Population Reports

IUDs—An Update

The intrauterine devices (IUDs) now available offer almost complete protection from pregnancy. Some models are effective longer than any other reversible family planning method. Correctly inserted, IUDs are safe for women at low risk of sexually transmitted disease. In fact, because IUDs prevent pregnancy so well, they save many lives.

HIGHLIGHTS

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Effective for the Long Term

Large international comparisons continue to collect evidence that IUDs are both safe and effective for long periods of time. In 1994 the United States Food and Drug Administration approved the TCu-380A IUD for use up to 10 years, recognizing it as the longest-lasting copper IUD. The TCu-380A is now the most widely available IUD and one of the most effective methods of contraception ever developed. In large studies fewer than one woman per 100 became pregnant in the first year of use and, in the longest comparative study, only 2.1 per 100 became pregnant in 10 years of use.

In practice the TCu-380A and other currently available IUDs—the TCu-220C, the *Multiload*-375, the *Nova T*, and the LNG-20—are more effective than oral contraceptives and on a par with injectables, implants, and voluntary sterilization. The hormone-releasing LNG-20 IUD, now approved in 10 countries, may be the most effective of all IUDs, with just 0.3 pregnancies per 100 women after five years of use.

Because modern IUDs prevent pregnancy so effectively, they avert many maternal deaths. Thus IUDs rank among the best family planning methods for protecting women's lives.

Clearer Understanding Updates Guidance

Recent research has helped to lift a cloud that hung over the IUD in the 1980s. It is now clear that an increased risk of pelvic inflammatory disease, or PID (infection in the upper genital tract), is concentrated in the first month after IUD insertion and among women exposed to sexually transmitted diseases (STDs). Also, there appears to be virtually no increased risk of infertility for a woman using a copper IUD who has a mutually monogamous relationship and thus is not exposed to STDs. Recent research suggests that IUDs work by preventing sperm and egg from joining. Evidence shows that copper and all-plastic IUDs help protect against ectopic pregnancy while in use.

Better scientific understanding has enabled experts to recommend updated guidance for providing IUDs. These recommendations eliminate unscientific limits on IUD use and better define who can use IUDs safely. For example:

- IUDs can be inserted at any time during the menstrual cycle if it is reasonably certain the woman is not pregnant.
- Current genital infection and high STD risk rule out IUD use, but past ectopic pregnancy and past PID do not.
- IUDs should be inserted only where infection-prevention procedures can be followed.
- Only one follow-up visit is necessary—three to six weeks after insertion to check for infection and expulsion. Still, IUD users should be encouraged to return any time they have questions or concerns or want the IUD taken out.
- A woman of any age can use an IUD, so long as she will face little risk of acquiring STDs.
- A rest or a wait for reinsertion is pointless, could increase PID risk, and is wasteful for both clients and programs.
- Properly trained providers can safely insert IUDs immediately after childbirth or early abortion.
- With training, not only doctors but also nurses, midwives, and other health care providers can safely insert IUDs.

The Provider's Crucial Role

The provider's good judgment, training, and skill help ensure:
(1) Screening to see that women who have STDs or are at high risk of STDs do not use IUDs.
(2) Careful and gentle insertion using high-level disinfected instruments, a sterile IUD, and "no touch" insertion technique. This minimizes pain at insertion and the chances of infection, perforation, pregnancy, and expulsion.
(3) Use of the longest-lasting IUD that meets a woman's needs, to minimize any PID risk associated with re-insertion.
(4) Informative and empathetic counseling. An IUD user needs to know when her IUD should be replaced, to return any time if she has any problems or questions, and that the IUD does not protect her against AIDS and other STDs.

When this good-quality product is delivered with good services, the IUD is an important option for many women.

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Background

Intrauterine devices (IUDs) have been used throughout the world for more than three decades. Millions of women have found them effective, safe, and convenient. During the 1960s and 1970s researchers developed the "second-generation" copper-bearing IUDs, which are highly effective, long-lasting, and have even fewer side effects than earlier models. Now that these improved IUDs have been thoroughly tested, attention is shifting toward identifying appropriate IUD users and providing good-quality medical care and counseling to maximize effectiveness, safety, and acceptability.

The first modern IUDs—the *Lippes Loop* and the *Margulies Spiral*—appeared in the early 1960s. They were made of polyethylene, a biologically inert plastic (137, 216). In the late 1960s researchers discovered that adding copper to a plastic IUD frame increased effectiveness, thus allowing sizes smaller than the all-plastic devices. The first copper IUDs—the Cu-7 and TCu-200—proved to cause fewer side effects such as pain and bleeding. They were just as effective in preventing pregnancy, however (370, 454). It was thought that these IUDs would have to be replaced every few years. Therefore a second generation of copper IUDs was developed, including the TCu-380A, the TCu-220C, the *Nova T*, the *Multiload-375* (MLCu-375), and others (see pp. 18–19). These IUDs last longer and are even more effective. IUDs that release a hormone in the uterus also were developed in the 1970s (5, 530).

International donor agencies are now providing second-generation copper IUDs for use in developing-country programs. The United States Agency for International Development (USAID), one of the major international donors of IUDs, began supplying the TCu-380A in 1985, the year after the IUD was approved by the United States Food and Drug Administration (US FDA) (547). Because this IUD is effective and long-lasting, USAID now supplies only the TCu-380A in response to programs that request IUDs (401, 402). The TCu-380A is now the most widely available IUD, distributed in more than 70 countries (626). Some other donor agencies provide the *Nova T* and *Multiloads* as well as the TCu-380A.

US Situation

The introduction of the TCu-380A in the US in 1988 filled a gap created in the mid-1980s when US manufacturers stopped selling the *Saf-T-Coil* (139), the *Lippes Loop* (246), and, in 1986, the TCu-200 and the Cu-7 (316). After the withdrawal of these devices from the market, the hormone-releasing *Progestasert®* was the only IUD available in the US for a number of years. This caused hardships for US women as well as concern in other countries (111).

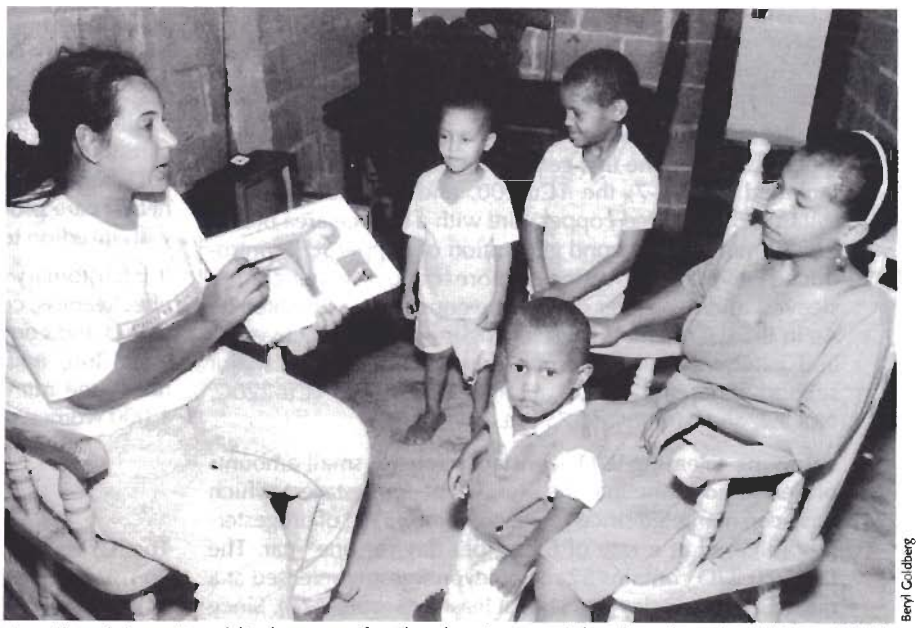
The reasons for this near absence of IUDs on the US market were unique and complex. They did not involve the safety or efficacy of these IUDs but instead involved business decisions. In the US, unlike many other countries, family planning services are provided largely through the private sector. As doctors switched to copper IUDs, sales of all-plastic devices declined, leading manufacturers of the *Saf-T-Coil* and the *Lippes Loop* to halt production (139, 246).

The manufacturer took the copper Cu-7 and TCu-200 off the market in 1986 for a somewhat different reason. Over 800 lawsuits had been filed against the company, charging that the IUDs had injured their users. As a result, continuing liability insurance became unavailable (316). Although the company had won most of the cases that went to trial, the costs of defending against the lawsuits were so high that the company decided for financial reasons to stop marketing IUDs (457). The US FDA did not request that these IUDs be taken off the market, and the agency never recommended that women have these IUDs removed.

Why were there so many lawsuits in the US over IUDs? This litigation is part of a larger US crisis in liability and liability insurance that is affecting many products and services in the health field as well as in other areas (3, 111, 292). IUDs became a particular target for US lawsuits because research in the mid 1970s linked one IUD, the *Dalkon Shield*, to spontaneous septic abortions and pelvic inflammatory disease (46). The *Dalkon Shield* was marketed nationwide between 1971 and 1974 (209). The extent of health risks with the *Dalkon Shield* may have been due to its particular design (372). Because of lawsuits and for other economic reasons, it has become more difficult and expensive for pharmaceutical companies and other institutions to obtain insurance (76, 111, 299, 338, 403).

The temporary lack of IUDs in the US market was widely misunderstood and caused confusion. Some providers thought incorrectly that the government had declared IUDs unsafe (97). As IUDs became less available, IUD use in the US dropped. In 1987 a survey found that 3% of all women ages 15 to 44 were using IUDs. In 1992 the same survey found that only 1% of US women were using IUDs (594).

US IUD users like the method, however. Among those who expressed an opinion, 96% of IUD users viewed their method of contraception favorably, topped only by users of



Beryl Goldberg

In a Dominican Republic home, a family planning provider describes the IUD—a highly effective reversible method and especially appropriate for a married woman with children.

implants, at 98%. By comparison, 94% of Pill users rated their method favorably, as did 93% of users of voluntary female sterilization and vasectomy, and 90% of condom users, while 76% of diaphragm users and 74% of rhythm method users had favorable views of their methods (594).

Public Health Organizations Reaffirm Support for IUDs

When the US pharmaceutical companies stopped selling IUDs, national and international health and family planning organizations protested. All reaffirmed their support for IUDs and recommended that they be made widely available (2, 6, 8, 159, 161, 274). A World Health Organization (WHO) Scientific Group, convened in 1986 to review the safety of IUDs, concluded, "The use of IUDs in both developed and developing countries should continue to be supported as a reliable and safe method of reversible fertility regulation" (437). More recently, in 1995 the International Medical Advisory Panel of the International Planned Parenthood Federation (IPPF) described the IUD as "an effective and safe method of contraception for properly screened women" (600). The Panel noted that:

> Most newer IUDs have now been studied in a large number of women for a long period of time. These studies demonstrate that these IUDs are highly effective and very safe among women at low risk of STDs.

All donor agencies continue to provide IUDs in response to requests from governments and private voluntary family planning agencies.

IUD Performance

IUDs can be classified as either:

- Medicated—that is, copper-bearing or hormone-releasing, or else
- Unmedicated, or inert.

The majority of the IUDs now widely used are copper-bearing.

Types of IUDs

Medicated IUDs have either copper or hormones added to a plastic frame. The first generation of copper IUDs, which included the Cu-7, the TCu-200, and the *Multiload*-250 (MLCu-250), carried copper wire with a surface area of 200 to 250 mm^2. The second generation of copper IUDs introduced several innovations—more copper wire, copper sleeves, and/or a silver core to the copper wire (denoted by Ag in the IUD name). These changes increase effectiveness and extend effective lifespan (see box, p. 8). The major second-generation IUDs are the TCu-380A, TCu-220C, *Nova T*, and *Multiload-375* (MLCu-375).

Hormone-releasing IUDs constantly release small amounts of steroid hormone into the uterus. The *Progestasert*, which has been marketed since 1976, contains 38 mg of progesterone released at a rate of 65 µg per day for one year. The LNG-20 IUD contains 52 mg of levonorgestrel released at a rate of 20 µg per day and lasts at least five years (610). Since the early 1990s it has been approved for use in Denmark, Finland, Norway, and Sweden (497, 610). Recently, the LNG-20 has also been approved in Belgium, France, Iceland, Singapore, Switzerland, and the United Kingdom.

The *Lippes Loop*, made of polyethylene, was the most widely used unmedicated IUD outside China. This IUD is no longer distributed internationally. The other major types of unmedicated IUDs are flexible stainless steel rings (either round or in the shape of the uterine cavity and made with a single or double coil). These rings have been widely used in China but not elsewhere.

Researchers continue to develop and test new IUDs that may reduce expulsion rates and side effects. Among the devices being considered are a smaller, lightweight, and flexible T-shaped copper IUD, the *Cu-SAFE 300*, which can be inserted without a plunger and is designed to move towards the uterine fundus (the top of the uterus) when the uterus contracts (522, 643). A frameless IUD consisting of six copper sleeves on a surgical nylon thread is called the *FlexiGard 330, GyneFix™*, or *CuFix PP330*. The thread is knotted at one end, which is anchored in the muscle of the fundus. In clinical trials the device has proved to be highly effective and comfortable to use (492, 563, 625, 641, 642, 647, 649). Researchers in Switzerland have taken yet another approach: a copper-bearing IUD with a T-shaped frame, called the *Sof-T*. The tip of each end of the arm consists of a soft ball, designed to prevent perforation and to block the openings to the fallopian tubes in order to prevent sperm from entering (500, 581).

Comparing IUDs

Second-generation copper IUDs are much more effective and have fewer side effects than unmedicated IUDs. The copper IUDs currently available are similar in terms of effectiveness, side effects, expulsion, and continuation rates. The hormone-releasing LNG-20 IUD may be even more effective than copper IUDs, and it generally reduces menstrual bleeding, while copper IUDs may increase it (609).

Pregnancy and complication rates, even with the same IUD, vary in different clinics and studies. This is partly because the women may be dissimilar—in age, parity, and other factors that influence IUD performance. Also, the quality of care may vary. Thus randomized multicenter studies usually are the most reliable way to evaluate and compare IUD performance. Results of such studies are presented in Table 1.

While efforts to design better IUDs continue, the quality of care that IUD users receive may make more difference to IUD performance than the design of a specific IUD. The health care provider's training and experience, particularly with insertion technique, are especially important.

It is customary to evaluate IUDs in terms of contraceptive effectiveness, continuation, and rates of removal due to side effects and complications—bleeding and pain, perforation, expulsion, and infection. All are measured in life-table rates—the number of pregnancies or removals per 100 or 1,000 women after a specified length of IUD use.

Effectiveness

The IUD is one of the most effective methods of contraception. With most devices, pregnancy rates range from less than one to three per 100 women per year. Among widely used copper IUDs, three are most effective—the TCu-380A, TCu-220C, and MLCu-375, with the TCu-380A being the

How IUDs Prevent Pregnancy

Research has shed new light on how IUDs prevent pregnancy. Studies suggest that IUDs prevent sperm from fertilizing ova (437, 501, 544). Current evidence does not support the common belief that the IUD usually works by preventing implantation (501).

Researchers in Chile recovered ova from 56 women using various IUDs and 115 women not using contraception. The researchers were significantly less likely to recover ova from the fallopian tubes of the IUD users, especially those using copper IUDs, than from the other women. Fourteen of the IUD users and 20 of the nonusers had recently had sexual intercourse around the time of ovulation. None of the ova recovered from these IUD users showed clear signs of fertilization and normal embryonic development. In contrast, half of the ova recovered from the nonusers did (478). These results provide the clearest evidence to date that IUDs work chiefly by preventing fertilization.

Studies using assays for human chorionic gonadotropin (hCG), a hormone secreted by cells surrounding the fertilized ovum, also suggest that IUDs generally prevent fertilization (317, 416, 427). These assays can detect fertilization within 7 to 10 days, well before implantation of a fertilized ovum is complete (106, 198, 437). Two studies of women using mainly copper IUDs have found hCG assays indicating fertilization in less than one percent of menstrual cycles (317, 427).

