirdly, both speculum examination and bimanual examination should be normal to ensure the woman does not have a previously unrecognized STI or other non-sexually transmitted genital tract infection. The presence of a foul-smelling vaginal discharge, purulent cervical discharge or easily bleeding cervix should warn the clinician to proceed with caution. However, if the clinic is in a place where the prevalence of STIs is >10%, the availability of microscopic testing adds a further measure of safety.

Correct infection prevention practices include:

- Thorough hand washing with soap and water
- Use of clean, HLD instruments and gloves on both hands

- Cleaning the cervix with an antiseptic solution before inserting the uterine sound
- Proper decontamination of used instruments and gloves directly after the insertion
- Proper handling and disposal of contaminated waste items (gauze, cotton and disposable gloves soaked with blood or mucus)

### INSERTION TECHNIQUE

The insertion technique of the LNG IUS is based on the “no touch” technique, which emphasizes the importance of:

- Loading the LNG IUS while still in the sterile package
- Reducing vaginal microbes by application of antiseptic solution to the cervix and vagina with an antiseptic solution
- Avoiding contamination of the uterine sound or loaded LNG IUS by inadvertently touching the vaginal wall or the speculum
- Passing both the sound and the loaded IUS inserter only once through the cervical canal, thus minimizing the contamination of the uterine cavity.

When these rules are obeyed, the risk for postinsertion infection is very low (<1%), and the use of prophylactic antibiotics is not recommended.

### SAFE AND GENTLE INSERTION METHOD FOR THE LNG IUS

#### STEP 1

Tell the client what you are going to do and encourage her to ask questions. This helps the client relax, making insertion easier and less painful.

Tell her that she may feel discomfort during some of the steps and that you will tell her in advance. This helps build confidence and trust.

Be sure that she has emptied her bladder. This helps the client relax, making the bimanual exam easier.

Talk to the client throughout the procedure.

Avoid saying “this won’t hurt”, when it might hurt, or “I’m almost done”, when you are not!

#### STEP 2

Inspect external genitalia. Check for ulcers, sores and groin swellings. Check for tenderness, swelling or discharge.

Wear gloves on BOTH hands (Use inexpensive disposable examination gloves; if reusable gloves are used, they must be decontaminated, cleaned and HLD or sterilized after each use).

Perform a vaginal speculum examination. Check for vaginal discharge, cervicitis or urethral discharge; if indicated, collect a specimen. Speculum must be decontaminated, cleaned and HLD or sterilized after each use.

Perform a bimanual pelvic examination. Determine the size, position, consistency, mobility and tenderness of the uterus. Assess for cervical motion tenderness and adnexal or cul-de-sac masses or tenderness.

**If any concern arises about possible pelvic infection or pregnancy, do not insert the LNG IUS!**

#### STEP 3

If indicated and available, perform a microscopic examination. Check for yeast, trichomonas or bacterial vaginosis (saline and KOH wet mounts and pH test). Check for GC or chlamydia (Gram stain)

If simple vaginitis, treat before inserting an LNG IUS.

**If suspected GC or chlamydia, treat and re-evaluate. Do not insert the LNG IUS.**

#### STEP 4

Load the LNG IUS in the sterile package (see insertion instructions in **Appendix D**). HLD and sterile gloves are not necessary if the LNG IUS is loaded in the package.

Do not load more than 5 minutes before insertion, otherwise, the LNG IUS may not return to its original shape when inserted.

#### STEP 5

Insert the speculum and prep vagina and cervix. Antiseptic solution reduces infection.

Thoroughly rinse the cervix and vagina (two or more applications).

Apply a tenaculum to the cervix. It stabilizes the uterus and minimizes the risk of perforation. Close the jaws of the tenaculum gently to minimize discomfort.

Inject local anesthesia at this point, if necessary.

#### STEP 6

Insert the uterine sound. Sounding confirms the position of the uterus and the depth of the uterine cavity.

Pass the sound only once through the cervix (“no-touch” technique) to minimize the chance of infection.

Gently apply counter-traction when inserting the sound. Do not touch the walls of vagina or speculum with the sound to avoid contamination. Do not force the sound in if you encounter resistance.

#### STEP 7

Insert the LNG IUS carefully following the insertion instructions. (**See Appendix D**)

Set the depth-gauge to the measured depth obtained with the sound. Carefully pass the loaded inserter tube through the cervical os until the depth-gauge touches the cervix. Do not force insertion if resistance is encountered.

Release the arms of the LNG IUS by pulling the insertion tube only until the edge of the insertion tube reaches the grooved part.

After the arms of the LNG IUS are released, gently push in the LNG IUS until the depth-gauge touches the cervix or until resistance is felt. This assures a high uterine (fundal) placement of the LNG IUS.

Gently remove the plunger and after that the insertion tube. Cut the strings approximately 2–3 cm from the cervix. Be careful not to inadvertently remove the LNG IUS if the scissors are dull and may possibly trap the strings in the closed scissor blades.

#### STEP 8

Before removing the gloves, dispose of any contaminated waste. This minimizes the risk of disease contamination (HBV, HIV) to staff. Place contaminated cotton or waste items in a covered container or bag and incinerate.

Wipe down the contaminated surface with 0.5% chlorine. 0.5% solution can be used liberally.

#### STEP 9

Immediately decontaminate the instruments and reusable gloves. This minimizes the risk of

disease transmission (HBV, HIV) to staff. Soak instruments for 10 minutes in a 0.5% chlorine solution prior to cleaning and disinfecting. Place disposable gloves in waste container. For reusable gloves, first immerse both gloved hands in 0.5% chlorine solution, then remove by inverting and place the gloves in chlorine solution. Soak for 10 minutes.

#### STEP 10

Teach the client how to check for strings (use a model if available). This decreases the risk of pregnancy from an unsuspected loss of the LNG IUS. If culturally acceptable, have the client perform a check in private before leaving. Have the client wait in the clinic for 15 to 30 minutes after the insertion. Observe for excessive cramping, nausea or fainting, which may necessitate removal if not relieved by simple analgesics (aspirin or ibuprofen). This occurs infrequently in women who have borne children.

### LNG IUS REPLACEMENT AND REMOVAL

The LNG IUS is effective for 5 years and it should be removed after that. It can be removed at any time before that if the client desires or if she wants to get pregnant. After removal, it can be immediately replaced by a new LNG IUS, if the client decides to continue to use this contraceptive method. There is no need for a “rest period”.

The removal is usually an uncomplicated and painless procedure, provided the clinician is gentle and careful. The LNG IUS can be removed at any time of the menstrual cycle, but if not removed during menstruation and the couple has had intercourse within 7 days before the removal, the woman is at risk of getting pregnant unless a new LNG IUS is inserted immediately following the removal.

To minimize the risk of infection during the removal, the same infection prevention practices as for insertion of the LNG IUS should be followed.

Removal of the LNG IUS is done by gently pulling the strings. To avoid breaking the strings, gentle, steady traction should be applied and the removal should be done slowly.

Instruments and equipment needed are the same as for insertion, but alligator forceps should be available as well.

The removal rarely turns out to be difficult. The most usual reason for a difficult removal

is “missing strings”. Typically the strings have slipped up into the cervical canal, sometimes because they were initially cut too short. Usually the strings can be reached by using narrow forceps, e.g. so-called alligator forceps, and probing the cervical canal with them. If the strings cannot be retrieved and the client insists on having the LNG IUS removed, alligator forceps can be used by the healthcare provider to gently remove the system from the uterus. Only trained health care providers should perform the removal with such an instrument, in order not to injure the uterus. Local anesthesia and cervical dilatation may be required.