Copper IUDs affect ova and sperm in various ways. They stimulate a pronounced inflammatory reaction, or foreign-body response, in the uterus. The concentration of various types of white blood cells, prostaglandins, and enzymes in uterine and tubal fluids increases markedly (174, 243, 264, 312, 322, 437), especially with copper IUDs (235). These changes may interfere with transport of sperm in the genital tract and may damage sperm and ova so that fertilization is impossible (260, 437). In most studies fewer sperm are found in the fallopian tubes, where fertilization is thought to take place, in IUD users than in nonusers (12, 193, 312, 386). Various types of white blood cells probably consume many sperm in the uterus (312). Other sperm may be damaged so that they cannot move into the fallopian tubes (260). Thus, while the precise mechanism of action of copper IUDs is still not certain, most likely the primary action is altering the function or survival of sperm and ova before they can meet (501). In contrast, the LNG-20 IUD, although it also prevents sperm and ova from joining, has a primarily hormonal mode of action, probably working chiefly by thickening cervical mucus so that sperm cannot pass through it (610).

most effective of these. Pregnancy rates for all major IUDs are less than one per 100 women per year (see Table 1). They are at least as effective as *Norplant*® implants, injectable contraceptives, and voluntary male or female sterilization (331, 547). In an ongoing international comparative trial sponsored by WHO, after 10 years of use the cumulative pregnancy rate for the TCu-380A was 2.1 per 100 women and for the TCu-220C was 5.7 (625). This difference is statistically significant. For the LNG-20 a pregnancy rate of 0.3 has been reported after five years of use (573).

Pregnancy rates for earlier devices—the TCu-200, the Cu-7, and the *Lippes Loop*—are about 2 per 100 women in the first year (331) (see Table 1). The stainless steel ring, widely used in China through the early 1900s, was less effective, with pregnancy rates as high as 10 per 100 women at two years (363, 364, 603). A 1982 survey found that 34% of induced abortions in China followed IUD failures (66). Analysis showed that more effective IUDs would reduce health risks and save the Chinese government substantial costs (603). Beginning in 1993 the Chinese government switched to supplying only copper-bearing IUDs to family planning providers (570, 632).

Like most other reversible contraceptives, the IUD is thought to perform less well in general use than in clinical trials (387, 505). Still, in practice it remains one of the most effective reversible contraceptive methods. According to data from Demographic and Health Surveys in 15 countries, for example, the pregnancy rate with various IUDs was 3.4 per 100 IUD users in the first year of use, 5.9 per 100 oral contraceptive users, 12.5 for withdrawal, and 19.9 for rhythm (533). An earlier analysis of World Fertility Survey data in five Latin American countries placed the pregnancy rate for condoms at 18 per 100 (122). A 1980 Philippine survey also reported markedly lower pregnancy rates among IUD users than among oral contraceptive users (204). In three provinces of Vietnam a retrospective study reported a pregnancy rate of about 3% in the first year of use among women whose IUDs remained in place (584).

Continuation

Women use IUDs longer than most other reversible contraceptive methods. In large multicenter trials in developing countries, about 70 to more than 90 per 100 women were still using their IUDs one year after insertion (see Table 1). In a Population Council study, eight years after insertion 25 of every 100 women were still using the TCu-380Ag (547). A WHO study found 44% continuing to use the TCu-380A after seven years (566). IUD continuation rates in clinical trials are as high or higher than for *Norplant* implants (470, 472, 562) and higher than for oral contraceptives, condoms, or diaphragms (204, 437, 473).

Even outside clinical trials, IUD continuation rates are high (505). The 1980 study in the Philippines estimated one-year continuation rates of 70% among IUD users compared with 42% among oral contraceptive users and 10% among condom users (204). Similarly, statistics from the Indonesian national family planning program showed that 65% to 75% of IUD users were still using their method after three years compared with 30% to 40% of oral contraceptive users (98). In Pakistan a 1992–93 interview study found that 72% of copper-T users still had their IUDs in place after 12 months, as did 64% of *Lippes Loop* users (621).

Table 1

Performance of Copper and LNG IUDs

Selected Randomized Multicenter Comparative Trials, 1975–1995

Author & Date (Ref. No.)	Place	Life-Table Method[a]	IUDs Studied	No. of Women	Rate per 100 Women of Removal for: Accidental Pregnancy	Expulsion	Bleeding/Pain	Infection	Other Medical	Continuation Rate
12-MONTH RATES										
Cole et al. 1985 (73)	Costa Rica, Egypt, Panama, Yugoslavia	Noncompeting	TCu-380Ag	737	0.3	3.3	3.6	—0.4—		90.9
			MLCu-375	740	0.8	4.1	3.6	—1.1—		88.7
Indian Council of Medical Research 1989 (517)	India	Competing	LNG	475	0.0	6.5	13.8*[b]	1.5	1.5	74.5*
			TCu-380Ag	434	0.8	5.3	7.1[b]	0.8	0.8	83.5
			TCu-220C	496	0.0	4.8	6.0[b]	1.1	1.1	84.4
			TCu-200B	500	0.9	5.9	5.7[b]	2.0	2.0	82.2
Luukkainen et al. 1983 (226)	Denmark, Finland, Sweden	Noncompeting	Nova T	918	0.8	5.8	11.9	2.5	0.9	76.1
			TCu-200Ag	947	2.1	4.6	12.2	2.0	1.5	76.7
Luukkainen et al. 1987 (224)	Denmark, Finland, Hungary, Norway, Sweden	Competing	Nova T	937	0.9	3.7	7.5	NA	3.1	82.2
			LNG-20	1,821	0.1*	3.5	8.7	NA	3.3	79.7
Sastrawinata et al. 1991 (540)	Indonesia	Noncompeting	TCu-380A	946	0.4*[c]	6.0	1.6	—0.9—		90.3
			Lippes Loop D	943	1.4	5.7	1.9	—0.8—		90.0
			MLCu-375	948	1.4	3.8	1.1	—0.9—		91.6
Sivin & Stern 1979 (332)	Canada, US	Competing	TCu-200	1,014	2.1	7.1	10.3	—3.6—		72.5
			TCu-220C	1,097	0.9	8.0	11.5	—2.3—		73.5
			TCu-200	1,851	3.1	7.1	11.5	—2.8—		70.8
			TCu-380A	1,679	1.0*	7.1	14.2	—3.0—		69.7
Sivin et al. 1987[d] (335)	Brazil, Chile, Dominican Rep., Egypt, Singapore, US	Competing	TCu-380Ag	1,120	0.3	5.5	7.0[e]	0.9	2.8	79.8
			LNG-20	1,124	0.2	6.0	10.9[e]	1.0	3.4	73.5*
Van Dierendonck et al. 1992 (560)	Nigeria	Noncompeting	MLCu-250	653	1.8	2.4	2.7	—1.9—		87.9
			MLCu-375	586	0.2	2.1	2.5	—1.8—		87.3
Wilson 1992 (564)	New Zealand	Competing	Nova T	608	2.0	4.3*	8.9	2.2	2.0	81.9*
			MLCu-375	586	1.2	1.9	6.0	1.1	0.6*[g]	89.6
			MLCu-250Ag	596	0.8	1.6	7.8	0.5*[f]	0.9	88.7
WHO 1982 (444)	Egypt, Hungary, India, Philippines, Thailand, UK, US, USSR, W. Germany	Noncompeting	TCu-220C	984	0.5*	3.7*	2.2*[h]	0.5	1.2	76.3
			Lippes Loop D	992	1.9	7.8	4.5[h]	0.1	0.5	68.8*[i]
			Cu-7	994	1.9	6.3	3.6[h]	0.1	1.3	70.6
WHO 1994 (648)	19 centers in 9 countries	Noncompeting	TCu-380A	1,823	0.8	3.8	NA	NA	NA	88.2
			MLCu-375	1,832	1.2	3.6	NA	NA	NA	89.1
WHO 1995 (649)	28 centers in 13 countries	Noncompeting	TCu-380A	2,184	0.6	2.4	3.6	0.3	0.2	89.9
			FlexiGard	2,102	1.2	5.7*	3.1	0.0	0.2	86.5
24-MONTH RATES										
Champion et al. 1988 (496)	Panama, Yugoslavia	Noncompeting	TCu-380Ag	441	0.6	4.5	7.8	—0.5—		79.7
			MLCu-375	441	1.3	5.6	7.6	—1.3—		76.6
Indian Council of Medical Research 1989 (517)	India	Competing	LNG	475	0.0	9.2	21.9*[b]	1.8	2.1	58.7*
			TCu-380Ag	434	1.0	7.1	10.8[b]	0.8	1.5	69.9
			TCu-220C	496	0.0	7.1	9.9[b]	1.2	1.9	66.6
			TCu-220B	500	0.9	7.7	8.8[b]	1.2	3.1	68.8
Luukkainen et al. 1983 (226)	Denmark, Finland, Sweden	Noncompeting	Nova T	918	1.8*	7.8	19.1	3.3	2.1	51.6
			TCu-200Ag	947	4.8	6.0	16.4	2.7	3.2	64.7
Sastrawinata et al. 1991 (540)	Indonesia	Noncompeting	TCu-380A	946	1.2	6.7	2.3	—1.7—		85.5
			Lippes Loop D	943	2.2	7.5	2.6	—1.1—		85.0
			MLCu-375	948	2.7	5.3	1.7	—1.3—		85.4
Sivin & Stern 1979 (332)	Canada, US	Competing	TCu-200	1,014	5.0	9.0	16.1	—5.0—		55.9
			TCu-220C	1,097	1.8*	9.8	17.1	—4.0—		59.7
			TCu-200	1,851	5.6	8.3	18.9*	—4.3—		50.0
			TCu-380A	1,679	1.0*	9.5	23.7	—4.7—		50.1
Sivin et al. 1987[i] (335)	Brazil, Chile, Dominican Rep., Egypt, Singapore, US	Competing	TCu-380Ag	1,120	0.7	6.1	11.5[e]	1.5	4.6	67.5
			LNG-20	1,124	0.2	7.3	17.0[e]	1.3	5.6	59.4*
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			MLCu-375	586	2.0	2.8	13.5	1.8	1.9	79.4
			MLCu-250Ag	596	3.2	2.5	14.7	1.1*[f]	1.4	78.5
WHO 1982 (444)	Egypt, Hungary, India, Philippines, Thailand, UK, US, USSR, W. Germany	Noncompeting	TCu-220C	984	1.7*	6.1*[i]	3.9*[h]	0.5	2.9	60.3*
			Lippes Loop D	992	3.7	10.0	7.9[h]	0.3	1.4	54.8
			Cu-7	994	3.6	7.9	6.5[h]	0.1	3.7	55.5
WHO 1994 (648)	19 centers in 9 countries	Noncompeting	TCu-380A	1,823	1.3	4.7	NA	NA	NA	82.0
			MLCu-375	1,832	2.2	5.2	NA	NA	NA	82.2
WHO 1995 (649)	28 centers in 13 countries	Noncompeting	TCu-380A	2,184	1.1	3.4	6.1	0.8	0.4	82.9
			Flexigard	2,102	1.7	6.4*	4.7	0.6	0.1	81.8

Population Reports

Table 1 *(continued)*

Author & Date (Ref. No.)	Place	Life-Table Method[a]	IUDs Studied	No. of Women	Rate per 100 Women of Removal for: Accidental Pregnancy	Expulsion	Bleeding/Pain	Infection	Other Medical	Continuation Rate
36-MONTH RATES										
Champion et al. 1988 (496)	Panama, Yugoslavia	Noncompeting	TCu-380Ag	441	0.6	5.4	8.8	—— 2.0 ——		67.4
			MLCu-375	441	1.8	6.5	11.4	—— 2.9 ——		61.4
Indian Council of Medical Research 1989 (517)	India	Competing	LNG	475	0.0	10.6	27.9*[b]	1.8	4.2	38.8*
			TCu-380Ag	434	1.0	7.6	13.4[b]	1.2	3.0	50.4
			TCu-220C	496	0.3	8.3	15.4[b]	1.7	4.2	45.4
			TCu-200B	500	1.6	8.5	14.6[b]	1.2	6.0	45.4
Luukkainen et al. 1983 (226)	Denmark, Finland, Sweden	Noncompeting	Nova T	918	2.7*	9.8	25.0	4.6	2.8	48.2
			TCu-200Ag	947	6.5	6.8*	23.2	4.9	4.4	51.1
Toivonen et al. 1991 (556)	Denmark, Finland, Hungary, Norway, Sweden	Noncompeting	Nova T	937	3.7	5.4	14.3	2.0	7.5	59.0
			LNG-20	1,821	0.3*	5.3	15.7	0.5*	14.0	57.0
Wilson 1992 (564)	New Zealand	Competing	Nova T	608	6.5	7.2	21.5	3.6	3.0	63.7
			MLCu-375	586	3.2*[g]	4.8	18.5	1.8	4.0	70.7*[g]
			MLCu-250Ag	596	5.7	4.3	21.9	1.7	3.2	67.0
WHO 1988 (307)	13 centers in 11 countries	Noncompeting	TCu-380A	1,396	1.0*	6.9	12.5	0.1	1.7	63.7
			TCu-220C	1,396	3.3	7.7	11.6	0.3	0.9	62.5
	19 centers worldwide	Noncompeting	Nova T	1,847	6.4	6.0	10.5	0.3	1.6	60.2
			TCu-220C	1,881	4.4*	6.6	11.4	0.2	1.4	62.5
WHO 1994 (648)	19 centers in 9 countries	Noncompeting	TCu-380A	1,823	1.6	5.2	NA	NA	NA	77.9
			MLCu-375	1,832	2.9*	6.4	NA	NA	NA	77.7
WHO 1995 (649)	28 centers in 13 countries	Noncompeting	TCu-380A	2,184	1.7	4.4	7.5	0.4	0.4	77.3
			Flexigard	2,102	2.0	7.4*	7.5	0.1	0.7	75.6
48-MONTH RATES										
Luukkainen et al. 1983 (226)	Denmark, Finland, Sweden	Noncompeting	Nova T	918	2.9*	11.0	30.0	5.9	3.4*	39.8
			TCu-200Ag	947	7.1	9.0	27.2	6.0	7.9	40.5
WHO 1988 (307)	13 centers in 11 countries	Noncompeting	TCu-380A	1,396	1.1*	7.7	14.4	0.1	2.3	56.6
			TCu-220C	1,396	3.9	8.4	14.1	0.4	1.4	54.3
	19 centers worldwide	Noncompeting	Nova T	1,847	8.4	6.2	11.6	0.4	1.7	54.2
			TCu-220C	1,881	5.1*	7.0	13.1	0.2	2.1	57.5
60-MONTH RATES										
Anderson et al. 1994 (573)	Denmark, Finland, Hungary, Norway, Sweden	Competing	Nova T	937	4.2	5.5	20.4	1.6	8.7	44.5
			LNG-20	1,821	0.3*	4.9	19.4	0.6*	6.4	46.9
Luukkainen et al. 1983 (226)	Denmark, Finland, Sweden	Noncompeting	Nova T	918	3.4*	12.5	34.7	7.2	5.1*	33.2
			TCu-200Ag	947	8.7	9.9	29.8	6.5	8.3	36.0
Sivin et al. 1990 (546)	Brazil, Chile, Dominican Rep., Egypt, Singapore, US	Noncompeting	TCu-380Ag	1,121	1.4	7.4*	23.7*[e]	—— 16.2 ——		40.6*
			LNG-20	1,124	1.1	11.8	35.1[e]	—— 16.9 ——		33.0
WHO 1988 (307)	13 centers in 11 countries	Noncompeting	TCu-380A	1,396	1.4*	8.0	17.3	0.1	2.4	50.5
			TCu-220C	1,396	3.9	9.1	16.4	0.6	1.5	49.0
	19 centers worldwide	Noncompeting	Nova T	1,847	10.0	6.2	13.4	0.4	2.0	50.6
			TCu-220C	1,881	5.4*	7.6	14.5	0.2	2.8	54.5
72-MONTH RATES										
WHO 1988 (625)	13 centers in 11 countries	Noncompeting	TCu-380A	1,396	1.7*	8.2	NA	NA	NA	40.3
			TCu-220C	1,396	4.6	9.9	NA	NA	NA	39.5
84-MONTH RATES										
Sivin et al. 1991 (549)	Brazil, Chile, Dominican Rep., Egypt, Singapore, US	Noncompeting	TCu-380Ag	1,121	1.4	8.4*	31.1*[e]	3.6	20.4	27.2*
			LNG-20	1,125	1.1	11.7	45.0[e]	3.6	23.3	23.1
WHO 1990 (566)	13 centers worldwide	Noncompeting	TCu-380A	1,396	1.6	8.6	22.7	—— 4.1 ——		43.7
			TCu-220C	1,396	4.9	10.0	19.8	—— 3.5 ——		43.7
96-MONTH RATES										
WHO 1988 (625)	13 centers in 11 countries	Noncompeting	TCu-380A	1,396	2.1*	10.3	NA	NA	NA	30.3
			TCu-220C	1,396	5.1	11.1	NA	NA	NA	30.7
120-MONTH RATES										
WHO 1993 (625)	13 centers in 11 countries	Noncompeting	TCu-380A	1,396	2.1*	10.4	NA	NA	NA	25.6
			TCu-220C	1,396	5.7	11.6	NA	NA	NA	26.1

*Reported as statistically significant difference. (In studies comparing three IUDs, the asterisked rate is significantly different from both other rates except where noted.)

[a]Life-table techniques are used to calculate rates of removal and continuation taking into account the varying lengths of time that women remain in a study. Noncompeting life-table rates, also known as gross cumulative rates or, by the World Health Organization, as cumulative net probability rates, are the discontinuation rates for a single event among current users. That is, when the rate is calculated, discontinuations for other reasons are taken into account. Competing rates, also called net cumulative rates or cumulative crude rates, are cumulative discontinuation rates for an event among all users without adjusting for other events. Noncompeting rates are most appropriate for comparing event rates among different devices. Competing rates provide an estimate of overall IUD performance, showing the relative importance of different reasons for discontinuation. Competing rates may be unreliable when comparing specific reasons for discontinuation between devices.

[b]Includes removals for amenorrhea: at 12 months, 5.4 for the LNG, 0.8 for the TCu-380Ag, 0.0 for the TCu-220C, and 0.7 for the TCu-200B. At 24 months, 10.3 for the LNG, 0.8 for the TCu-380Ag, 0.3 for the TCu-220C, and 1.5 for the TCu-200B. At 36 months, 14.1 for the LNG, 0.8 for the TCu-380Ag, 0.3 for the TCu-220C, and 3.2 for the TCu-200B.

[c]TCu-380A and MLCu-375 significantly different

[d]13-month rates

[e]Includes removals for amenorrhea: at 13 months, 0.1 for the TCu-380Ag and 4.9 for the LNG-20; at 25 months, 0.2 for the TCu-380Ag and 8.4 for the LNG-20; at 60 months, 0.4 for the TCu-380Ag and 19.7 for the LNG-20; at 84 months, 1.1 for the TCu-380Ag and 24.6 for the LNG-20.

[f]MLCu-250Ag and Nova T significantly different

[g]MLCu-375 and Nova T significantly different

[h]Removals for bleeding only

[i]Lippes Loop and TCu-220C significantly different

[j]25-month rates

Bleeding and Pain

Increased menstrual bleeding, often with pain, is the most common problem of IUD use and the most common medical reason for removing IUDs. In clinical trials about 4% to 15% of women stop using IUDs for this reason within a year after insertion. Percentages are usually higher for the *Lippes Loops* and other unmedicated devices than for copper IUDs.

Older women and women with children generally have lower rates of removal due to bleeding and pain (332, 463). The kind of counseling and support women receive and their attitudes toward using IUDs also influence rates of discontinuation due to bleeding and pain (27). Women who want no more children, for example, may be more tolerant of heavy bleeding and less likely to discontinue than younger women who plan to have more children. Unmedicated and copper IUDs increase the volume of menstrual bleeding per cycle, probably because the IUD disturbs the blood vessels or alters the normal blood clotting mechanism in the lining of the uterus (341, 437). With unmedicated devices, blood flow increases on average by 50% to 100% above preinsertion levels (10, 132, 135, 167, 437); with copper IUDs, 20% to 50% (115, 135, 167, 207, 212, 229).

Unlike other IUDs, hormone-releasing devices decrease menstrual blood flow or, in the case of the LNG-20, may even stop menstruation altogether (amenorrhea)—an effect of the progestin hormone that they release (131, 222, 258, 308, 465, 517, 549, 562, 630). In fact, the LNG-20 has been used successfully to treat women with menorrhagia, or excessive menstrual flow (479). Hormone-releasing IUDs may increase the number of days of light bleeding and spotting. Largely because of removals due to amenorrhea, rates of removal for bleeding or pain for the LNG IUD in developing-country clinical trials were higher than for copper IUDs (517, 549). In contrast, in a European study discontinuation for bleeding and pain was less common with the LNG-20 than with the *Nova T* (573) (see Table 1). With good counseling, many women recognize the benefits of decreased menstrual flow, and continuation rates are high (530).

With all IUDs, abnormal bleeding and pain may be due not to the IUD itself but to pelvic inflammatory disease (PID), ectopic pregnancy, malignancy, or other conditions (45, 154). Therefore the health care provider should consider whether there is reason to suspect other conditions that might cause bleeding and pain.

Risk of anemia. An estimated 45% of nonpregnant women in developing countries are anemic by WHO's definition (460). Many more have marginal iron levels (10). Thus increased bleeding with copper and unmedicated IUDs could be a cause for concern.

IUD use has not been proved to induce clinical anemia, however. Some 1- and 2-year studies of copper and unmedicated IUDs show significant declines in levels of serum

Lifespan of Copper IUDs

Clinical trials show that all of the widely used copper IUDs are effective for at least five years and many are effective longer (21, 225, 226, 307, 380, 383, 405, 451, 453, 491, 547, 549, 566). The only IUD currently approved for more than five years, however, is the TCu-380A, which in 1993 was approved by the United States Food and Drug Administration for 10 years of use (620). Regulatory approvals are generally based on effectiveness demonstrated in clinical trials but must await the sponsor's application and often lag behind the latest research findings.

Long-term randomized clinical trials of copper IUDs report low cumulative pregnancy rates for the second-generation copper IUDs—after 10 years, 2.1 per 100 women with the TCu-380A and 5.7 with the TCu-220C, and after five years, 3.4 to 10.0 in three trials with the *Nova T* (226, 307, 566, 573, 625) (see Table 1). In WHO comparative trials the TCu-380A was significantly more effective than the TCu-220C (625), and the TCu-220C was significantly more effective than the *Nova T* (307). In a WHO 3-year comparative trial the pregnancy rate for the MLCu-375 was low, at 2.9 pregnancies per 100 women, but this IUD was significantly less effective than the TCu-380A, at a rate of 1.6 (648) (see Table 1). By comparison, nonrandomized trials of the TCu-200, a first-generation copper IUD with less copper, reported generally higher 5-year pregnancy rates—from 7 to 12 per 100 women (331, 451, 453).

Annual pregnancy rates do not increase over time for long-term IUD users, and they may decrease. For example, in WHO clinical trials annual pregnancy rates for the TCu-220C fell from 1.3 during the first two years to 0.5 during the third through fifth years to 0.4 during the sixth through eighth years. Over the same period annual pregnancy rates for the TCu-380A fell from 0.3 to 0.1 (545). Over 10 years of use pregnancy rates averaged less than 0.5 per 100 women per year for the TCu-380A and less than 1.0 for the TCu-220C from the second year of use (625). This study has continued through 12 years of use, and data covering the last two years will be published in 1996.

The fall in annual pregnancy rates after the first two years of IUD use does not appear to reflect a cumulative effect of the IUD. Rather, it occurs largely because the women using IUDs for long periods tend to be older and thus less fertile than short-term users (437). Also, women whose IUDs are improperly inserted, are expelled without their noticing, or perforate the uterus are most likely to become pregnant early in the study. Declining annual pregnancy rates over long periods are seen also in women using inert devices such as the *Lippes Loop* (385).

As researchers study women using second-generation copper IUDs for increasing lengths of time, the approved lifespans of some copper IUDs may be further extended. Less frequent replacement reduces the risks of pelvic inflammatory disease, perforation, and other complications that mainly occur at or soon after insertion. Also, less frequent insertions cost less and are more convenient.

ferritin, which decrease in the early stages of iron depletion, and/or in hemoglobin, which show only in later stages (10, 115, 117, 134, 147, 167, 188, 378, 481). Others find no changes (212, 271, 284, 298, 320, 615). The few long-term studies done have found little increase in the prevalence of anemia (378, 437). In a study of the TCu-380Ag carried out in several developing countries and the US, the proportion of women with anemia rose only from 24% to 25.4% during four years of use (329). Among these women, hemoglobin levels dropped slightly during the first two years of use but then rose even higher than they had been when the women first began using the IUD (549). In a case-control study in the Dominican Republic that involved a population with a high incidence of anemia, women who had used the TCu-380Ag for three or four years were no more likely to have low serum ferritin or hematocrit than women who were not using IUDs (509). In the US and Finland studies report lower serum ferritin levels in long-term IUD users than in nonusers, but no cases of clinical anemia were seen (250, 378). Recent research suggests that women may tolerate much lower serum ferritin levels without developing clinical anemia than had been thought and that intestinal absorption of iron may increase to compensate for heavier menstrual bleeding (615). Also, in developing countries protection against repeated pregnancies—a major cause of iron depletion and anemia—may offset the increased menstrual bleeding caused by IUDs (437).

Hormone-releasing IUDs, by reducing menstrual bleeding and sometimes stopping it completely, may actually protect against anemia (479, 531, 588). The Dominican Republic study found that women who used the LNG-20 for more than three years were significantly less likely to have low serum ferritin or hematocrit than either women not using IUDs or women using unmedicated or copper IUDs (509).

"IUD: The best family planning method during natural breastfeeding," says a poster from the State Information Service in Egypt. The IUD offers excellent protection against early pregnancy that might disrupt breastfeeding, and it has no effect on breast milk quality or quantity.

Perforation

Perforation of the uterus occurs when the IUD, the inserter tube, the sound, or another gynecological instrument used during insertion pierces the uterine muscle wall, most often at the fundus, or top of the uterus. Careful insertion technique can prevent most perforations (see p. 11). In large clinical trials perforation has been rare—no more than 1.3 per 1,000 insertions (73, 90, 200, 314, 332, 364, 437, 444, 564). Perforations may go unnoticed at the time of insertion, however (42). Perforations may be partial, with just part of the IUD piercing the uterine wall or cervix, or complete, with the IUD passing through the uterine wall into the abdominal cavity. Also, over time IUDs may become embedded in the uterine wall without perforating it (42, 130, 340, 450).

In general, a partial perforation of the uterine fundus heals quickly, and no treatment is required. If perforation is obvious during insertion, the procedure should be stopped, and the IUD, removed (587). Copper and hormone-releasing IUDs that have completely perforated the uterus after insertion should be removed only if the perforation is discovered within a few days or weeks after insertion and then only by a surgeon experienced at removing such IUDs by laparoscopy. While copper IUDs may become partially or completely encased in adhesions, they rarely cause any problems, whereas removal may lead to pelvic abscesses and other complications (614). Some researchers think that unmedicated devices should be removed (42, 183, 237, 449). The IPPF International Medical Advisory Panel considers this necessary only if the woman has abdominal symptoms (164).

Expulsion

After IUD insertion, uterine contractions can push the device downward, causing partial or complete expulsion. Expulsion rates vary from less than one to more than 7 per 100 women in the first year of use (see Table 1). Most expulsions occur in the first year and especially the first three months after insertion (173, 314, 368, 385). Because undetected partial or complete expulsion can lead to unplanned pregnancy, IUD users should know how to check for the IUD strings to make sure that the device is still in place (see box, p. 25).

Several factors influence the chances of expulsion. Younger women and women who have never been pregnant or have never had children are more likely to expel their IUDs (333, 334, 340, 383, 437, 444, 516, 546, 583). A recent case-control study based on data from an international clinical trial also found that women who had painful menstruation or abnormally large menstrual flows were more likely to expel copper-T IUDs (569). Correct insertion, with the IUD placed up to the fundus, is thought to reduce the chances of expulsion (60, 71) (see p. 11).

Intrauterine Pregnancy

The IUD is a very effective contraceptive. If pregnancy does occur, however, potentially severe complications can result. Medical attention is always needed.

Spontaneous abortion is the most frequent complication of pregnancy with an IUD in place. Some 50% to 60% of uterine pregnancies spontaneously abort if the IUD is not removed (4, 195, 358, 371, 413, 463). This is $2^1/_2$ to 5 times more often than in other women (186, 413, 459). More than half of the spontaneous abortions in IUD users occur in the second trimester (215, 358). Early studies found that septic (infected) second-trimester spontaneous abortion—a rare but life-threatening event—was more common in women whose IUDs were left in place than in women not using IUDs at the time of conception (109). This increase in risk was associated, however, with the *Dalkon Shield* IUD, which is no longer available, and there is no conclusive evidence linking other types of IUDs with increased risks of septic abortion (488).

Because infection can occur in any pregnancy with an IUD in place, the IUD should be removed as soon as pregnancy is confirmed (1, 437). This virtually eliminates any risk of septic abortion and reduces risk of spontaneous abortion to the same levels faced by other women (4, 109, 195, 371, 557).

An IUD left in place during pregnancy also increases the risk of premature delivery (413, 463, 488). It does *not* increase the risk of other complications—birth defects, genetic abnormalities, or molar pregnancy (a uterine growth that mimics pregnancy) (152, 232, 276, 344, 371, 413, 488, 557).

Ectopic Pregnancies

Mounting evidence indicates that most IUDs help to protect against ectopic pregnancy while they are in use. In the WHO multicenter study, IUD users were half as likely to experience ectopic pregnancies as women using no contraception (442). In recent studies in the US and Indonesia, IUD users faced about 20% of the risk of ectopic pregnancy faced by women using no contraception (576, 623). A recent analysis of randomized trials found that second-generation copper IUDs and the LNG-20 reduce ectopic pregnancy rates to 10% of the level among women using no contraception (543). Still, IUDs provide less protection against ectopic pregnancy than consistently used oral contraceptives (261, 442, 576) or barrier methods (442, 623).

IUDs protect against intrauterine pregnancies better than against ectopic pregnancies. Thus, *when* an IUD user becomes pregnant, the pregnancy is more likely to be ectopic than a pregnancy in another woman (369, 424, 442, 463). In IUD users an estimated one in 25 to 30 pregnancies, or 3% to 4%, is ectopic. Rates of ectopic pregnancy in the general population vary. In the US, Canada, and Europe, more than 1% of all pregnancies are ectopic (543, 628).

Any pregnancy in an IUD user is uncommon, however. Thus ectopic pregnancy in an IUD user is rare. For most of the widely used IUDs, less than 1.5 ectopic pregnancies occur per 1,000 woman-years of IUD use (69, 73, 314, 327, 330, 335, 543).

Differences among devices. With inert and copper-bearing IUDs, ectopic pregnancy rates seem to reflect overall effectiveness. For example, two of the most effective IUDs, the TCu-380A and MLCu-375, have the lowest ectopic pregnancy rates—0.25 and close to 0 per 1,000 woman-years, respectively, according to results of major clinical trials (69, 73, 314, 330, 335, 543, 648). The highly effective LNG-20 IUD has had even lower ectopic pregnancy rates than most copper IUDs with which it has been compared (546, 556), perhaps because it sometimes suppresses ovulation (257). In contrast, the *Progestasert* has had higher rates—4 to 5 per 1,000 woman-years (116, 327, 400).

While some questions about IUDs and ectopic pregnancy remain unanswered (see p. 21), the clinical implications are clear:

- Women using IUDs should be told about the signs of ectopic pregnancy. They should know the signs—abdominal pain, dark and scanty or intermenstrual bleeding along with the usual signs of pregnancy—and to return for care promptly if they appear.
- If an IUD user conceives or shows signs of pregnancy, health care providers should always look for ectopic pregnancy.