A very uncommon and serious reason for missing strings and an unsuccessful removal of the LNG IUS is that the system has totally or partially perforated the uterine wall or is embedded in the wall. With missing strings, the client should first be seen after the next menstrual bleeding, as the strings sometimes come out by themselves during menstruation. Pregnancy has to be excluded. If the strings cannot be found by probing in the cervix, anterior-posterior and lateral X-ray should be done to assess the possible

location of the LNG IUS outside the uterus. If the system is lying in the free abdominal cavity, its removal should be considered. In such a case, the removal is preferably done laparoscopically by an experienced operator. An LNG IUS that has partially perforated the uterine wall can often be carefully removed by performing a hysteroscopy.

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#### REFERENCES:

- Angle MA et al. IUD protocols for international training. *Studies in Family Planning* 24:125–131, 1993
- Burnhill MS. Inserting IUDs safely. *American Journal of Gynecology Health* 3: 11–18, 1989
- Center for Communication Programs (Population Information Program) Intrauterine Devices. *Population Reports, Series B*(5), 1989
- Dajani AS. Prevention of bacterial endocarditis; recommendations by the American Heart Association. *Journal of American Medical Association* 264: 2929–22, 1990
- Farley TM et al. Intrauterine devices and pelvic inflammatory disease: an international perspective. *Lancet* 339: 785–8, 1992



# Management of Side Effects and Other Problems

## BACKGROUND

Satisfied clients and high continuation rates cannot be secured, unless the clinical staff recognizes the importance of follow-up care (including counseling) and prompt management of adverse effects as well as other problems if they occur.

Every client should know that the intrauterine contraceptive she is having inserted is an LNG IUS, which is a hormonal contraceptive method and needs to be replaced after 5 years. The provider should give her a card with the name of the inserted system, the insertion date and the date when it should be removed.

It is recommended that the client should return for a routine check-up no later than three months after insertion. At the first follow-up visit, the healthcare provider should

- inquire about the bleeding pattern and problems, side effects,
- answer any questions,
- perform a speculum inspection to visualize the strings and check for vaginal discharge,
- palpate the cervical os for any hard plastic that might indicate the system is dislodged,
- and check for uterine and adnexal tenderness.

Continuing users normally come to follow-up visits only once a year for a periodic health assessment. However, they should check for the strings themselves after menstrual bleeding.

Most side effects and other problems associated with the use of the LNG IUS are not serious. As mentioned previously, changes in menstrual bleeding patterns are by far the most common side effect. In addition to menstrual bleeding changes, women using an LNG IUS occasionally develop enlarged ovarian follicles. Fortunately they rarely cause symptoms and usually are discovered only incidentally during

pelvic examinations. In addition, they generally shrink and disappear spontaneously and rarely require treatment. Although ectopic pregnancies have occurred in LNG IUS users, clinical studies have shown that the LNG IUS is extremely protective against ectopic pregnancies, ranking with the most effective contraceptive methods in its protection.

However, if a client becomes pregnant with the LNG IUS, the location of the pregnancy should always be verified. **PID**, most often caused by a STI, is a potentially serious complication with the LNG IUS, and often requires the removal of the system and effective antimicrobial medication. According to some studies, the risk for PID with the LNG IUS is smaller than with copper IUDs because the thick cervical mucus may act as a barrier against infective agents. Only in rare instances, a perforation of the uterine wall takes place, typically in connection with insertion.

Finally, several adverse conditions, which may or may not be associated with the use of the LNG IUS, have been reported. They include headaches, edema, breast tenderness, weight gain, vaginal discharge, cervicitis, dysmenorrhea, nervousness, depressive mood, mental lability, pelvic pain, nausea and acne.

In this chapter, additional information for assessing and managing the most common side effects and other problems is provided.

## MENSTRUAL BLEEDING CHANGES

The most frequently reported side effect of the LNG IUS is a change in the menstrual bleeding pattern. It takes place in all users. It is a result of the direct action of LNG in the endometrium and does not reflect the ovarian secretion of hormones. During the first 2–3 months there is an increase in spotting and irregular bleeding, followed by a strong reduction in both the amount and duration of bleeding. Scanty flow frequently develops into oligomenorrhea (long

interval between the menses) or amenorrhea (no bleeding at all). In clinical studies, at the end of the first year with the LNG IUS nearly 20% of women had amenorrhea that had lasted for at least three 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. However, it is understandable that the inconvenience caused by more or less continual bleeding or spotting interferes with the daily and sexual life of women, and is especially troublesome in some religious cultures. So far there is no evidence of any effective medical treatments for this initial spotting period with the LNG IUS. Nevertheless, it has been shown that preinsertion counseling helps the women to understand the reversible and benign nature of the initial bleeding. The women who have been properly and honestly counseled about the bleeding pattern are more likely to cope with it and less likely to insist on the removal of the system.

However, if the initial bleeding continues to be heavy, or if the excessive spotting and irregular bleeding shows no improvement after the first 6–8 months, it may be necessary to remove the system. Sometimes the incorrect position of the LNG IUS in the uterus may be the reason for continuous bleeding. The LNG IUS can be too low in the cervical canal or too high, partly penetrating the uterine wall. Other medical reasons for spotting (e.g. an endometrial polyp or incomplete abortion) should be considered as well.

Regarding the absence of bleeding or amenorrhea, there may be some difficulties with acceptance in certain cultures where femininity is linked with monthly menstrual bleeding. The possibility of developing amenorrhea should be clearly discussed before the insertion, preferably with the client and her partner, and an LNG IUS should not be inserted in a woman if amenorrhea is not acceptable. However, from a medical point of view, the absence of menstrual bleeding should not be seen as a side effect but rather as a health benefit of the system. The hemoglobin concentration and body iron

stores are improved. The hormonal secretion of ovaries is not disturbed, and there is no risk of preterm menopause or increased osteoporosis with the LNG IUS. After the removal of the LNG IUS, normal menstrual bleeding and fertility return shortly. It is the duty of the healthcare provider to clearly explain these items for each possible acceptor of the LNG IUS.

## PREGNANCY

Pregnancy with the LNG IUS is very rare. In some cases, LNG IUS-related pregnancy may be due to undetected partial or total expulsion of the system. However, pregnancies may occur even if the LNG IUS is correctly in place. According to clinical studies, 20–50% of pregnancies with the LNG IUS are ectopic, which must be considered when the woman is evaluated. Pregnancies with any intrauterine contraceptive may be complicated with septic abortion, septicemia, septic shock and even death. For this reason, the LNG IUS should be removed as soon as possible.

- If the strings are visible, the LNG IUS should be removed with gentle traction. After removal there is a slightly increased risk for abortion. Otherwise, the pregnancy will continue as a normal pregnancy.
- If the strings are not visible, and they cannot be retrieved from the cervical canal, removal may be more difficult or even impossible. In this case, carefully discuss with the woman the option of a therapeutic abortion, if legally available.
- If the woman wants to continue her pregnancy with the LNG IUS in the uterus, inform her about the increased risk for spontaneous abortion, sepsis and preterm delivery. Inform her about the possible consequences of premature birth to the infant. Such a pregnancy should be closely followed up. In addition, teratogenicity caused by the local exposure to levonorgestrel in the uterus cannot be completely excluded; however, to date there is no evidence of birth defects caused by the use of the LNG IUS in cases where pregnancy continues to term with the system in place.