A woman who has had an ectopic pregnancy can use an IUD, however, if this is the method that she prefers (565).

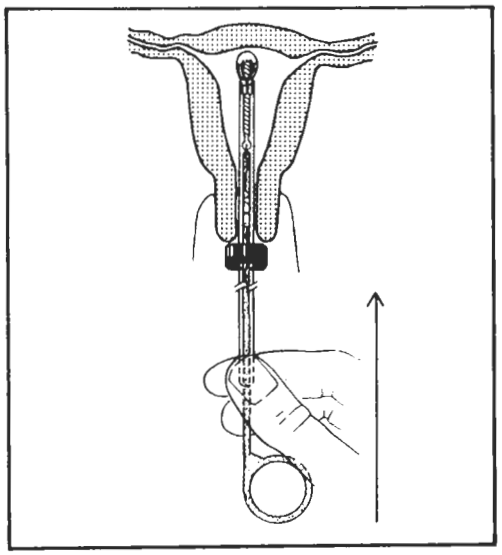
Other Conditions

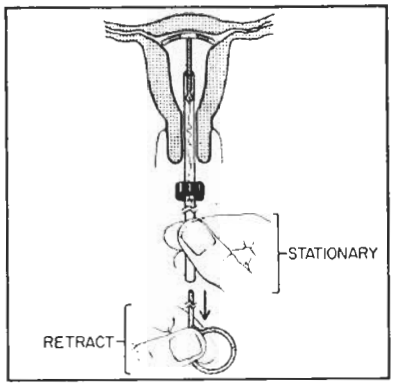
There is no evidence that IUDs cause any type of cancer (148, 194, 280, 332, 436). In fact, US and Italian case-control studies have found that women who used IUDs were about half as likely to develop endometrial cancer as other women (578, 617). These findings must be interpreted cautiously, however, because women who have long or heavy menstrual bleeding may be both more likely to develop endometrial cancer and to avoid IUD use (617). One US case-control study suggested that copper IUDs offer some protection against cervical cancer. The reduction in risk to about 60% was not statistically significant. The analysis did adjust for number of sexual partners, history of genital infections, and other factors (526).

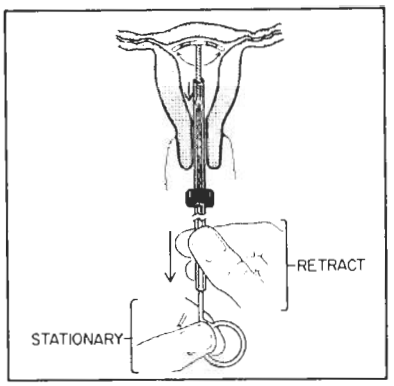
IUD users may be more likely to develop nonspecific vaginitis (often called bacterial vaginosis), according to two studies (455, 474). More research is needed, however. (For discussion of pelvic inflammatory disease, a more severe but uncommon complication, see pp. 16–17, 21.)

Lives Saved

Because the latest IUDs prevent pregnancy so effectively, IUD use saves many lives that otherwise would be lost due to pregnancy-related causes. In developing countries the estimated average annual risk of dying from causes related to pregnancy and childbirth may be about 185 per 100,000 women not using contraception; in developed countries the estimated annual risk may be about 11 per 100,000. These estimates are based on estimated maternal mortality ratios of 420 deaths per 100,000 live births in developing countries and 26 per 100,000 in developed countries (636) and estimated annual fertility rates of 444 births per 1,000 sexually active women not using contraception in developing countries and 420 per 1,000 in developed countries (638). In contrast, death from causes related to reproduction are rare among IUD users. WHO and US researchers have estimated about one to two deaths per 100,000 IUD users per year—







The withdrawal method of IUD insertion is used for copper Ts, Multiloads, Nova T, and Progestasert. The tube containing the IUD is inserted up to the uterine fundus (left). The tube is withdrawn while the rod is held steady (center). Then the rod is withdrawn (right). Because insertion techniques vary among IUDs, the manufacturer's specific instructions should be followed exactly. These diagrams from The Copper T380 IUD: A Manual for Clinicians, *prepared by PIACT (now PATH), show insertion of a TCu-380A IUD (290).*

from infection, ectopic pregnancy, or second-trimester septic abortion (262, 301, 384, 436).

The IUD is one of the safest family planning methods, according to estimates of annual death rates among US women using various family planning methods or no method. For each method and for no method, the study estimated the risks of dying either from pregnancy and childbearing, if the method fails, or from complications of method use. For almost all methods, pregnancy after method failure accounts for most or all of the risk. Thus, in general, the most effective methods, including the IUD, are the safest, and any method is much safer than no method at all. In every 5-year age group, from 15 to 44, the IUD has the lowest estimated mortality rates except for vasectomy (596).

Insertion

Proper IUD insertion reduces the risks of pregnancy and of all major side effects—expulsion, bleeding and pain, perforation, and infection. IUDs can be inserted safely at any time during the menstrual cycle as long as it is reasonably certain that the woman is not pregnant and there are no signs of genital infection. Cervical infections should be treated before the insertion. Insertion immediately postpartum also is safe and convenient. Higher expulsion rates are a drawback, however.

Insertion Technique

The objective of IUD insertion is to place the IUD correctly while minimizing the woman's discomfort and the risk of complications. Successful IUD insertion requires:

- **Explaining the procedure** to the client and responding to her questions and concerns. This helps the client relax, making insertion easier and less painful.
- **Infection-prevention procedures** including use of high-level disinfected instruments and cleaning of the cervix with a water-based antiseptic such as chlorhexidene gluconate or an iodophor (for example, *Betadine®*). This minimizes the chances of uterine infection following insertion. Particularly useful is the "no-touch" technique, which includes loading sterile packaged IUDs in their inserters while both IUD and inserter are still in the sterile packaging (614) (see box, p. 20).
- **Speculum examination and bimanual pelvic examination.** The speculum exam should come first, to check for signs of genital tract infection. The bimanual exam determines the size, position, consistency, and mobility of the uterus and identifies any tenderness, which might indicate infection (614). A retroverted uterus—that is, bent backward—requires special care during insertion (449).
- **Sounding of the uterus** slowly and gently to determine its depth and direction. This reduces the risk of perforating the uterus, which usually occurs because the sound or IUD is inserted too deeply or at the wrong angle (7, 63, 190, 395, 437).
- **Careful and slow technique** during all phases of sounding and insertion. This reduces the client's discomfort and minimizes the chances of uterine perforation, cervical laceration, and other complications (57, 62, 63, 123).
- **IUD placement high in the uterus** (that is, at the fundus). This minimizes expulsions, accidental pregnancies, and possibly bleeding (71, 269, 332, 382).
- **Following the manufacturer's instructions** for insertion. Most IUDs are inserted by the withdrawal technique: The inserter tube, loaded with the IUD, is inserted to the depth indicated by sounding. Then the inserter tube is withdrawn while the inner plunger is held steady. This leaves the IUD in position. Then the plunger is withdrawn (591).

IUD insertion is usually uncomplicated. While many women experience discomfort, less than 5% experience moderate to severe pain. Vasovagal reactions—such as perspiring, vomiting, and brief fainting—and cervical laceration occur in 1% of women or less. These problems are generally brief and rarely require immediate IUD removal. They do not affect later IUD performance (58). Women who have never given birth, have had few births, or have had a long interval since last giving birth are most likely to have these problems. Analgesics reduce discomfort (300).

Health care providers should never use force to insert an IUD. Instead, the provider may ask the client to return during her menstrual period, when insertion may be easier, or refer her to

(continued on page 14)

An Expert Group Answers Questions:

Procedures for Providing IUDs

To develop a consensus in light of current scientific understanding, a group of experts recently answered important questions concerning procedures for providing various family planning methods including IUDs. The group was convened by the USAID Collaborating Agencies, private and nonprofit organizations working with support from the US Agency for International Development (USAID).

The group, named the Technical Guidance Working Group, intends its answers as guidance for programs developing or revising their own procedural and service guidelines. In issuing its report, the group sought to address two problems—(1) inconsistencies or conflicts in existing procedural guidelines can cause confusion; and (2) guidelines that are out of date in light of scientific evidence often restrict access to contraceptive methods unnecessarily (634).

Assessing the value of specific clinic procedures, the Working Group concluded that counseling, including discussion of increased bleeding, reasons to return, STD risk behavior, and condom use for STD protection; pelvic examination; and verbal STD screening are essential procedures. In contrast, a blood pressure test, breast examination, lab tests for STDs in women without symptoms, and cervical cancer screening may be appropriate for good preventive health care when indicated but are not required or not related to safe use of IUDs. Routine, mandatory lab tests such as cholesterol, glucose, and liver-function tests are irrelevant (634).

Questions and answers from the Working Group include the following:

1. Q: **When can an IUD be inserted in a woman who is having menstrual cycles?**

A: Any time during the menstrual cycle, at the woman's convenience, when the provider can be reasonably sure that the woman is not pregnant (426). It is not necessary to limit insertion to the time of a woman's menstrual bleeding since there are other ways to be reasonably sure that she is not pregnant—for example, she may not have had sex since her last menstrual period or she may have been using another effective contraceptive method.

2. Q: **When can an IUD be inserted postpartum?**

A: An IUD can be inserted immediately after delivery of the placenta or at the time of cesarian section and any time up to 48 hours after delivery. IUD insertion is not advisable between 48 hours and four weeks postpartum. As early as four weeks postpartum copper IUDs can be inserted because their "withdrawal" insertion technique minimizes risk of uterine perforation; other types of IUDs can be inserted as early as six weeks postpartum (233, 498, 535). Breastfeeding women can safely use IUDs (508).

3. Q: **Can an IUD be inserted immediately postabortion?**

A: Yes, provided the uterus is not infected. Also, an IUD can be inserted at any time during the first seven days after abortion or any other time that the provider can be reasonably sure that the woman is not pregnant. IUD insertion should be delayed in cases of: (1) evidence or reason to presume that the uterus is infected (septic); (2) serious injury to the genital tract; (3) hemorrhage leading to severe anemia (progestin-releasing IUDs can be used in cases of severe anemia because they decrease menstrual bleeding) (605).

4. Q: **What is an appropriate follow-up schedule after IUD insertion?**

A: One follow-up visit should be planned for three to six weeks after IUD insertion, after the woman's next menstrual period (507). At this visit the provider should check that the IUD is still in place and that no signs of infection have developed. Further routine visits are not required (601). Women should be encouraged, however, to return at any time that they have problems, questions, or concerns (see box, pp. 26–27).

5. Q: **Is there a need for a routine separate visit for an examination before IUD insertion?**

A: No. If at all possible, counseling, screening, and insertion all should be done at one visit, for the convenience of the client.

6. Q: **Is there a minimum or maximum age for starting IUD use?**

A: There is no minimum or maximum age for IUD use. All women who use IUDs, and especially young women, should be at low risk of sexually transmitted diseases (STDs). Before choosing the IUD, a woman should understand that IUD use may involve a heightened risk of infection that could lead to infertility.

7. Q: **Can women who have had no children use IUDs?**

A: Yes, but IUD expulsion, bleeding, and pain may be more likely than for women who have had children (618). A young woman who has not had children may need special help thinking through a decision on IUD use. A young woman, especially if not married, is less likely than an older, married woman to have a mutually faithful sexual relationship. Thus she faces a risk of STDs and of subsequent infertility that might be increased by IUD use. Still, understanding the possible risks, each woman should be permitted to make her own decision.

8. Q: **After removing an IUD, how soon can another IUD be inserted? Is there a need for a "rest period" after using an IUD for a time?**

A: If a woman wants to continue IUD use, she can have another IUD inserted immediately after an expired IUD is removed or an IUD is expelled, so long as she does not have any uterine infection. There is no benefit in a "rest period" or waiting time. In fact, immediately replacing an IUD poses less risk of infection than separate removal and insertion procedures (507).

9. Q: **What are valid reasons for IUD removal?**

A: 1. The woman requests removal, whatever her reason.

2. The woman develops a complication.

3. The effective life of the IUD has expired.

10. Q: **Can an IUD be inserted without any lab tests?**

A: Yes, provided the woman is not at risk for STDs, has no clinical signs or symptoms of infection including purulent discharge, cervicitis, and pelvic inflammatory disease (PID), and is not likely to be pregnant.

11. Q: **Should an IUD be removed if a woman's sexual partner complains about the IUD string?**

A: Not necessarily. The couple may need reassurance and an explanation of what the string is. If this is not satisfactory, the end of the string can be tucked behind the cervix. If this too is not satisfactory, the string can be cut flush with the cervix. (This should be noted in the woman's record.) Such short strings will mean that the woman will not be able to check the strings and a provider will need narrow forceps to grasp the strings when removing the IUD. The woman should be given the choice of what she wants done, including whether the IUD should be removed.

12. Q: **If the cervix is red due to ectropion, can an IUD be inserted without further investigation?**

A: Yes, an IUD can be inserted. Ectropion is the presence of cells from inside the cervical canal appearing on the outside of the cervix, causing a reddening. This is not a sign of infection. It occurs normally and routinely during adolescence and pregnancy.

13. Q: **Are heavier menstrual periods or bleeding between menstrual periods a medical reason to remove the IUD?**

A: Not necessarily. If the client wishes, or if bleeding or pain is severe, the IUD should be removed. Abnormal conditions that might cause heavy bleeding should be investigated. For most women, copper and all-plastic IUDs increase the amount of menstrual blood loss, particularly in the first few months of use. Women should be counseled to expect this. Bleeding and pain usually decrease over time. For mild to moderate bleeding and pain in the first month after insertion, a woman who wants to keep her IUD can take a short course of nonsteroidal anti-inflammatory drugs such as ibuprofen, which decrease uterine bleeding and cramping (but not aspirin, which promotes bleeding). The LNG-20 IUD reduces menstrual blood loss (see p. 8).

14. Q: **Can specifically trained nurses and midwives insert IUDs?**

A: Yes. Nurses and midwives have learned to perform interval, postpartum, and postabortion IUD insertions successfully (see p. 29).

15. Q: **How much time should elapse between STD treatment and IUD insertion?**

A: After an STD infection has been treated and resolved, an IUD can be inserted provided the woman will not face a risk of STDs in the future. After treatment of PID, waiting three months before IUD insertion will allow healthy tissue to form.

16. Q: **Should IUDs be provided if infection prevention measures cannot be followed?**

A: No. Infection prevention measures must always be followed (see box, p. 20). Basic infection prevention requirements for IUD insertion or removal are:

- Aseptic technique including appropriate handwashing by the provider and careful preparation of the cervix,
- Sterile or high-level disinfected IUDs and equipment,
- Correct decontamination of instruments, and
- Safe disposal of contaminated disposable items (635).

Other Questions and Answers

Here are some other commonly asked questions about IUDs and the answers (597):

1. Q: **Can the IUD travel from the woman's uterus to distant parts of her body, such as her heart or her brain?**

A: No. The IUD normally stays within the uterus. Very rarely, the IUD may come through the wall of the uterus and rest in the abdomen. This is probably due to a mistake during insertion and not to slow migration through the wall of the uterus. It never travels farther than the abdomen.

2. Q: **Will the IUD prevent a woman from having babies after it is removed?**

A: No. A woman can become pregnant after her IUD is removed. But the IUD does not protect her from sexually transmitted diseases (STDs). A woman should understand that the IUD may somewhat increase her chances of getting pelvic inflammatory disease (PID) if she contracts an STD. PID could make her infertile. Therefore, it is important for a woman who uses an IUD to have sex only with one, uninfected man and for him to have sex only with her. Then she is protected from STDs.

3. Q: **Should antibiotics be given routinely before IUD insertion to prevent infection?**

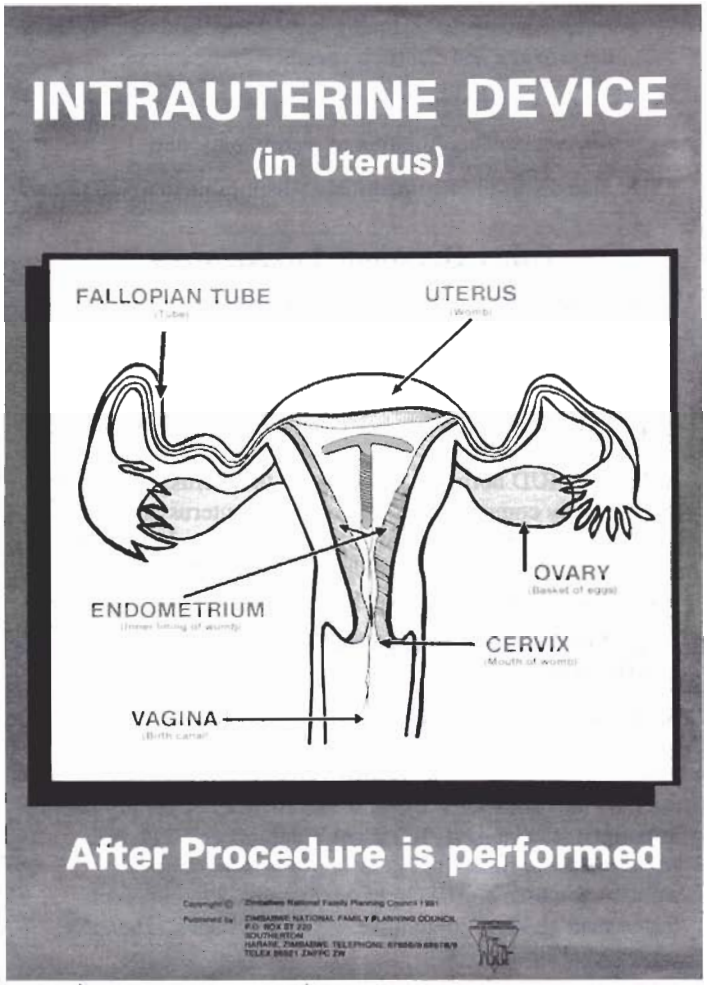
A: No. No benefit has been demonstrated in routine use of antibiotics at the time of IUD insertion. When the IUD is inserted correctly, using proper infection-prevention techniques (see box, p. 20), there is little risk of infection for healthy women. Antibiotics should be given before insertion, however, to women at high risk for endocarditis (inflammation of the membrane lining the heart). Women at high risk for endocarditis include those with symptoms of valvular heart disease, history of endocarditis, artificial heart valves, or cardiopulmonary shunt (abnormal passage of blood within the heart).

4. Q: **Can a woman with diabetes use an IUD?**

A: Yes. IUDs are safe for women with diabetes. Women with diabetes are at greater risk of many infections, however. They should see a nurse or doctor if they notice possible signs of sexually transmitted disease or other infection, particularly right after IUD insertion.

5. Q: **When does a copper IUD need to be replaced?**

A: The latest models of copper-bearing IUDs are effective for many years. The TCu-380A has been approved by the US Food and Drug Administration for 10 years of use. It probably can prevent pregnancy even longer. (Inert IUDs do not need to be removed until menopause.)



According to recent research, IUDs protect against pregnancy by preventing egg and sperm from joining. A poster from the Zimbabwe National Family Planning Council shows a TCu-380A in the uterus.

a more experienced provider, who may use dilators, with or without paracervical anesthesia, if the cervical canal is narrow. Cervical dilation does not increase the risk of later expulsion (55). Insertion failures are rare—2 to 8 per 1,000 attempted insertions—and are usually due to excessive pain or to the larger size of inserter used with some types of IUDs (63).

Many currently available IUDs are supplied in individual sterile packages with a sterile inserter. The packaged TCu-380A has a shelf-life approved by the US Food and Drug Administration of seven years. The copper on IUDs may become discolored in the packaging, but the IUD can still be used. It is still sterile, and the IUD will still be effective. If the package is damaged, however, the IUD and inserter may no longer be sterile, and it is best to discard them (36, 191, 213). Copper and plastic IUDs should never be boiled or autoclaved because heat deforms them (436).

Timing of Insertion

IUD insertion is safe and effective at any time during the menstrual cycle (70, 90, 375, 426, 437). An international study of about 12,000 women who had IUDs inserted at different times during their menstrual cycles and similar US studies found no advantage to the conventional practice of insertion during the first five days of the menstrual cycle (70, 91, 426). Thus, when it is reasonably sure that a woman is not pregnant, the best time to insert an IUD is when she comes to the health center to request it (398).

Postpartum Insertion

If performed by a specifically trained and experienced provider, postpartum IUD insertion within 48 hours after delivery is safe and convenient, with no increased risk of infection, perforation, or bleeding (19, 71, 160, 304, 305, 373, 375, 535, 650). Postpartum insertion is best carried out in a program that can counsel women during prenatal care, since a woman may have difficulty making a carefully considered decision about contraceptive use while she is in labor. Also, such programs can better assure that a practitioner trained in postpartum IUD insertion will be available when a woman delivers. In the Mexican social security system, Instituto Mexicano del Seguro Social, delivery-room staff are trained to insert IUDs, and women are counseled during prenatal care about postpartum contraceptive options. IUDs are the most popular method of postpartum contraception in Mexico (99).

The major disadvantage of postpartum insertion is the higher expulsion rate. The IUD is more easily expelled after childbirth because the uterus is contracting and the cervix is dilated (341). Expulsion rates following postpartum IUD insertion are lowest when the IUD is inserted within 10 minutes after the expulsion of the placenta (60, 71, 494, 498), when a copper IUD rather than an unmedicated IUD is used (382, 555, 567), and when the provider is skilled and experienced and places the IUD correctly, high in the fundus (498, 535, 555, 650). When a copper T IUD is inserted within 48 hours after delivery by an experienced provider, expulsion rates at six months range from 6 to 15 per 100 (60, 71, 382, 483, 498, 535, 561). Because insertion between one week and four to six weeks after delivery carries an increased risk of perforation, many groups advise special caution or even advise against inserting IUDs during this period (164, 398, 433, 487, 498, 535, 565).

The health care provider's skill and experience are probably more important in reducing expulsions and other complications than the type of device used (60, 361, 377, 382). A large international study of immediate postpartum insertions found that expulsion rates at three months were almost twice as high for insertions performed during the first half of the study, when the practitioners were less experienced, than in the second half (60). Similarly, a Belgian study found that rates of expulsion, accidental pregnancy, and removal for pain, bleeding, and other medical reasons were lower when postpartum insertions were performed by more experienced practitioners (382).

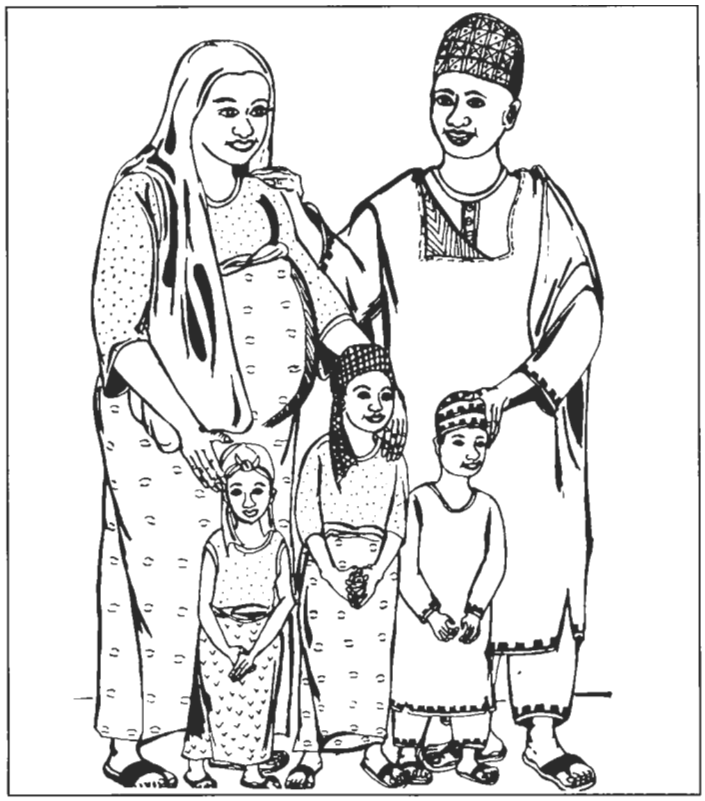
Insertion at cesarean section. Studies in China, Belgium, and Mexico, examining IUD insertion through the abdominal incision immediately after cesarean delivery, have found the procedure to be safe and expulsion rates to be low (59, 64, 409, 437, 524, 535, 567, 650). When there has been prolonged labor or premature rupture of the membranes, however, postcesarean insertion should be avoided because of the risk of infection (437).

Breastfeeding and IUDs. A copper or unmedicated IUD is a good contraceptive method for a lactating woman (437) because it has no effect on the quantity or composition of

breast milk (53, 72). With the LNG IUD, small amounts of progestin are found in breast milk, although these low levels apparently do not affect child health (146, 531).

There has been some concern, based on a few case reports and a small case-control study, that insertion during lactation might involve a higher risk of uterine perforation (54, 144, 228, 328). Results from international clinical trials conducted by Family Health International have been largely reassuring, however. There were no instances of uterine perforation, either among the 1,243 women who were breastfeeding when the TCu-380A was inserted at least 42 days postpartum or among the 1,032 women who were not (508). Similar results were reported in clinical trials of the *Gyne T-380* IUD (548). In clinical trials of the TCu-380A, *Lippes Loop* D, and MLCu-375 in Indonesia, there were no statistically significant differences in rates of expulsion/displacement between 724 breastfeeding women and 2,096 nonbreastfeeding women at either 12 or 24 months. All three reported perforations occurred among breastfeeding women, however (540).

Postpartum insertion requires special techniques to minimize the risk of perforation. Sounding the uterus should be avoided because of the risk of perforating the soft uterus. IUDs usually are inserted postpartum with ring forceps or by hand rather than with a standard inserter (71, 535). If the inserter is used, Tapani Luukkainen recommends that the arms of a T-shaped IUD be released from the inserter once it has passed the internal os of the cervical canal. Then the open IUD can be lifted to the fundus. The outspread arms of the T reduce the risk of perforation (608).



Iyali sai farin ciki, ga Uwargida da wani ciki bayan da na karshe ya girma. Da zaran an cire wanna roba sai ciki.

A booklet for IUD users, produced by the Planned Parenthood Federation of Nigeria, suggests IUDs for spacing births: "The happy family with the mother pregnant again after the last child is more grown up. Once the IUD is removed, the woman can become pregnant again."

Postabortion Insertion

Conception can occur as early as 10 days after abortion. Therefore effective contraception is needed immediately (34). IUDs can safely be inserted after spontaneous or induced abortion except in women with pelvic infections or septic abortion (211, 436, 445, 565). WHO studies show moderate expulsion rates associated with IUD insertion following first-trimester abortions—ranging at two years from 5 to 9 per 100 women after induced abortion and from 10 to 14 after spontaneous abortion. With IUD insertion following second-trimester abortion, rates of expulsion and of removal for pain and for other medical reasons are markedly higher (436, 445).

Removal

IUD removal is usually a routine and uncomplicated procedure. It can be done at any time during the menstrual cycle. To remove the IUD, the health care provider pulls the strings slowly and gently with forceps. A tenaculum can be used to steady the cervix and align the endocervical canal and the vaginal and uterine cavities (357). If removal is not easy, the client should be sent to an experienced clinician, who may dilate the cervix. Alternatively, removal can be attempted again during menstruation, when the cervix is naturally softened (142, 190). An international multicenter study found that less than 2% of attempted removals of standard IUDs proved to be difficult (61).

One common reason for difficult IUD removal is that the IUD strings are "missing"—that is, they cannot be located in the vagina near the cervix (342). Usually, the strings have slipped up into the cervical canal, perhaps because they were cut too short at insertion. After ruling out pregnancy, the health care provider can use narrow forceps to probe the cervical canal and draw out the strings. A study in the UK found that missing strings could be retrieved this way in 50% of cases (202). If this fails, the strings may have retracted into the uterine cavity, or the IUD may have been expelled without the woman's knowledge. A sound can be used to check whether the IUD is in place. Vacuum aspiration can be used to find the strings. This usually dislodges the IUD (130). If the strings cannot be retrieved, IUDs can be removed from the uterus with forceps, curettes, or hooks. The provider must be very careful not to injure the uterus.

A less common reason for difficult removal is that the IUD has partially or completely perforated the uterus or become embedded in the uterine wall. Perforation should be suspected particularly if the woman is experiencing abdominal or pelvic pain or irregular bleeding (449). If facilities are available, x-rays, hysterography (x-rays of the uterine cavity after instillation of a contrast medium), hysteroscopy (direct visualization of the uterine cavity with a fiberoptic instrument), or sometimes ultrasound imaging can be used to diagnose perforation and embedding (7, 15, 133, 237, 303, 449). Only experienced clinicians should attempt to remove an embedded or perforating IUD (614).

Infection

Overall, women using IUDs are about twice as likely to develop pelvic inflammatory disease (PID) as women using no contraception, according to most studies. These studies have involved women with both high and low risk of sexually transmitted diseases (STDs), which cause PID (41, 78, 81, 209, 265, 421). This increased risk of PID is largely concentrated in the first few weeks after insertion and is due to poor infection prevention during insertion. Thereafter, the risk is among women exposed to STDs. Thus, for women in mutually faithful sexual relationships, IUDs pose little ongoing risk of PID (208, 227, 507).

Pelvic inflammatory disease is a broad term for any infection ascending from the cervix into the uterus, fallopian tubes, and ovaries (422). PID is fairly common in developed countries. About 1% to 2% of all women of reproductive age develop PID each year (30, 421, 532). In developing countries the incidence is unknown but may be higher in some areas (244, 302). In addition to STDs, postpartum and postabortion infections are major causes of PID (464).

The complications of PID sometimes are severe. Even a single infection can permanently damage the lining of the fallopian tubes. This may partially or totally block one or both tubes, substantially increasing the chances of ectopic pregnancy and infertility (136, 369, 421, 424). With each episode of PID the chances of tubal blockage and infertility increase (422). A woman who has had PID is more likely to have chronic pelvic pain than other women and is more susceptible to repeated infections (422). All these complications are most likely if PID is not treated promptly and appropriately (see **Population Reports**, *Controlling Sexually Transmitted Diseases*, L-9, June 1993).

PID and IUD Use

Epidemiologic research in the 1970s and early 1980s tended to overestimate the risk of pelvic infection from IUD use. These studies reported that IUD users were up to 10 times more likely to develop PID than other women (219). Several factors account for the initial overestimate, including:

- In most early studies the comparison group included women using oral contraceptives and barrier methods—methods that protect against PID.
- The risks for specific types of IUDs, particularly the *Dalkon Shield*, were not analyzed separately. The higher risk with the *Dalkon Shield* inflated overall risk estimates for all IUDs (627).
- Many studies did not take into account a number of important factors that affect the risk of PID—age, number of sexual partners, and history of PID (437, 521).

Three large studies published since the early 1980s have taken these earlier problems into account and found a lower risk. The US Women's Health Study found that IUD users were 1.6 times as likely to be hospitalized for PID as women using other methods or no method (41). In the Oxford University/Family Planning Association cohort study, the relative risks were 1.8 for women using medicated (mostly copper) IUDs and 3.3 for women using inert IUDs (495). A WHO study in 12 countries found that in developing countries IUD users with children were 2.3 times more likely to develop PID than women using no contraception. The relative risk for similar women in developed countries was 4.1 (446). A reanalysis of data from 13 WHO clinical trials found that the incidence of PID among IUD users dropped substantially after 1980. The PID rate among women who had IUDs inserted after 1980 was less than half that among women who had earlier insertions (507). The decrease may have occurred because participants in the later studies faced less exposure to STDs.

Although IUD users are more likely to develop PID than nonusers, it is still an uncommon complication. A WHO study of multiparous women, mostly in developing countries, who were using copper IUDs reported a cumulative rate of removal for PID of less than one per 100 women after six years of use (307). Another international multicenter study reported 3.4 removals of copper IUDs per 100 women after seven years of use (549). In a European study involving many young, unmarried women, who are at higher risk for PID, the 5-year removal rate was seven per 100 women (226) (see Table 1).