## PELVIC INFLAMMATORY DISEASE (PID)

Pelvic inflammatory disease occurring with an LNG IUS can cause serious complications (tubo-ovarian abscesses, peritonitis, tubal occlusion

and infertility). Symptoms of pelvic infection include abnormal vaginal discharge, abdominal or pelvic pain, pain with sexual intercourse and fever. Note that these symptoms, except fever, may occur also normally immediately after the insertion of the LNG IUS. When suspecting a PID, appropriate diagnostic tests, such as a Gram stain, a cervical smear or a culture of cervical discharge should be done if available. If diagnosis of PID is made, antibiotic therapy should be initiated and removal of the LNG IUS considered. If marked improvement does not happen within 24–48 hours, the LNG IUS should definitely be removed and treatment reassessed. The client should be referred to a facility where intravenous antibiotic therapy is available.

### ENLARGED OVARIAN FOLLICLES (BENIGN FOLLICULAR CYSTS)

Enlarged ovarian follicles, or benign follicular cysts, occur sometimes in women without any contraception. They are rare in users of combined oral contraceptives, which inhibit ovulation and follicular maturation. Although the LNG IUS is a local, hormonal contraceptive method that does not inhibit follicular development, it is linked with a slightly increased rate for these enlarged follicles. The situation is similar with all progestin-only contraceptives including mini-pills (POPs) and progestin contraceptive implants. The rate of enlarged ovarian follicles with the LNG IUS depends on the diagnostic method used.

In clinical trials they have been diagnosed in 12% of subjects with the LNG IUS. Most often, the enlarged ovarian follicles do not cause any harm or symptoms, and they are discovered only incidentally during a pelvic examination or ultrasound check. However, sometimes they may cause pelvic pain or pain during intercourse. The enlarged ovarian follicles with the LNG IUS typically disappear by themselves within 3–4 months. Small follicles (up to 4 cm in diameter) are considered as normal in fertile aged women, and they need no follow-up. However, if the size of an enlarged ovarian follicle is greater than 4 cm in an LNG IUS user, she should be re-examined after 4 months. At this point, the ovarian follicle has typically disappeared and no further actions are needed. If the enlarged ovarian follicle has not disappeared or clearly diminished in size, a laparoscopy should be considered.

### PELVIC PAIN AND DYSMENORRHEA

During the first couple of months after the insertion, the client may experience some increased pelvic pain, which is presumably caused by cramping of the uterus. Another reason may be that the LNG IUS causes flatulence, as LNG relaxes the contractile activity of colon. The “normal” pain during the early days with the LNG IUS tends to be light, not accompanied by fever or foul-smelling vaginal discharge (which might be signs of an infection), and it can be treated with aspirin or similar anti-inflammatory analgesic. In typical cases, the pain subsides after the first 2–3 months. If the client has had dysmenorrhea (severe menstrual pain) prior to the insertion of the LNG IUS, she may well experience relief after insertion. This reported benefit is the result of reduced menstrual flow caused by the hormone LNG. However, if the pain is severe and/or continues for more than 3 months, you should do a pelvic examination with a speculum and bimanual palpation to exclude PID and other causes of cramping such as partial expulsion of the LNG IUS, cervical or uterine perforation or ectopic pregnancy. If no cause can be found and the cramping is not severe, reassure the client and provide her with analgesics. If no cause is found but the cramping is severe, remove the LNG IUS, replace it with a new one or help the client choose another method of contraception.

### MISSING STRINGS

If the strings cannot be seen, do a pelvic (speculum and bimanual) examination to check for signs of pregnancy. If the client is not pregnant and has not noticed that the LNG IUS has come out, ask about her menstrual bleeding pattern.

- If bleeding is as heavy as normal menstruation before the LNG IUS was inserted, it is likely that the LNG IUS is not in the uterus. It may have been expelled without her noticing it, or it has perforated the uterus and lies in the abdominal cavity (see section Insertion and Removal). If no LNG IUS can be seen by abdominal x-ray examination, insert a new one or help the client choose another method.
- If the bleeding is scanty or nearly missing, the LNG IUS is most likely inside the uterus but the strings are hidden in the cervical canal. An X-ray localization may be considered in such a case. Reassure the patient. When the

time of removal comes, the LNG IUS can be removed by an experienced clinician using special forceps.

### PARTNER COMPLAINTS ABOUT STRINGS

Make an examination to be sure that the LNG IUS is in place, and e.g. not partially expelled. Counsel the patient that one option is to cut the strings even with the cervical os. Inform the client that she will no longer be able to feel the strings and record in the card for future removal that the strings have been cut even with the cervix.

### VAGINAL DISCHARGE

During the first 3–6 months with increased spotting and intermenstrual bleeding, there may also be increased clear or color tinged vaginal discharge as a result of the hormone action of the LNG IUS. However, especially when combined with pain and/or fever, an abnormal vaginal discharge may also be a sign of infection. Thus, check the history for exposure to STIs and conduct a pelvic examination.

Check saline and KOH wet mounts for vaginal discharge for trichomonas, monilia (Candida) and Gardnerella. If positive for GNID, treat appropriately for the specific organism.

If needed, check a Gram stain of cervical discharge and observe for gram-negative intracellular diplococci (GNID) and WBC (PMNs). If positive for GNID, treat as gonorrhea. If negative for GNID, but purulent cervicitis is present, treat as chlamydia. Consider the removal of the LNG IUS and help the client choose another method of contraception.

### DAMAGED LNG IUS STERILE PACKAGE

Inspect package before use. Be alert for a break in the seal or plastic cover. If the package is damaged, discard the LNG IUS and insert an LNG IUS from a new package. The LNG IUS cannot be re-sterilized.

### MANAGEMENT OF HORMONAL SIDE EFFECTS

The serum level of LNG with the LNG IUS is lower than with any other hormonal contraceptive and it remains virtually stable for 5 years. Hormonal side effects are infrequent with the system. If they occur, they tend to be most severe during the initial months with the system in the uterus. However, clients may present

with hormonal side effects that may or may not be method related. The management of these problems must be dealt with individually, considering the situation for each client separately. The assessment of these problems is presented below.

#### Acne

In some women who are sensitive to the androgenic effects of progestins, the LNG IUS can make acne worse.

If a woman has had serious problems with acne before, the LNG IUS might not be the first alternative for her. The greasiness of skin with the LNG IUS tends to be worst during the first 2–3 months. Cleaning of face should be done twice a day and heavy facial creams should be avoided. If the condition is not tolerable and does not improve during the next few months, help the client choose another method.

#### Weight gain

Clinical studies with the LNG IUS show that, it does not cause more weight gain than non-hormonal copper IUDs. Thus, check that the client is eating and exercising properly. Counsel the client that normal fluctuation of 1–2 kg (2 to 4 lbs) may occur. Weight gain rarely leads to removal of the system.

#### Depression

There are typically a great variety of reasons for depression, mood changes or loss of libido. The current life situation should be discussed with the client. However, depression or loss of libido may be associated with progestins, and therefore, if the client is convinced her depression worsened while using the LNG IUS, help her choose another method.

#### Breast tension

Breast tension can increase after insertion of the LNG IUS, and it typically decreases with time. Examine breasts for lumps and cysts and breast infection. If palpation of the breasts is abnormal, refer to the appropriate source for diagnosis. Do not remove the LNG IUS unless the client requests it after counseling.