Factors Influencing the Risk of Infection

A number of factors appear to influence the risk of infection among IUD users:

Insertion. A woman is most likely to develop PID just after insertion (33, 41, 78, 209, 247, 307, 326, 356). Analysis of data from 13 WHO clinical trials found that for women using IUDs the risk of developing PID was 6.3 times greater during the 20 days after insertion than at any later time. After the first 20 days, the incidence of PID remained at a constant low level—1.4 per 1,000 woman-years—throughout eight years of use (507) (see Figure 1). Similarly, the Women's Health Study found that women using IUDs (excluding the *Dalkon Shield*) faced the greatest risk of developing PID during the first month after insertion—an adjusted relative risk of 3.8. By 5 to 12 months after insertion, the relative risk of developing PID was 1.1—not significantly higher for IUD users than for women using no contraceptive method (209).

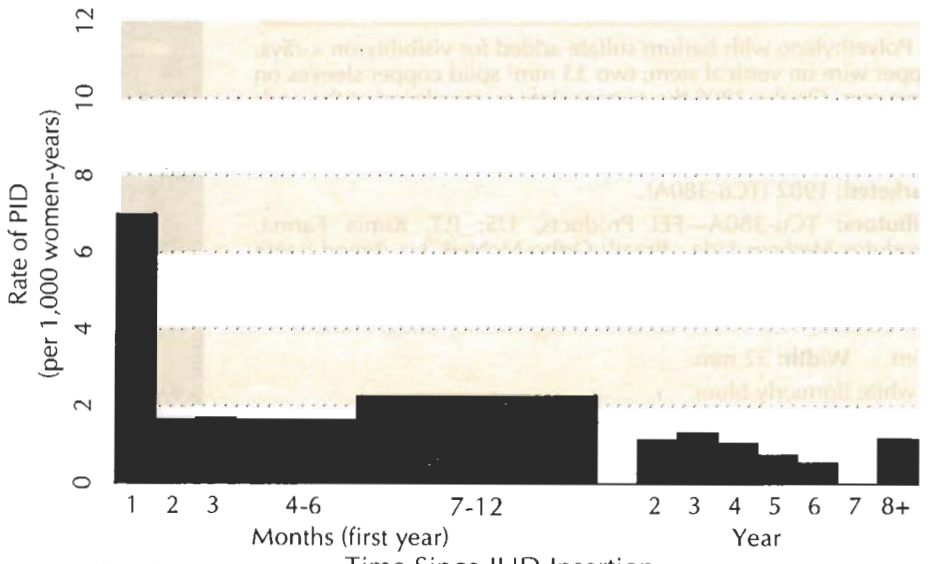
Providers can minimize the risk of infection just after IUD insertion by carefully following infection-prevention procedures during IUD insertion (see p. 20). In a recent study in which cervical infections were treated before IUD insertion and infection-prevention measures were followed, there was no increase in PID associated with insertion of the *Nova T* or LNG-20 (573). At the same time, providers should describe PID symptoms to women receiving IUDs, encourage special attention to any of these symptoms in the first month after insertion, and urge them to obtain medical attention promptly if symptoms appear (see box, p. 25).

Type of IUD. The *Dalkon Shield*—which is no longer on the market—was as much as five times more likely to be linked to PID and two times more likely to lead to tubal infertility than other IUDs (78, 81, 177, 209, 415, 495, 627). Moreover, with the *Dalkon Shield*, the higher risk of developing PID persisted in long-term users (209).

It is not clear whether the risk of PID varies among other IUDs. Several studies, including a recent analysis of WHO clinical trial data, show no difference in infection rates among unmedicated, copper, and hormonal IUDs (177, 209, 335, 343, 422, 507). In the Oxford University/Family Planning Association cohort study, however, the relative risk of developing PID was greater for women using unmedicated than copper IUDs (3.3 versus 1.8) (495). Likewise, two

studies on *infertility*, rather than PID, reported lower risks of tubal blockage with copper IUDs than with unmedicated IUDs (78, 81, 502). A European multicenter study, although not designed especially to detect PID, found significantly lower rates of PID associated with the LNG-20 IUD than with the *Nova T* (530, 556, 573), but two other large international studies did not find that the LNG-20 protects against PID (334, 517, 546).

Figure 1. Rate of PID by Time Since IUD Insertion in 13 WHO Clinical Trials



Source: Farley et al. 1992 (507)

Population Reports

Exposure to sexually transmitted diseases. Much of the risk of PID in IUD users, apart from the first weeks after insertion, may be due to sexually transmitted diseases (208, 253, 437). Having multiple sexual partners—and, as a result, greater exposure to STDs—is thus a major PID risk for IUD users, as it is for all women regardless of contraceptive use. Also, as for all other women, if an IUD user's partner has more than one sexual partner, this increases her risk of PID (208, 356, 528). IUD users in mutually faithful sexual relationships face minimal risks, presumably because of less exposure to STDs (94, 208, 359, 360, 366, 423). Indeed, the low long-term relative risks of PID seen in the most careful studies raise doubt whether, beyond the first few weeks after insertion, PID risk is really any greater among users of currently available IUDs than among women with the same STD risks who do not use contraception.

Age. As in other women, PID in IUD users occurs more often among women under age 25 (24, 33, 41, 227, 360, 418, 421, 446, 528). In international clinical trials sponsored by WHO, for example, younger women suffered from PID at 2.5 times the rate of older women (507). This may be at least in part because these younger women are less likely to be married or to have mutually faithful sexual relationships (24, 33, 418, 446).

Duration of IUD use. In most studies the chances of ever developing PID remain unchanged or even decrease with duration of IUD use (41, 209, 332, 343, 385, 415, 463, 507, 550). Two studies concluded that the risk of very severe PID increased with time (356, 463). One involved few cases, and long-term users may have been more likely to have used the *Dalkon Shield* than copper IUDs (545). The other study involved predominantly inert IUDs (463). Of course, if, as time passes, women change sexual partners, their exposure to STDs and thus their risk of PID may change.

Mechanisms of Infection

Infection related to IUD insertion probably occurs because the instruments or IUD carry with them organisms from the lower genital tract (234). Careful insertion technique can minimize this risk (see p. 11).

Mechanisms of subsequent infection are less clear. Several hypotheses have been suggested. Nonbacterial inflammation of the fallopian tubes is more common in IUD users than nonusers (22, 74, 277, 339, 440). This inflammation may reduce resistance to disease-causing organisms (95, 339). Some researchers suspect that cervical bacteria can move up the IUD string into the uterus (350, 352). Studies of IUDs without strings generally have not found lower rates of infection, however (see p. 21). One proposed explanation for the high rate of infection with the *Dalkon Shield* is that its multifilament string permitted bacteria to rise into the uterus more readily (296, 336, 372). Strings on all currently available IUDs are monofilament.

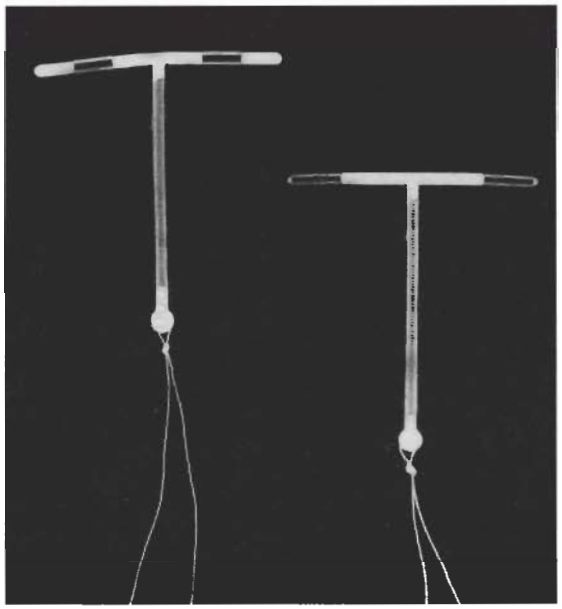
Clinical Implications

Research on PID and IUD use reinforces the importance of good clinical care. I-C. Chi points particularly to three programmatic measures that minimize the risk of infection (579):

- Careful infection-prevention procedures, including cleaning the cervix during IUD insertion, and careful checking, at the follow-up visit, for signs of infection (see p. 11 and box, p. 20);
- Careful screening to assure that women who choose IUDs face little risk of STDs. Screening involves both asking questions and conducting a pelvic examination. Because PID is linked to sexually transmitted diseases, the best candidate for an IUD is a woman living in a stable, mutually faithful sexual relationship (127, 437, 442). Providers can ask questions to find out about a woman's patterns of sexual behavior. During the pelvic exam, the provider can check for signs of cervical infection. Cervical infection should be treated, if possible. Once the infection is resolved, the IUD can be inserted, provided the woman will not face a high risk of STDs in the future.

(continued on page 21)

TCu-380A and TCu-380 Slimline (TCu-380S)



Description: Polyethylene with barium sulfate added for visibility on x-rays. 314 mm² copper wire on vertical stem; two 33 mm² solid copper sleeves on each transverse arm. On the 380S the copper sleeves are placed at the ends of the arms and recessed into the plastic.

Developers: Population Council (US) and Ortho Canada (TCu-380S).

Date first marketed: 1982 (TCu-380A).

Major distributors: TCu-380A—FEI Products, US; P.T. Kimia Farma, Indonesia; Produtos Medicos Ltda., Brazil; Ortho-McNeil, US (brand name *ParaGard*); Schering AG, Commonwealth of Independent States (CIS) (formerly USSR); TCu-380A and TCu-380S (brand name *Gyne T Slimline*)—Janssen-Ortho Canada; TCu-380S—Janssen-Cilag, Russia; Cilag, France.

Length: 36 mm. **Width:** 32 mm.

Strings: Two white (formerly blue).

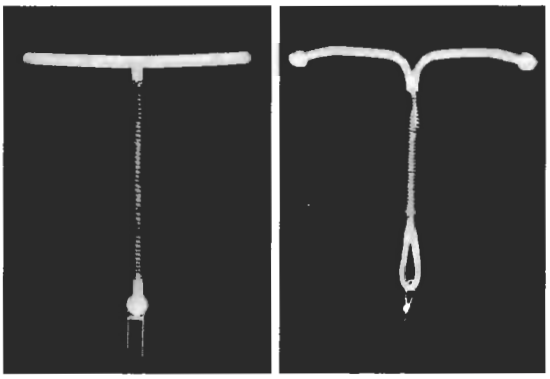
Inserter type and diameter: Withdrawal; 4.4 mm. (Both use the same inserter tube. TCu-380S arms fit completely in tube. With TCu-380A only the tips of the arms fit inside tube.)

Lifespan demonstrated in clinical trials: 10 years.

Approved lifespan: TCu-380A—US, 10 years; CIS, 6 years. TCu-380S—Canada, 2½ years; Europe, various.

Areas of major use: TCu-380A—worldwide; TCu-380S—Canada, Western Europe, Hong Kong.

TCu-200 and TCu-200B



Description: Polyethylene with barium sulfate added for visibility on x-rays. 200 mm² copper wire wrapped around stem. The TCu-200B (shown) has a ball at the tip of the stem; the TCu-200 does not.

Developers: Howard Tatum (US) and Jaime Zipper (Chile).

Date first marketed: 1972.

Major distributors: TCu-200B—Produtos Medicos Ltda., Brazil; TCu-200—Janssen-Ortho Canada.

Length: 36 mm. **Width:** 32 mm.

Strings: Two; color varies.

Inserter type and diameter: Withdrawal; 4.4 mm.

Lifespan demonstrated in clinical trials: 6 years.

Approved lifespan: US, 4 years; various European countries, 3 years; Canada, 2 years.

Areas of major use: Bangladesh, India.

Nova T and CuNovaT

Description: Polyethylene with barium sulfate added for visibility on x-rays. Nova T (shown) has 200 mm² copper wire with a silver core wrapped around the stem. CuNovaT has 380 mm² wire wrapped around the stem.

Developers: Leiras Oy, Finland.

Date first marketed: Nova T—1979; CuNovaT—1994.

Major distributors: Nova T—Leiras Oy in Scandinavian countries; Schering AG in other countries worldwide; also Pharmacia (Novagard) in UK. CuNovaT—Leiras Oy.

Length: 32 mm. **Width:** 32 mm.

Strings: Two brown.

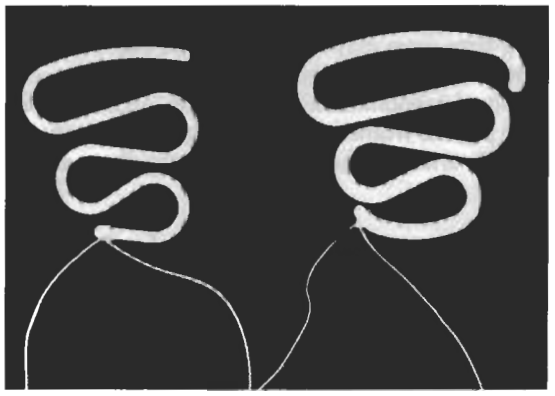
Inserter type and diameter: Withdrawal; 3.6 mm.

Lifespan demonstrated in clinical trials: Nova T—5 years; CuNovaT—3 years to date.

Approved lifespan: Nova T and CuNovaT—5 years in various European countries.

Areas of major use: Nova T—Europe, Canada, Asia and Pacific; CuNovaT—Denmark, Finland, Norway, Sweden.

Lippes Loop



Description: Polyethylene with barium sulfate added for visibility on x-rays. Four sizes, designated A (left) through D (right).

Developer: Jack Lippes (US).

Date first marketed: 1962.

Major distributor: P.T. Kimia Farma, Indonesia (in-country distribution only).

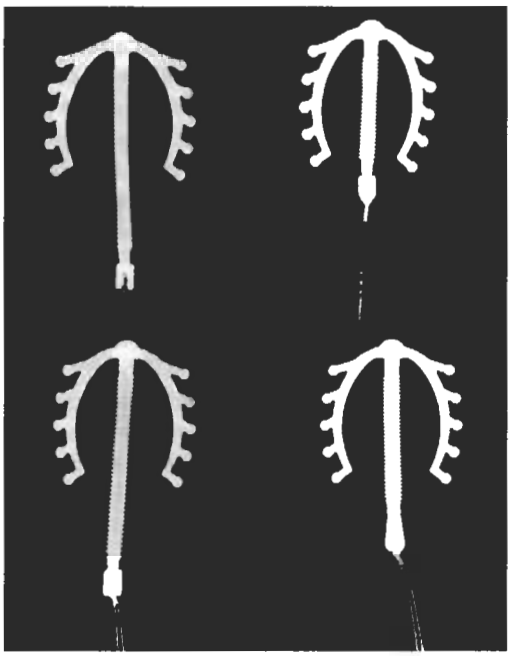
Length: A—26.2 mm; B—25.2 mm; C—27.5 mm; D—27.5 mm.

Width: A—22.2 mm; B—27.4 mm; C—30.0 mm; D—30.0 mm.

Strings: Two; A—blue, B—black, C—yellow, D—white.

Inserter type and diameter: Push-out; 4.7 mm.

Areas of major use: Formerly, worldwide except China; currently, Indonesia.



Multiload-250 (MLCu-250) and 375 (MLCu-375)

Description: Polyethylene with two flexible arms with spurs. The MLCu-250 has 250 mm² copper wire on the stem and is available in 2 sizes, Standard (top left) and Short (top right). The MLCu-375 has 375 mm² copper wire and is available in 2 sizes, Standard (bottom left) and SL (bottom right).

Developer: W.A.A. van Os (Netherlands).

Date first marketed: 1974.

Distributors: Produced by Multilan AG, Switzerland, in Ireland and by Nanjing Organon Pharmaceutical Products, China. Distributed through subsidiaries of NV Organon, the Netherlands, member of AKZO-NOBEL Pharma Division; Laboratoires CCD, France. Also manufactured for in-country use in Indonesia.