#### Excess of hair growth or hair loss

Review history before and after insertion. Pre-existing conditions such as excess facial or body hair might be worsened by the LNG IUS use. Changes usually are not excessive, may



improve over time, and do not require removal of the LNG IUS unless the client requests it after counseling.

### Headache

Ask if there has been a change in the pattern or severity of headaches since the insertion of the LNG IUS. Perform a physical examination and measure the blood pressure. If headaches are mild, treat with analgesics and reassure. Re-evaluate after 1 month if mild headaches persist.

If headaches have changed and are accompanied with focal neurological symptoms since starting the LNG IUS (i.e., numbness or tingling accompanied by loss of speech, visual changes or blurred vision) remove the system and help the client choose another (non-hormonal) method.

### Jaundice

If jaundice occurs after insertion of the LNG IUS, it is not method related. The client should be checked for acute liver disease (hepatitis), gall bladder disease and liver tumors. Levonorgestrel has little effect on liver function and does not increase the risk of liver tumors. If the client has jaundice due to viral hepatitis and does not want to stop using the LNG IUS, it is unlikely that it will worsen a liver disease and its use is safer than pregnancy.

### High blood pressure

In clinical studies with the LNG IUS, no significant change in blood pressure with the LNG IUS has been discovered.

If a woman, for the first time in her life, has a high blood pressure value after insertion of the LNG IUS, and the blood pressure increase is mild (<140/90), she should be counseled about the benign nature of this finding. The check should be repeated after 3 months. If the BP has not returned to normal, refer her for further examination.

If she has a BP of > 140/90 or arterial vascular problems (e.g., heart attack, stroke, kidney failure or retinopathy), the LNG IUS should be removed. Help her choose another method.

### Acute thromboembolic disorder

Acute thromboembolic disorder includes blood clots in the legs, lungs, brain, and eyes. Even if the LNG IUS does not increase the risk of blood

clotting problems, remove the LNG IUS because of the seriousness of these conditions. If there is strong evidence of a blood clotting disorder, refer for further evaluation.

### REFERENCES:

- Andersson K, Batar I, Rybo G. Return to fertility after removal of a levonorgestrel releasing intrauterine device and Nova T. *Contraception* 45: 575–584, 1992
- Andersson K, Odling V, Rybo G. Levonorgestrel-releasing and copper-releasing (Nova-T) IUDs during five years of use: a randomized comparative trial. *Contraception* 49: 56–72, 1994
- Backman T, Huhtala S, Blom T, et al. Length of use and symptoms associated with premature removal of the levonorgestrel intrauterine system: a nation-wide study of 17,360 users. *British Journal of Obstetrics and Gynaecology* 107: 335–339, 2000
- Barbosa I, Bakos O, Olsson SE, et al. Ovarian function during the use of a levonorgestrel-releasing IUD. *Contraception* 42: 51–66, 1990.
- Luukkainen T. Contraception after thirty-five. *Acta Obstetrica et Gynecologica Scandinavica* 71: 169–174, 1992
- Luukkainen T, Lähteenmäki P, Toivonen J. Levonorgestrel-releasing intrauterine device. *Annals of Medicine* 22: 85–90, 1990
- Lähteenmäki P. Serum levonorgestrel concentration during 78 month use of LNG IUD. *Leiras Clinical Study Report No. 1207*, 1991
- Mc Cann MF, Potter LS. Progestin-only contraception: a comprehensive review. *Contraception* 50(6): 1–195, 1994
- Pakarinen P, Toivonen J, Luukkainen T. Therapeutic use of LNG IUS and counseling. *Seminars in reproductive medicine* 19: 365–372, 2001
- Scholten PC, van Eykeren MA, Christiaens GCML, et al. Menstrual blood loss with levonorgestrel Nova T and Multiload CU 250 intrauterine devices. In Scholten PC (Ed.). *Thesis. The levonorgestrel IUD: clinical performance and impact on menstruation*, pp. 35–45, University Hospital, Utrecht, 1989a
- Sivin I, Stern J. Health during prolonged use of levonorgestrel 2020 g/day and the Copper TCU 380 Ag intrauterine contraceptive devices: a multicenter study. *Fertility and Sterility* 61: 70–77, 1994

# APPENDIX A

## Family Planning Counseling Guidelines

### Contents

<b>Section One:</b>	<b>Framework for Family Planning Counseling</b>
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## 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 about reproductive options, including pregnancy and contraceptive use. If the client chooses to use a contraceptive method, counseling should also help the client (or couple) select a method s/he is satisfied with and prepare her/him to use it safely and effectively.

Since information about how to use a contraceptive 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 the 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.

- **Specificity**

Instructions should be specific and concrete rather than abstract and vague. For example, a vague instruction would be: the LNG IUS is effective for several years. The more helpful, specific instruction might be: the LNG IUS is effective for up to 5 years. Then it should be removed. At the time of removal, either a new LNG IUS can be inserted or another contraceptive method selected.

### WHO SHOULD COUNSEL?

Every healthcare worker who talks to women (or couples) about contraception should understand why counseling is important and the role it plays in increasing satisfaction with a family planning method. The provider's sensitivity to the needs of clients is important, especially for provider-dependent methods such as the LNG IUS and other IUDs or 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 will probably be curious about contraception. If they are also 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 ensure that they will be satisfied and also reduces unnecessary returns to the clinic or discontinuation due to a 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 she/he can talk about beliefs and feelings about family planning. 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 discuss chosen contraceptive methods adequately. 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) and helps the client make her own decision.
- 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 makes assumptions.
- determines the client's fears, concerns and other issues that could serve as barriers to effective learning.

### GENERAL ADVICE WHEN COUNSELING

- Clients may become embarrassed when discussing contraceptive methods. Try to set the tone of the visit in a low-key, non-pressured manner. Assure the client (or couple) that the conversation is confidential.
- Encourage the client to express her/his 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.

#### A GOOD COUNSELOR:

- Knows and respects the client's rights
- Listens attentively
- Knows the benefits and limitations of all contraceptive methods
- Encourages the client to ask questions and answers them objectively
- Presents information in an unbiased, client-sensitive manner
- Reinforces important information on adverse effects, warning signs, etc.
- Understands the cultural and emotional factors that affect couple's decision to use a particular family planning method
- Lets the client (couple) make her/his (their) own decision
- Recognizes when s/he cannot sufficiently help a client and refers the client to someone who can

## COUNSELING PROCESS

Counseling is an ongoing process that 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 information provided and discussed in an interactive and culturally appropriate manner throughout the client's visit.

Good counseling focuses on the individual needs and situation, and good counselors are willing to listen to the client'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/his reproductive goals;
- make free, informed choices about family planning; and
- understand how to use her/his method of choice safely and effectively.

Clients who have made an informed choice of a method are more likely to be satisfied with it. By talking about their positive experience, they become the most effective means of promoting it (Gallen, Lettenmaier and Green 1987).

To counsel clients effectively, healthcare 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 the client's choice, not to persuade, press or induce a person to use a particular method. Furthermore, the decision to refuse a method, 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 healthcare workers dealing with family planning clients should be trained in counseling techniques and develop good communication skills. In addition, appropriate edu-

cational materials must be produced for both literate and illiterate clients (Gallen, Lettenmaier and Green 1987).

In reviewing contraceptive alternatives with clients, all available methods should be discussed. Healthcare 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 be needed to use the method;
- benefits and limitations of the method;
- reversibility;
- adverse effects and other problems; and
- need for protection against STIs, including HBV and HIV/AIDS.

## GATHER COUNSELING TECHNIQUE

The **GATHER** system, outlined in *Table A-1*, is one method used to organize the elements of the counseling process (Gallen, Lettenmaier and Green, 1987). This acronym is designed to help staff remember important points in an effective counseling session. **GATHER** stands for:

<b>G</b>	Greet
<b>A</b>	Ask
<b>T</b>	Tell
<b>H</b>	Help
<b>E</b>	Explain
<b>R</b>	Return visit/Refer

Although **GATHER** is a useful technique for learning the elements of counseling, in practice counseling should be tailored to the individual circumstances and may follow a different sequence or technique.

**TABLE A-1.***The GATHER Technique*

STEPS	ACTIVITIES
<b>GREET</b> the woman	Greet the woman (or couple) with a warm and personalized welcome. 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.
<b>ASK</b> for information	Establish age, marital status, cultural orientation and motivation for the visit without being judgmental or biased. 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? Collect basic medical information to ensure there are no reasons why she should not use a specific method.
<b>TELL</b> her about family planning	Be direct and specific and use simple words. Emphasize the most important points the woman needs to remember. Explain all available methods and how they are used. Use support materials such as pamphlets, brochures and samples to emphasize points. Let her handle samples of different methods.
<b>HELP</b> her select a method	Inform the client of the characteristics, benefits, limitations and adverse effects of each method. Explain that barrier methods may also be needed to protect against STIs, including HBV and HIV/AIDS. Do not decide for her; let the client choose the method. Give more details about the selected method and let the client repeat it back to you. 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.
<b>EXPLAIN</b> how to use the method	Ask the client to repeat all instructions. Encourage her to ask questions or state any remaining concerns.
<b>RETURN</b>	Specific return visit instructions should be provided. Be sure the woman knows whom to contact if she has questions. Refer the client to an appropriate clinic for follow-up care as needed. For most women, a clinic near home is the best option.

*Adapted from: Gallen, Lettenmaier and Green 1987.*

## 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, **individual counseling** prior to service provision and **follow-up 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 needs to work as a team. In addition, staffing patterns as well as client load may require shifting counseling

activities to other 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 provided effectively in a group setting. Initial counseling helps the client **identify** an appropriate method for herself and her partner. 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,
- information that can help clients decide which methods they are interested in,
- 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 how to conduct group discussions can be found in *Section Two* of this Appendix.

### INDIVIDUAL 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 assess her need for protection against STIs, 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.
- 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 the 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 not possible to start the method at this time, she should be offered 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 a LNG IUS, explain how it will be inserted) and possible problems.

#### After providing the method:

- Discuss with the client the need for periodic preventive health assessments. Depending on the method, emphasis should be placed on the continuing need for supplies and their availability, advice about side effects, detecting problems early (warning signs) and the availability of removal services for the LNG IUS, IUDs and implants.
- 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, but it is also important not to require return visits more often than is necessary for her health.
- when appropriate reassurance is given, expected symptoms and minor side effects do not lead to discontinuation.
- frequent contact builds trust.
- regular contact can allow providers to detect problems unnoticed by clients (e.g., early pregnancy).

### FOLLOW-UP COUNSELING

When clients return for follow-up visits, providers and counselors need to listen carefully and be prepared to answer any questions. Doing this can help a client accept any minor adverse effects or other problems that may occur.

The specific objectives of follow-up counseling are to:

- review information provided previously.
- find out whether the client is satisfied and wants to continue using the method.
- make sure that the client is using the method correctly and repeat instructions for use, if appropriate.
- talk to her about the need for protection against STIs, including HBV and HIV/AIDS.
- 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 switch methods or stop a method if she desires.

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## REFERENCES

Gallen M, C Lettenmaier and CP Green. Counseling makes a difference. Population Reports Series J(35): 1B31, 1987

Lettenmaier C and ME Gallen. Why counseling counts! Population Reports Series J(36): 1B28, 1987



## SECTION TWO

# How To Hold Group Discussions

### GROUP DISCUSSIONS:

- Give information about family planning methods to more than one person at a time, which saves time.
- Help people share their own experiences and support one another in their family planning decisions.
- 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.
- 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 10 or fewer if possible. It is desirable that someone not in the group looks 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 everyone 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 flipcharts, 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.

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### REFERENCES:

JHPIEGO. IUD Guidelines for Family Planning Service Programs. A Problem-Solving Reference Manual. JHPIEGO Corporation, Baltimore, Maryland, 1993

## APPENDIX B

### Sample Client Assessment Checklist For Potential LNG IUS Users

#### MEDICAL HISTORY

Service Provider's Questions	Instruction, if the answer is YES
1. Do you have a disease such as diabetes, AIDS or other immunological disorder, or are you now taking cortisone or similar drugs?	People with immunological disorders, or those using high-dose corticosteroids or immunosuppressive drugs, are at a higher risk for infection.
2. Do you have a valvular or rheumatic heart disease?	Symptomatic valvular or rheumatic heart disease can be aggravated by infection due to bacteria from any source entering the blood stream. This can happen during insertion or removal of an LNG IUS, and prophylactic antimicrobial therapy should be given.

#### REPRODUCTIVE HISTORY

Service Provider's Questions	Instruction, if the answer is YES
1. Did your last full-term pregnancy end less than six weeks ago?	An LNG IUS should not be inserted before 6 weeks have elapsed from the delivery
2. If you have had a miscarriage or abortion within the last three months, did you have any infection?	A woman who has recently had a miscarriage or first-trimester abortion can only have an LNG IUS if heavy bleeding has stopped and there are no signs of infection.
3. Is there a chance that you are pregnant; is your period late? Do you have nausea or breast tenderness?	If there is any chance that the client is pregnant <b>DO NOT INSERT</b> an LNG IUS
4. Have you had a severe pelvic infection during the last three months?	<b>DO NOT INSERT</b> an LNG IUS, as any IUD users with a history of PID have increased problems with infection and infertility.
5. During the past three months, have you had any abnormal bleeding between periods or after intercourse?	These symptoms may indicate a serious health problem, such as cervicitis, cervical polyp or, rarely, cancer. Pay special attention during the pelvic examination.
6. Assure the client of confidentiality before asking the following questions: <ul style="list-style-type: none"> <li>• Does your sex partner have other sex partners that you know of?</li> <li>• Do you have more than one sex partner?</li> </ul>	If any of these questions are answered with yes, the client should be screened for STIs, counseled about the risks associated with GTIs and STIs, and she should be helped to choose another contraceptive method and advised to use condoms to protect herself against diseases

7. Have you ever had a pregnancy outside your uterus (in one of your tubes)?	The client should be informed that the LNG IUS does not prevent all ectopic pregnancies. If she still chooses the LNG IUS, teach her the warning signs for ectopic pregnancy.
8. Is it impossible for you to manage the first 3–6 months with increased intermenstrual bleeding and spotting?	Help the client choose another method.
9. Do you think you might not be able to accept the possibility of having no menstrual bleeding during the use of the LNG IUS?	Help the client choose another method.
10. Do you have a problem with greasy skin and acne?	Counsel the client about the possibility that the LNG IUS may aggravate these symptoms.