Length: Standard (250 and 375)—35 mm; 375SL—29 mm; 250 Short—24 mm.

Width: All types—18 mm.

Strings: Two blue or colorless.

Inserter type: Withdrawal (no plunger).

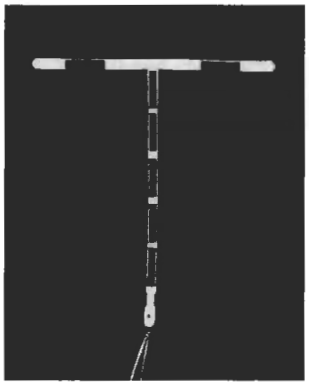
Insertion diameter: All types—12 mm (arms remain outside inserter tube).

Lifespan demonstrated in clinical trials: MLCu-375—5 years.

Approved lifespan: MLCu-250—3 years; MLCu-375—5 years.

Areas of major use: Europe (including Russia and other members of the Commonwealth of Independent States), Australia, India, Vietnam and other Southeast Asian countries, New Zealand, Latin America.

TCu-220C



Description: Polyethylene with barium sulfate added for visibility on x-rays. 220 mm² copper in 7 copper sleeves—2 on the arms and 5 on the stem.

Developer: Population Council (US).

Date first marketed: 1980.

Major distributors: Laboratorios Alpha, Mexico; Tianjin Medical Instrument Corporation, Factory No. 4, China (in-country distribution only).

Length: 36 mm. **Width:** 32 mm.

Strings: Two.

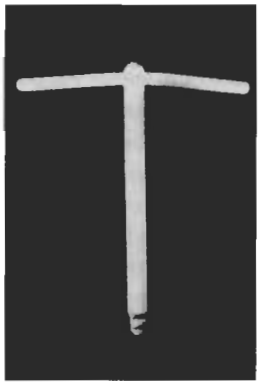
Inserter type and diameter: Withdrawal; 4.4 mm.

Lifespan demonstrated in clinical trials: 10 years.

Approved lifespan: Mexico, 3 years.

Areas of major use: China, Mexico

Progestasert Intrauterine Progesterone Contraceptive System



Description: Ethylene vinyl acetate copolymer. Vertical stem contains a reservoir of 38 mg progesterone and barium sulfate (for visibility on x-rays) in silicone oil base. Releases 65 µg progesterone per 24 hours.

Developer: Alza Corporation (US).

Date first marketed: 1976.

Distributors: Alza Corporation, US; Theraplix Divison, Rhone-Poulenc Rorer, France.

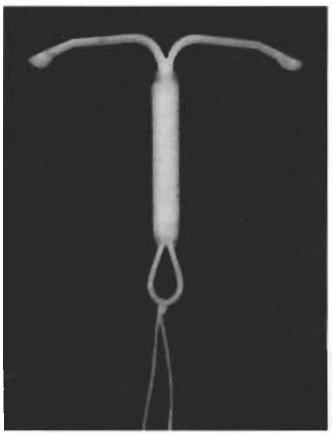
Length: 36 mm. **Width:** 32 mm.

Strings: Two blue-black.

Inserter type and diameter: Withdrawal; 8 mm.

Approved lifespan: US, one year; France,18 months.

Areas of major use: US, France.



Levonorgestrel (LNG-20) Intrauterine System (Mirena/Levonova)

Description: Polyethylene T frame surrounded by a levonorgestrel-containing cylinder. The cylinder is covered with a rate-controlling membrane. The release rate is 20 µg levonorgestrel per 24 hours.

Developers: Leiras Oy with the Population Council.

Date first marketed: 1990 in Finland.

Major distributors: Leiras Oy in Scandinavian countries and Asia-Pacific, Pharmacia-Leiras in selected European countries.

Length: 32 mm. **Width:** 32 mm.

Hormone cylinder: length 19 mm, outer diameter 2.8 mm, inner diameter 1.2 mm.

Strings: Two brown.

Inserter type and diameter: Withdrawal; 4.75 mm.

Lifespan demonstrated in clinical trials: 5 years.

Approved lifespan: UK, 3 years; other countries, 5 years.

Areas of major use: Denmark, Finland, Norway, Sweden. Launched in UK and Singapore in 1995. Also approved for use in Belgium, France, Iceland, and Switzerland.

Infection Prevention for IUD Insertion and Removal

Careful infection-prevention practices are essential during IUD insertion and removal. IUDs should not be inserted or removed if infection-prevention procedures cannot be followed (634).

For insertion, infection-prevention practices involve four steps:

(1) ***Washing hands and then putting on gloves.*** Washing hands may be the single most important infection-prevention measure (614). Either new disposable gloves or gloves that have been high-level disinfected (HLD) by boiling or steaming for 20 minutes (655, 656) should be used for each new client. Gloves need not be sterile.

(2) ***Cleaning the cervix and vagina.*** After the speculum is inserted, an effective antiseptic solution should be liberally applied first to the cervix (especially the os) two or three times and then to the vagina. A water-based antiseptic should be used, such as an iodophor or chlorhexidine gluconate. Alcohol should not be used because it burns and it dries out and irritates mucous membranes, making them more susceptible to infection. When using an iodophor, such as povidone iodine (e.g., *Betadine*®), the provider should wait one or two minutes for these antiseptics to become effective before proceeding (614).

(3) ***Using the "no touch" insertion technique.*** For the TCu-380A and other IUDs that come with inserters in sterile packaging, the IUD is loaded into the inserter while both are still in the package (591). During sounding and insertion, the provider avoids touching the vaginal wall or speculum blades, which would contaminate the HDL (or sterile) uterine sound or loaded IUD. The provider passes the HDL sound and the sterile IUD, loaded in the inserter tube, each only *once* through the cervical canal (614). This "no touch" technique is easy to learn and use.

(4) After the insertion procedure, ***washing hands again and then processing instruments*** for the next use (283, 635).

Similar steps—handwashing before and after, applying disinfectant to the cervix, and proper processing of instruments—also apply to IUD removal.

Processing Instruments for Reuse

Processing instruments for reuse (step 4) consists of three steps in itself — (a) decontamination, (b) cleaning, and (c) either high-level disinfection or sterilization.

(a) **Decontamination** requires soaking soiled instruments and gloves in 0.5% chlorine (bleach) solution for 10 minutes and then rinsing several times with clean water. The bleach kills viruses including hepatitis B virus and human immunodeficiency virus (HIV), bacteria, fungi, and parasites. Surfaces contaminated with body fluids, such as table tops, should be wiped with bleach solution.

(b) **Cleaning** requires scrubbing instruments with a soft brush in water and detergent to remove all debris, and then rinsing well and drying (281, 283, 435).

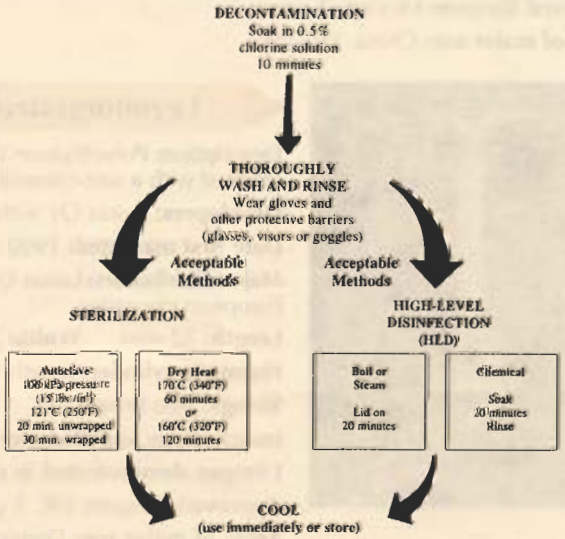
(c) **High-level disinfection** can be accomplished by boiling for 20 minutes in a container with a lid (longer at high altitudes). Alternatively, instruments and gloves can be soaked for 30 minutes in activated 2% glutaraldehyde or 8% formaldehyde and then washed thoroughly in sterile or boiled water to remove the disinfectant, which can irritate the skin (281, 435). High-level disinfectants must be carefully prepared according to the manufacturer's instructions. Fresh solution should be prepared daily or more often, as needed (190, 436).

High-level disinfection, if properly carried out, destroys most microorganisms including hepatitis B, herpes simplex type 2, human papilloma virus, and HIV, which causes AIDS (96, 435). Low-level disinfectants such as benzalkonium chloride (for example, *Zephiran*®) and antiseptic solutions (such as *Savlon*®, which is a mixture of cetrimide and chlorhexidene), as well as alcohols and iodine solutions, do not quickly kill viruses and some other microorganisms and should not be used (96, 283, 635). Sterilization—that is, destroying *all* microorganisms, including bacterial endospores—is desirable but not necessary with instruments used for IUD insertion and removal since the instruments touch only mucous membranes and do not come in contact with the blood stream (96, 191, 436).

HLD or sterile instruments and loaded IUD inserters should be carefully handled so that they are not contaminated. Providers should touch them only with HLD or sterile gloves or instruments, and there is no need to touch the loaded IUD at all. HLD or sterile instruments can be stored dry for about a week in a HLD container with a tight-fitting lid (635).

For more information and guidance about infection-prevention practices for IUD insertion and removal, see McIntosh, N., Kinzie, B., and Blouse, A., eds. IUD guidelines for family planning service providers: A problem-solving reference manual. Baltimore, Johns Hopkins Program for International Education in Reproductive Health (JHPIEGO), 1993 (614); Tietjen, L., Cronin, W., and McIntosh, N. Infection prevention for family planning service programs. Baltimore, JHPIEGO, 1992 (635).

Processing Instruments, Gloves and Other Items



Source: Adapted from JHPIEGO (655).

- Use long-lasting IUDs and do not remove them unless a woman requests removal, complications develop, or the IUD reaches the end of its effectiveness (634). Since much of the increase in risk of PID is linked to IUD insertion, the longer-lasting the IUD, the less need for periodic replacement and the less risk of infection over the long term. From this perspective, a very long-acting IUD, such as the TCu-380A, is the best IUD for the woman who wants many years of contraceptive protection.

It is not clear whether administering broad-spectrum antibiotics just before IUD insertion would reduce pelvic infection in the first months of use. Several studies have suggested some protective effect (523, 542), but small size or methodological problems prevent firm conclusions (579). A large, randomized trial underway in the US is designed to gather more conclusive data about the effectiveness of prophylactic antibiotics (513, 644). *In any case, antibiotics should not be seen as a substitute for good infection-prevention procedures.*

IUDs without strings also have been considered. The evidence is conflicting. Two laboratory studies of IUDs removed from women reported more bacterial colonization on IUDs with monofilament strings than on IUDs without strings (350, 434). In addition, two studies comparing women using IUDs with and without monofilament strings reported a difference in rates of infection (92, 493), as did research on inserting the IUD strings into the uterus together with the device (536). An international clinical trial of 1,265 women randomly assigned TCu-200 IUDs with and without strings, however, found no significant difference in the incidence of PID, STDs, or other infections or inflammation (538). Other clinical trials also have not found an association between the presence of strings and the incidence of infection (38, 68, 114, 210, 428).

Many authorities recommend that, if a woman develops PID while using an IUD, it should be removed 24 to 48 hours after she starts taking antibiotics (7, 93, 368, 397, 420, 437, 559). Three small studies comparing women whose IUDs were removed and those whose IUDs were left in place after a diagnosis of PID found little difference in their course of recovery, however (346, 525, 554). In fact, women whose IUDs were removed had longer hospital stays than women whose IUDs were left in place in two of the studies (525, 554). A WHO scientific group recently advised that the IUD might be allowed to remain in place if the woman no longer faces a high risk of STD infection and she understands the risks of repeated PID (565).

IUD Use and Long-Term Effects of PID

Since PID increases the risk of subsequent ectopic pregnancy and infertility, researchers have investigated whether IUD use is linked to either of these conditions. As noted (see p. 10), a woman currently using an IUD faces considerably less risk of having an ectopic pregnancy than a woman not using any contraception. Studies looking at ectopic pregnancy and infertility *after* IUD use have yielded mixed findings, depending at least partly on the study methodology.

Ectopic pregnancy and past IUD use. Two recent studies have concluded that IUD use somewhat increases the risk of ectopic pregnancy *after* the IUD is removed (576, 624). These studies, conducted by some of the same researchers in the US and in Indonesia, reported a similar increase in risk—1.6 and 1.7 times greater—associated with past IUD use. Both these studies were case-control designs, comparing women who had ectopic pregnancies with nonpregnant women of the same age and area of residence, and not currently using IUDs, and seeing whether one group was more likely to have used IUDs in the past.

Earlier studies—all using case-control methology—of ectopic pregnancy and IUD use before conception produced mixed findings. Two studies involving sexually active nonpregnant woman as controls found low or no risk linked with

Clinical Signs of Genital Infections

An IUD should not be inserted in a woman with certain lower genital tract infections—particularly acute mucopurulent cervicitis (inflammation of the cervix with pus and mucus discharge), gonorrhea, and chlamydial infection (419, 458, 565). Also, an IUD should not be inserted in a woman likely to have pelvic inflammatory disease (126, 398, 419, 437, 565). All potential IUD users should be screened for the clinical signs and symptoms of these infections. Since gonorrhea and chlamydial infection are often asymptomatic in women, family planning providers also should ask a woman if her sexual partner has symptoms, although men also may show no symptoms. The common clinical signs and symptoms of genital infections include:

Signs and Symptoms in Women

Lower genital tract infections:

- **Discharge (from the cervix or urethra) containing pus and mucus, sometimes with a cervix that bleeds easily;**
- **Difficult or painful (burning) urination; and**
- **Ulcers, sores, or swellings in the groin.**

Pelvic inflammatory disease:

- **Lower abdominal or pelvic pain*,**
- **Pain on manipulation of the cervix during pelvic exam*,**
- **Tenderness in the area of the fallopian tube or ovary on both sides of the body*,**
- **Oral temperature of 38.3°C (100°F) or higher,**
- **Abnormal cervical or vaginal discharge,**
- **Bleeding between menstrual periods.**

***To ensure that cases of PID do not go untreated, the presence of any of these three signs, in the absence of evidence for a competing diagnosis such as pregnancy or appendicitis, is considered reason to treat for PID (520, 558).**

Signs and Symptoms in Men

Gonorrhea, chlamydial or other infection:

- **Discharge from the penis containing pus and/or mucus,**
- **Painful (burning) urination,**
- **Ulcers, sores, or swellings in the groin.**

Sources: Hatcher et al. (142), Kahn et al. (520), McIntosh et al. (614), US CDC (399, 558, 559)

past IUD use (261, 442). In contrast, some (582, 602) but not all (442, 612) studies involving, as controls, pregnant women or women who had just given birth found a somewhat greater level of risk. Still other studies found risk only for former users of the *Dalkon Shield* (81, 580). A meta-analysis of all studies available through 1994 concluded that past IUD use might increase the risk of ectopic pregnancy by about 40% and that choice of pregnant or nonpregnant controls made no difference (651).

Still, these findings are difficult to interpret because neither pregnant nor nonpregnant women is an ideal control group (645, 651). Carolyn Westhoff has argued that the best control group for an analysis of whether past IUD use increases the risk that a pregnancy will be ectopic would be women who conceive, including those who have spontaneous or induced abortions (646). She points out that the duration-of-use effect, as seen in the recent US and Indonesian studies (576, 624), may appear because long-term IUD users are more likely to stop IUD use to become pregnant, whereas short-term users are more likely to stop IUD use because of side effects and then switch to other methods, thus protecting themselves from pregnancies, including ectopics (646).

At the same time, in studies to assess whether former IUD users face an increased risk of ectopic pregnancies, control groups that include ever-users of contraception will tend to increase the apparent relative risk. Thus, for example, when Irving Sivin used data from the Women's Health Study (261) to compare former IUD users with women not protected from ectopic pregnancy by use of other contraception, he calculated the relative risk for past IUD use at 0.7, suggesting a modest protective effect (327). Similarly, a WHO case-control study of ectopic pregnancy found that the relative risk of past IUD use was 0.7 whether past IUD users were compared with currently pregnant women or with nonpregnant women (442). A small study examining tissue from women operated on for ectopic pregnancies found that inflammation of the fallopian tubes, which might be related to PID, was not more common in current or past IUD users than in woman who had never used IUDs (607).