### PELVIC EXAMINATION

Service provider's observation	Service provider's instructions
1. Are there ulcers or sores on the external genitalia? Is there an abnormal discharge from the Bartholin's or Skene's glands? Are there enlarged glands in the groin area?	Any of these suggest a possible STI. Do not insert an LNG IUS. Refer, if needed for further evaluations. Help to choose another method. Encourage the use of condoms.
2. Is the vaginal wall inflamed, and is there a yellowish, pus-like discharge in the vagina?	This suggests vaginitis or cervicitis. Diagnose the cause and treat before inserting an LNG IUS.
3. Is the cervix red and inflamed, and is there a yellowish, pus-like discharge from the cervical canal?	This suggests cervicitis: <b>DO NOT INSERT</b> an LNG IUS at this time. Diagnose and treat. Help the client choose another method. Encourage use of condoms.
4. Is there a mass, ulcer or bleeding on contact with the cervix?	This suggests cervical polyp, cervicitis or, rarely, a cancer. <b>DO NOT INSERT</b> an LNG IUS at this time. Refer, if needed, for further evaluation. Help to consider another method.
5. Is there marked tenderness of the cervix, uterus or adnexal area?	This suggests PID or cervicitis. <b>DO NOT INSERT</b> an LNG IUS. Diagnose and treat properly, help to choose another method and encourage use of condoms.
6. Are you unable to determine the position of the uterus?	If the result of bimanual palpation is unclear, perform a rectal examination and, if needed, carefully sound the uterus to confirm its position, or refer to a more experienced clinician. If no IUS is inserted, provide temporary contraception.
7. Is the uterus enlarged, soft and smooth?	If the woman has missed a period she is likely to be pregnant. <b>DO NOT INSERT AN LNG IUS</b> . Perform a pregnancy test. Give condoms.

8. Is the uterus enlarged, firm or markedly irregular?	This may indicate uterine fibroids which can distort (change the shape of) the uterine cavity. Attempt insertion only if you are experienced; otherwise, refer for further evaluation or help the client choose another method.
9. Is there a palpable mass in the adnexal area?	This may indicate PID or a pelvic tumor. <b>DO NOT INSERT</b> an LNG IUS. Diagnose and treat as appropriate or refer for further evaluation. Help client choose temporary contraception until the problem is solved.
10. On sounding, is the uterine cavity irregular or deeper than 10 cm?	This suggests submucous fibroids, possible pregnancy or perforation by the uterine sound. If perforation is suspected, observe the client for possible intra-abdominal bleeding, which is characterized by decreased blood pressure, rising pulse and / or syncope. <b>DO NOT INSERT</b> an LNG IUS at this time. Provide temporary contraception.

Source: Adapted from *Program for International Training in Health (INTRAH): Guidelines for Clinical Procedures in Family Planning: A Reference for Trainers*. Chapel Hill, North Carolina, INTRAH 1993.

# APPENDIX C

## Infection Prevention

### BACKGROUND

The two primary objectives of infection prevention in family planning facilities are:

- to prevent infections when providing reversible contraceptive methods such as copper IUDs, the LNG IUS or contraceptive implants
- to minimize the risk of transmitting serious infections such as hepatitis B<sup>2</sup> and AIDS not only to clients but also to service providers and staff, including cleaning and housekeeping personnel

To reduce the risk of infection, 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 (by boiling or steaming or special high-level disinfectant solution) is the only acceptable alternative.

The infection prevention (IP) practices described in this chapter are intended for use in all types of medical and healthcare facilities, ranging from large urban hospitals to small rural clinics. They are designed to minimize costs and the need for expensive and often fragile equipment, while at the same time assuring a high degree of safety.

### DEFINITIONS

**Micro-organisms** 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.

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

- **Asepsis** and **aseptic technique** are general terms used to describe the combination of efforts made to prevent entry of micro-organisms 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 object (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 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 micro-organisms 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, diseasecausing microorganisms from inanimate objects.
- **High-level disinfection (HLD)** by boiling, steaming or the use of chemicals eliminates **all** micro-organisms except some bacterial endospores from inanimate objects.

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

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

only intact mucous membranes or broken skin or come in contact with the blood stream, tissue deep beneath the skin or tissue which normally is sterile. See the summary in Table C-1.

## WHICH PROCESS TO USE

Which method is used in individual situations depends on whether the instrument will touch

To Make Instruments / Items Safer to Contact	Appropriate Infection Prevention Process	Example
Intact (unbroken) skin	<b>Decontamination</b> destroys viruses (HBV, HIV), bacteria, fungi and parasites	Contaminated instruments and gloves prior to cleaning; pelvic exam table or other surfaces contaminated by body fluids
Intact mucous membranes or broken skin	<b>High-level disinfection (HDL)</b> destroys all micro-organisms except some endospores*; HDL should be preceded by decontamination and cleaning	Uterine sounds, specula, forceps, gloves for pelvic exams
Blood vessels or tissue beneath the skin	<b>Sterilization</b> destroys all micro-organisms, including endospores; sterilization should be preceded by decontamination and cleaning	Instruments such as needles and syringes, scalpels, trocars for implants, reusable gloves for surgery

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

Adapted from Spaulding EH: *Chemical disinfection of medical and surgical materials*. In: Lawrence CA et al (eds): *Disinfection, Sterilization and Preservation*, 1st ed. Philadelphia, Pennsylvania, Lea & Febiger, 1968

## PROTECTIVE BARRIERS

Placing a physical, mechanical or chemical barrier between micro-organisms and an individual, whether it be 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:

- hand washing;
- wearing gloves (on both hands) when touching bodily fluids, in any procedure with exposure to mucous membranes or broken skin, including surgery or when handling contaminated waste materials or used instruments;
- using antiseptic solutions for cleaning wounds or prepping the skin prior to surgery

- decontaminating, cleaning and high-level disinfecting or sterilizing surgical instruments, reusable gloves and other items

## HAND WASHING AND GLOVES

Thorough hand washing and use of protective gloves, when inserting or removing an LNG IUS or handling contaminated waste materials, are key components in minimizing the spread of disease and maintaining an infection-free environment. In addition, understanding when sterile or high-level disinfected surgical gloves are required and, equally important, when they are not, can maintain safety for both clients and staff, while reducing costs.

**Hand washing may be the single most important procedure in preventing infection.** The vigorous rubbing together of all surfaces of lathered



hands mechanically removes and inactivates most organisms. To encourage hand washing, program managers should make every effort to provide soap and a continual supply of clean water, either from a tap or bucket, and single use towels. Do not use shared towels to dry hands.

**Experience** has shown that the most effective way to increase hand washing is to have **physicians or other respected individuals** (role models) consistently wash their hands and encourage others to do the same.

### WHEN TO WASH HANDS

Hand washing is indicated **before**:

- examining (direct contact with) a client, and
- putting on sterile or high-level disinfected surgical gloves for insertion or removal of a LNG IUS

Hand washing is indicated **after**:

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

Micro-organisms grow and multiply in moisture and in standing water. Therefore:

- If bar soap is used, provide small bars and soap racks that drain.
- Avoid dipping hands repeatedly into basins containing standing water. Even with the addition of antiseptic agents such as Dettol<sup>®</sup> or Savlon<sup>®</sup>, micro-organisms can survive and multiply in these solutions.
- 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 that does not require water.
- Dry hands with a clean, dry towel or air dry; shared towels quickly become contaminated.
- Collect used water in a basin and discard in a toilet or latrine if a drain is not available.

**Note:** A non-irritating 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). 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.

### WHEN TO WEAR GLOVES

Gloves on both hands should be worn by all staff prior to contact with blood and body fluids from any client. Wear gloves:

- When performing a procedure, such as inserting or removing an LNG IUS, in the clinic
- When handling used instruments, gloves and other items
- When disposing of contaminated waste items (cotton, gauze or dressings)

**A separate pair of gloves must be used for each client to avoid cross-contamination.**

Using single-use, disposable gloves is preferable, but where resources are limited, surgical gloves can be reused if they are:

- decontaminated by soaking in a 0.5% chlorine solution for 10 minutes,
- washed and rinsed, and
- sterilized (by autoclaving) or high-level disinfected (by steaming or boiling).

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

### ANTISEPSIS

Infection following minor procedures, such as insertion or removal of an LNG IUS, may be caused by microbial flora from the skin or vagina of the client or from the hands of the healthcare provider. Washing hands and cleaning the client's cervix and vagina with antiseptic solution prior to inserting or removing an LNG IUS are important infection prevention measures.

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

For cervical and vaginal preparation prior to inserting or removing an LNG IUS, use a water-based antiseptic, such as an iodophor or

chlorhexidine gluconate. Do not use alcohol. Alcohols burn, dry and irritate mucous membranes, which in turn promotes the growth of micro-organisms.

### Instructions for performing cervical and vaginal preps

**Step 1.** Ask the client about previous allergic reactions before selecting an antiseptic.

**Step 2.** After inserting the speculum, thoroughly apply antiseptic solution two or more times to the cervix and vagina. (It is not necessary to prep the external genital area if it appears clean. If heavily soiled, it is better to have the client wash her genitalia thoroughly with soap and water before starting the procedure.)

**Step 3.** If iodophors are used, allow one or two minutes before proceeding. (Iodophors require time to release free iodine, the active substance.)

### HANDLING USED INSTRUMENTS, GLOVES AND OTHER ITEMS

With either insertion or removal of an LNG IUS, the infection prevention steps that should be used to reduce disease transmission from contaminated instruments, gloves and other items are:

- waste disposal and decontamination
- cleaning and rinsing
- high-level disinfection or sterilization.

After completing either insertion or removal of an LNG IUS, and while still wearing gloves, properly dispose of contaminated objects (gauze, cotton and other waste items) in a leak-proof container or a plastic bag.

Surgical instruments and reusable gloves, which were in contact with blood or body fluids, should be decontaminated by soaking for ten minutes in a disinfectant (0.5% chlorine solution).

Surfaces, such as an examination table, that may have been in contact with body fluids should also be decontaminated before reuse.

Instruments and reusable gloves should be thoroughly cleaned with a detergent and water and completely rinsed before further treatment.

Instruments that touch only broken skin or mucous membranes (such as vaginal specula) should be high-level disinfected by boiling for 20 minutes or using chemicals (eg. glutaraldehyde solution). After cooling or rinsing in boiled

water and drying, the instruments are ready to use. Alternatively, instruments and gloves used for insertion or removal of an LNG IUS can be sterilized by autoclaving. Reuse immediately or store for up to one week in a clean, dry, HLD container with a tight-fitting lid or cover.

The LNG IUS is supplied as a single-packed, sterile system. It should never be reused.

### INFECTION PREVENTION TIPS: LNG IUS INSERTION

Maintaining a safe, infection-free environment is an ongoing process, which requires frequent retraining and close supervision of the clinic staff. The practices and processes described in this chapter, however, 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.

- Exclude clients who are by history and physical examination currently at risk for STI's.
- Wash hands thoroughly with water and soap before and after each insertion.
- If possible, have the client wash her genital area before doing the screening examination.
- Use clean, high-level disinfected or sterilized instruments and gloves (on both hands). Disposable gloves can be used as well.
- After inserting the speculum, thoroughly rinse the cervix and vagina with antiseptic solution two or three times before beginning the insertion.
- Load the LNG IUS in the sterile package.
- Use a non-touch insertion technique to reduce contamination of the uterine cavity ( i.e. do not touch the vaginal wall with your instrument or pass the uterine sound or loaded LNG IUS through the cervical canal more than once).
- Properly dispose of waste material after inserting the LNG IUS.

### INFECTION PREVENTION TIPS: REMOVAL OF THE LNG IUS

To minimize risk to service providers and their co-workers during the removal of an LNG IUS:

- Wash hands thoroughly with soap and water before and after each removal
- When possible, have the client wash her genitalia before doing the pelvic examination
- Use clean, high-level disinfected or sterilized instruments and gloves (on both hands)
- After inserting the speculum, thoroughly rinse the cervix and vagina with antiseptic solution two or three times before beginning the removal
- Properly dispose of waste material after removing the LNG IUS
- Decontaminate instruments and reusable items immediately after using them.

### REFERENCES:

- American Association of Operating Room Nurses (AORN). Clinical issues. AORN Journal 52(3): 613-615, 1990
- Department of Health and Mental Hygiene. Occupational exposure to human immunodeficiency virus. Communication disease bulletin (December) State of Maryland, 1990
- Gardnes J, Favero M. CDC guidelines for hand washing and hospital environment control. Infection Control 7: 231–235, 1986
- Larson EL. APIC Guidelines for Infection Control Practice: APIC guideline for hand washing and hand antisepsis in health care settings. American Journal of Infection Control 23(4): 251-259, 1995
- Larson EL et al. Alcohol for surgical scrubbing? Infection Control and Hospital Epidemiology 11(3): 139-141, 1990
- Rotter M, W Koller and G Wewalka. Povidone-iodine and chlorhexidine gluconate-containing detergents for disinfection of hands. Journal of Hospital Infection 1(2): 149-151, 1980
- Spaulding EH et al. Chemical disinfection of medical and surgical materials, in Disinfection, Sterilization and Preservation, First edition. Lawrence CA et al (eds). Lea & Febiger: Philadelphia, Pennsylvania, 1968
- Tietjen L, W Cronin and N McIntosh. Infection Prevention for Family Planning Service Programs: A Problem-Solving Reference Manual. Essential Medical Information Systems, Inc.: Durant, Oklahoma, 1992
- Tietjen L and N McIntosh. Infection control in family planning facilities. Outlook 7(2): 2-8, 1989
- Wenzel RP (ed). Prevention and Control of Nosocomial Infections. Baltimore, Maryland, Williams & Wilkins, 1987

# The LNG IUS

*Levonorgestrel intrauterine system 20µg/24h*

## INSERTION INSTRUCTIONS

The LNG IUS is inserted into the uterine cavity within seven days of the onset of menstruation. It can be replaced by a new system at any time of the cycle.

Examine the patient gynaecologically to clarify the size and position of the uterus and to exclude pregnancy or other contra-indications.

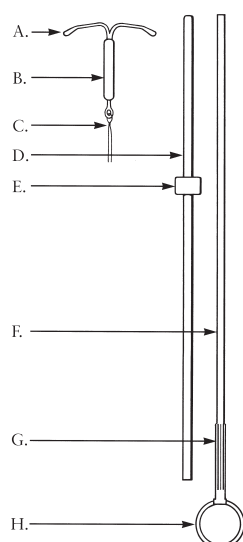
Make sure that the insertion technique will be aseptic. Use an appropriate antiseptic solution to clean the vagina.

Visualize the cervix by means of a speculum and cleanse it using antiseptic solution. Grasp

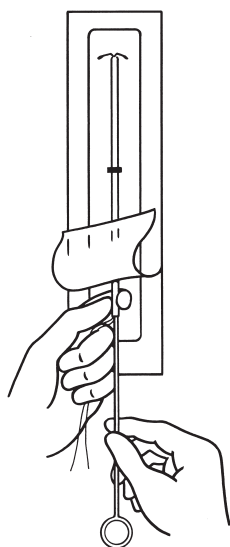
its anterior lip with a comfortable forceps. A gentle traction on the forceps will tend to reduce the angle between the cervical canal and the uterine cavity and so facilitate the introduction of a uterine sound. The forceps should remain in position throughout the insertion of the LNG IUS to maintain a gentle traction on the cervix against the pushing force of the insertion.

Define the direction of the cervical canal and the uterine cavity as well as the depth of the uterine cavity by using a uterine sound. Also ensure that the cavity is unobstructed, e.g. by a submucous fibroid. Should the cervical canal be tight, consider the need for dilation of the canal and use of analgesics/a paracervical block.

# 1

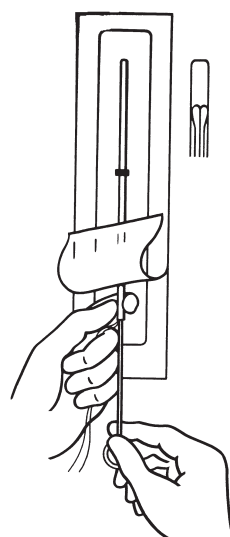


- A. Horizontal arms
- B. Hormone cylinder
- C. Removal threads
- D. Insertion tube
- E. Flange
- F. Plunger
- G. Grooved part of the plunger
- H. Ring-part of the plunger

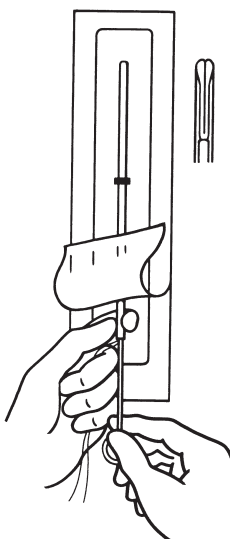
**2**

Open the plastic covering far enough to reveal the insertion tube. While keeping the removal threads stretched, place the plunger in the insertion tube.

Grasp the threads and pull the device slowly and steadily into the insertion tube until the knobs at the ends of the horizontal arms of the system cover the distal opening of the tube.

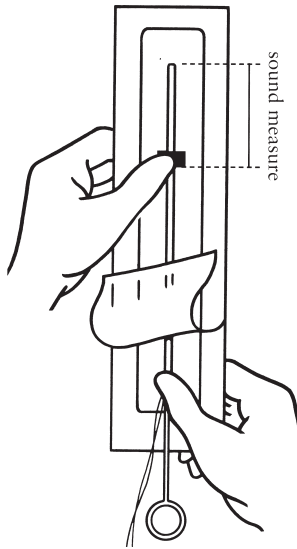
**3A**

A) Should you pull the system too far inside the insertion tube,

**3B**

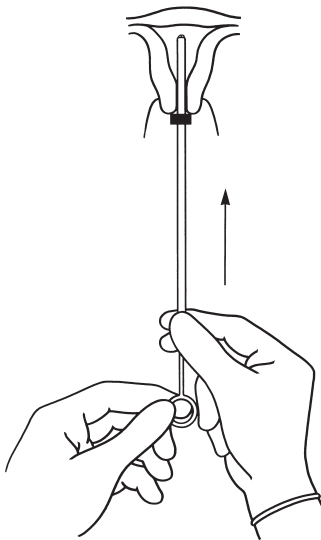
B) you can correct the position with the plunger.

4



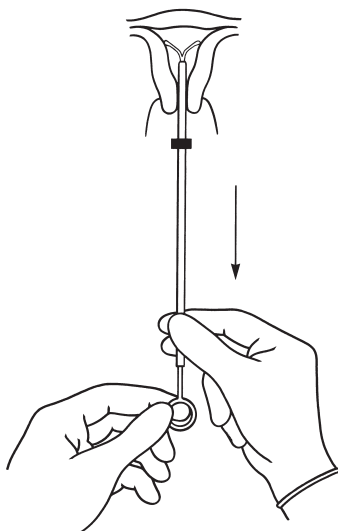
Steadying the flange with one hand, move the insertion tube until the distance between the tip of the loaded inserter and the edge of the flange nearest to the physician corresponds to the sound measure. Ensure that the flange is the same plane as the arms will be when horizontal.

5



Remove the loaded system from the plastic cover and introduce the insertion tube gently into the cervical canal until the flange touches the cervix. The flange must be horizontal to ensure the subsequent correct unfoldings of the arms.

6

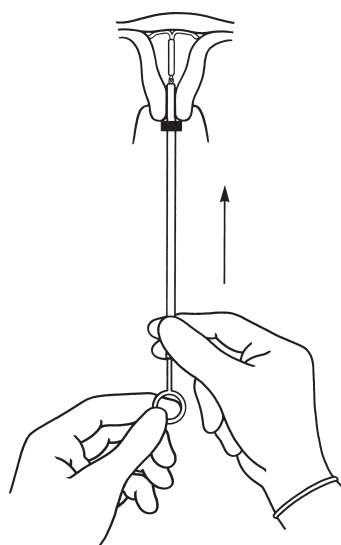


Note the grooved part on the plunger. Hold the plunger still and release the horizontal arms of the system by pulling the insertion tube only until the edge of the insertion tube reaches the grooved part.

Observe that the distance between the flange and external cervical os is now about 1.5 cm.

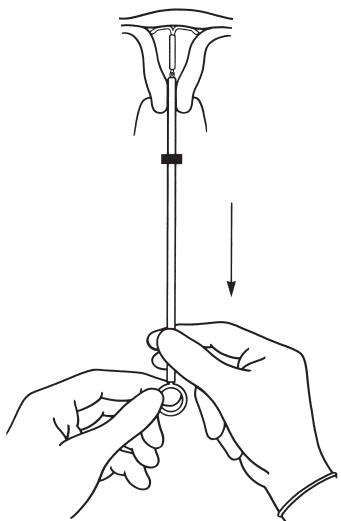


7



Holding the tube and plunger together, gently push the system until the flange again touches the cervix.

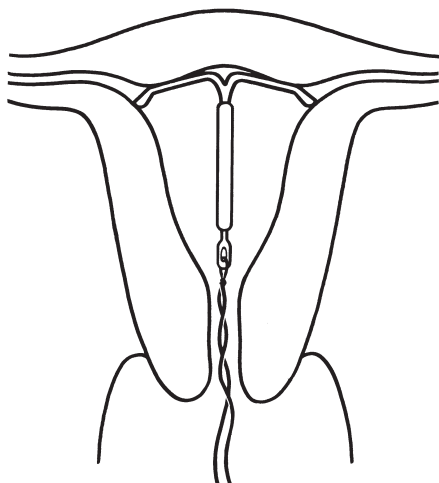
8



Release the system completely from the insertion tube by holding the plunger still and then pulling the tube until it touches the ring part of the plunger.

Remove the plunger by keeping the tube stationary and then carefully remove the tube. Make sure that the removal threads run freely through the tube and do not draw the system from its fundal position in the uterine cavity.

9



Cut the removal threads so that 2 cm remain visible outside the cervix.

# Important!

Should you suspect that the system is not in the correct position, remove it and insert a new one.

## REMOVAL OF THE LNG IUS

The LNG IUS can be removed by pulling the removal threads with forceps. Unless a pregnancy is desired, the system should not be removed after the fifth day of the menstrual cycle in a sexually active woman.