Infertility. Most women who discontinue IUD use to become pregnant conceive as rapidly as nonusers. As noted, however, IUD insertion can increase the risk of developing pelvic inflammatory disease (PID). The extent to which this leads to tubal infertility has been debated (437, 586, 595).

Two US case-control studies reported in 1985 that, overall, childless women with tubal infertility were two to three times more likely to have used IUDs than women having their first child (78, 81). The risk of tubal infertility varied markedly with the number of a woman's sexual partners. For example, in one study women who had had only one sexual partner in their lifetimes, regardless of the type of IUD used, had *no* increased risk of tubal infertility. Women who had had more than one partner had three to four times higher risk.

Adjusted Relative Risks of Tubal Infertility Among Childless Women by Type of IUD and Number of Sexual Partners

	Number of Partners	
Type of IUD	**One**	**More than One**
None	1.0	1.5*
Copper	1.1	2.8*
Other	0.7	4.2*

*Statistically significant ($p < .05$) compared with nonusers with one partner

Adjusted for year of menarche, time between menarche and date women began trying to conceive, religion, education, and smoking

Source: Cramer et al. 1985 (78)

Risk also varied among types of IUDs, with the *Dalkon Shield* posing higher risks than others. In a reanalysis using additional controls, the authors of one of these studies found that past use of copper IUDs also posed a statistically significant increase in risk (502), whereas in the 1985 report the increased risk had not been significant (81). Studying infertility and past IUD use is difficult, particularly because the infertility cases are self-selected—women who seek treatment for infertility—and former IUD users may be more likely to seek treatment than other women, as Norwegian data suggest (631).

In contrast to these two case-control studies, most cohort studies that have followed women who stopped using IUDs have found no indication of impaired fertility. In over a dozen studies, from 72% to 96% of women *conceived* within a year after discontinuation (5, 9, 23, 84, 267, 291, 294, 332, 337, 431, 485, 514, 529, 549, 550, 553) and in one large study 51% *gave birth* within a year (and therefore a higher percentage presumably were pregnant) (414). These rates are in the same range as rates among women who have never used contraception (32, 323) and apply to the LNG-20 IUD as well as copper IUDs (480, 550). When studies have followed former IUD users for longer periods of time, on average for four years, they have found the prevalence of tubal infertility to be low (from 3 to 14 per 1,000 IUD removals) compared with rates in the general population (337, 431, 539, 551).

Of course, cohort studies cannot be expected to gauge whether IUD insertion leads to infertility in a very small fraction of users. In fact, most of these studies have involved women who had no complications with IUD use (5, 9, 23, 84, 267, 291, 294, 332, 337, 514, 529, 549, 553). In most studies all the women were married (9, 294, 337, 414, 514), and thus were not at high risk for STDs, or had had children (9, 23, 84, 267, 414, 514). Two studies did examine conception rates in women who had never been pregnant before using IUDs (337, 431). After these women stopped using IUDs, they conceived at a slightly slower rate than women with children, as would be expected among women in general. The difference was not statistically significant, however, and the gap diminished over time. Also, studies have found no clear difference in the return of fertility between women who had discontinued use of the IUD for medical reasons, which might have included PID or its symptoms, and women who had stopped using IUDs in order to become pregnant (414, 431).

Most cohort studies have found that women who use IUDs for long periods of time conceive about as rapidly as short-term users (9, 20, 23, 179, 291, 294, 337, 431, 486, 514, 550, 553). One of the US case-control studies, however, found that the risk of infertility was slightly higher with longer use, once women who had used their IUDs for less than three months were excluded (78).

A large case-control study found that current and former IUD users were no more likely than nonusers to develop tubal adhesions (fibrous bands of tissue), which can be caused by PID and are a major reason for tubal infertility. These results fail to support other reports that IUD use increases the risk of infertility (462).

IUDs Do Not Prevent AIDS

In contrast to condoms, IUDs provide no protection against AIDS. AIDS—acquired immune deficiency syndrome—is caused by the human immunodeficiency virus (HIV). No vaccine against this virus has been developed. HIV is found in semen as well as blood. Thus both male and female condoms, which prevent semen from entering the vagina, and possibly spermicides and diaphragms, can protect against HIV. Other family planning methods cannot.

To protect against AIDS, all women who are not sure whether they or their partners are infected should use condoms during every act of sexual intercourse (see **Population Reports**, *Condoms—Now More than Ever,* H-8, September 1990). If a woman's partner will not use a condom, she should at least use a spermicide. Any couple whose sexual relationship has not been or will not continue to be a long-term, mutually faithful one faces a risk of exposure to HIV. Women who have more than one sexual partner or whose partners have more than one partner are not the best candidates for IUDs in any case. Nonetheless, any such woman using another effective method of family planning to prevent pregnancy should be encouraged to continue it even while she uses condoms and spermicides to prevent HIV infection (231). HIV can spread from a woman to her fetus during pregnancy. Therefore preventing pregnancy is especially important if a woman or her partner is likely to be infected.

Available evidence does not show that IUD use makes a woman more susceptible to HIV infection, but little research has been done to date. An Italian case-control study concluding that IUD use increased a woman's risk of being infected by an HIV-positive sexual partner (616) had serious methodological flaws (629). An analysis in Kenya that took account of other methods used found that current or past use of IUDs, injectables, and oral contraceptives did not affect the chances of being HIV-positive, and use of condoms reduced the chances (613).

There also has been little research on whether IUDs pose any special risk to a woman already infected with HIV. In practice, a WHO scientific group recommending eligibility criteria for various family planning methods concluded that HIV infection or high risk for HIV infection, as with other STDs, rules out IUD use (565). HIV testing should not be required for women who want IUDs, however (599). Both the WHO scientific group and the IPPF International Medical Advisory Panel recommend that IUDs be removed from HIV-positive women (565, 599).

There are no reports that HIV has been transmitted to a woman during IUD insertion or that a health care provider has been infected with HIV while inserting an IUD in an infected woman. Still, reports in Kenya suggest that concern about HIV transmission has affected providers' practices. While many providers are more scrupulous about infection-prevention procedures when inserting IUDs, fear of AIDS may also be creating reluctance to insert IUDs (633).

The same clinic procedures that protect both clients and health care providers against other infections also can protect them against HIV infection. To avoid any risk of infecting a client during IUD insertion, providers should see that all instruments are high-level disinfected before each use (see box, p. 20). To avoid any risk of transmission from a client to a health care provider, standard procedures for preventing blood-borne diseases such as hepatitis B should be followed. Providers should:

- Wear latex or plastic gloves if hands might come in contact with blood, body fluids, or mucous membranes;
- Change gloves after each client;
- Wash hands immediately and thoroughly after any direct contact with blood, body fluids, or mucous membranes and after removing gloves;
- Take care to avoid pricking or cutting themselves with a syringe or other instrument that might have blood or body fluid on it; and
- Clean up blood spills with disinfectant immediately (396, 435, 635).

Worldwide Use

More than 106 million women worldwide are using IUDs, according to estimates based on findings of the Demographic and Health Surveys and similar surveys (see Table 2). Thus the IUD is the second most commonly used family

Table 2

Worldwide Use of IUDs, 1995

Estimated Use Among Married Women of Reproductive Age

MWRA = married women of reproductive age

Region & Country	% of MWRA Using IUDs	Number of MWRA (in 1,000s)
DEVELOPING AREAS		
Asia		
China	33.0	72,000
Indian Subcontinent	2.1	5,200
Other Asian	12.9	10,900
Latin America & Caribbean	6.2	4,000
Near East & North Africa	11.6	4,900
Tropical Africa	0.8	600
All Developing Areas	13.4	97,600
All Developing Areas except China	5.0	25,600
DEVELOPED AREAS		
Australia & New Zealand	5.2	200
Europe		
North (Scandinavia)	18.2	700
Other Europe (includes former USSR)	7.2	6,400
Japan	3.5	650
North America	1.5	650
All Developed Areas	5.3	8,600
WORLD	11.9	106,200
World, except China	5.1	34,200
World, except China & India	6.1	30,700

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planning method, after voluntary female sterilization (see **Population Reports**, *Number One and Growing*, Series C, No. 10, November 1990) and the most commonly used reversible method. The high numbers are attributable to China, where about two-thirds of the world's IUD users live. In most countries that have conducted more than one representative sample survey of contraceptive prevalence, IUD use has remained stable or increased since the 1970s. Where voluntary sterilization and injectable contraceptives are available, however, use of these methods has usually grown faster than IUD use (391).

Developing Countries

The highest prevalence of IUD use in developing countries is in Vietnam and China, where 30% or more of married women of reproductive age use IUDs. In Vietnam the IUD accounts for almost two-thirds of all contraceptive use (584). In China the IUD and voluntary female sterilization are used by approximately equal numbers of women (66, 67). IUDs are widely used in several other Asian countries, particularly in Indonesia and in Taiwan, where as early as the 1970s the government contracted with private physicians for IUD insertion and voluntary sterilization (606).

In the Near East and North Africa, the IUD is a leading method in several countries. In Egypt, Jordan, and Tunisia, sharp rises in the use of the IUD accounted for most of the growth in overall contraceptive prevalence during the 1980s (477, 489, 506, 518). In two of these countries, Egypt and Jordan, the rise in IUD use came at the expense of the Pill. More than one-third of all contraceptors in Egypt, Jordan, and Tunisia now rely on IUDs (see Table 3). In Turkey IUD use has also grown in recent years (388). In 1988 IUD use increased by about one-third after a 3-month mass-media campaign that encouraged people to visit clinics for family planning services (604).

Table 3

IUD Use

Among Married Women of Reproductive Age as Reported in Representative Sample Surveys, 1984–1995

Source: Demographic and Health Surveys except China (640), El Salvador (652), and India (598)

Region, Country & Year	% Using Any Method	% Using IUDs	% of Contraceptors Using IUDs
AFRICA, SUB-SAHARAN			
Botswana 1988	35	6	17
Burkina Faso 1993	8	1	9
Burundi 1987	9	0	0
Cameroon 1991	16	0	0
Central African Republic 1994–95	15	0	1
Côte d'Ivoire 1994	11	0	3
Ghana 1988	13	1	8
1993	20	1	4
Kenya 1989	27	4	15
1993	33	4	13
Liberia 1986	6	1	17
Madagascar 1992	17	1	3
Malawi 1992	13	0	2
Mali 1987	5	0	0
Mauritius 1985	75	2	3
1991	75	3	4
Namibia 1992	29	2	7
Niger 1992	4	0	0
Nigeria 1990	6	1	17
Rwanda 1992	21	0	1
Senegal 1986	12	1	8
1992–93	7	1	19
Sudan 1989–90	9	1	11
Swaziland 1988	21	2	10
Tanzania 1991–92	10	0	0
1994	20	1	5
Togo 1988	12	1	8
Uganda 1988–89	5	0	0
Zambia 1992	15	0	0
Zimbabwe 1988–89	45	1	2
1994	48	1	2
ASIA & PACIFIC			
Bangladesh 1991	40	2	5
1993–94	45	2	5
China 1988	72	30	42
1992	83	33	40
India 1992–93	40	2	5
Indonesia 1987	51	14	27
1991	50	13	26
1994	55	10	19
Pakistan 1990–91	12	1	8
Philippines 1988	34	2	6
1993	40	3	8
Sri Lanka 1987	62	2	3
Thailand 1987	68	7	10
Vietnam 1988	53	33	62
LATIN AMERICA & CARIBBEAN			
Belize 1991	47	2	4
Bolivia 1989	32	5	16
1994	45	8	18
Brazil 1986	66	1	2
Colombia 1986	67	12	18
1990	66	12	18
Costa Rica 1986	70	8	11
Dominican Rep. 1986	51	3	6
1991	56	2	4
Ecuador 1987	46	11	24
1989	53	12	23
El Salvador 1985	49	4	8
1988	47	2	4
1993	53	2	4
Guatemala 1987	23	2	9
Haiti 1989	10	1	10
Jamaica 1989	55	2	4
Mexico 1987	55	11	20
Panama 1984	58	6	10
Paraguay 1987	38	5	13
1990	48	6	13
Peru 1986	48	8	17
1991–92	59	13	22
Trinidad & Tobago 1987	54	5	9
NEAR EAST & NORTH AFRICA			
Egypt 1988–89	40	17	43
Jordan 1990	35	15	43
Morocco 1987	37	3	8
1992	42	3	7
Tunisia 1988	51	18	35
Turkey 1988	60	14	23
1993	63	19	30
Yemen 1991–92	10	1	12

In most Latin American and Caribbean countries, voluntary female sterilization and oral contraceptives are more commonly used than IUDs. Among recently surveyed countries, the IUD is the most widely used modern contraceptive method only in Peru, where 22% of all contraceptors relied on it in 1991–93 (622), and Bolivia, where 18% of all contraceptors used IUDs in 1994 (653). More than 10% of married women of reproductive age use IUDs in Colombia, Ecuador, Mexico, and Peru (see Table 3).

In sub-Saharan Africa levels of IUD use are generally the lowest in the world, as are overall contraceptive use rates. Among countries with surveys, Botswana has the highest level of IUD use, at 6% of married women of reproductive age (see Table 3).

Developed Countries

Among developed countries IUDs may be most widely used in Europe, where in some countries more than one-quarter of married women of reproductive age relied on IUDs according to surveys in the 1980s (297, 640). Surveys in the 1990s report 15% of married women of reproductive age using IUDs in the Czech Republic and 11% in Slovakia but lower elsewhere— 5% in Belgium, 6% in Germany, and 4% in Romania (640). In Russia 33% of married women age 20–49 surveyed in 1994 used IUDs. IUD users accounted for half of all contraceptive users (585). A recent survey in Kazakstan reported that 40% of married women use IUDs, accounting for two-thirds of all contraceptive use (611). In Canada, the US, Australia, New Zealand, and Japan, no more than about 5% of married women of reproductive age use IUDs (43, 187, 192, 220, 242, 324, 325). IUD use has leveled off or declined in many developed countries (181, 242, 263, 295, 324, 325, 390), in part because voluntary sterilization has become widely available and popular among older women (52, 182, 242, 324, 390).

IUDs in Family Planning Programs

The safety, effectiveness, and acceptability of the currently available IUDs depend partly on the IUD itself but even more on the quality of IUD services. For the best outcome, family planning programs must assure:

- Careful screening of potential IUD users,
- Informative and empathetic counseling,
- Practical clinical training for health care providers, and
- Regular follow-up care and back-up medical care in case of complications.

Family planning programs should offer IUDs along with other methods of contraception and help clients choose the methods that best suit them. Because serious misperceptions about IUDs persist in many places (589), programs need to make every effort to reach the public and providers with accurate information about IUDs.

Screening Potential IUD Users

The IUD is a safe and effective contraceptive method for many women. Like any other method, however, it is better suited for some women than others.

This information can be copied and given to IUD users.

Important Information About the TCu-380A IUD

Very effective, convenient, long-lasting, reversible.

The TCu-380A IUD is one of the safest and most effective family planning methods. It can be used right after giving birth, during breastfeeding, and any other time. It can be taken out if you want to become pregnant.

Little to do once the IUD is in place.

Your IUD works by itself. You do not need to do anything to keep it working.

You may have cramps for the first few days, vaginal discharge or spotting for a few weeks, and somewhat heavier menstrual periods.

You can check the IUD strings to be sure the IUD is still in place. Always wash your hands first. Then, with your finger, you should be able to feel the IUD string in the vagina. Check once a week for the first month. Then check after each menstrual period. If the string feels longer, shorter, or missing, or if you feel something hard, come to the clinic. The IUD may be out of place.

The IUD is safe for most women, but some should not use the IUD.

Pregnant women should not have an IUD put in.

Women who have a sexually transmitted disease (STD) or who think they might get an STD should not use IUDs. People can get STDs if they have more than one sexual partner or their sexual partner has other partners.

If you already have an IUD and now might get a sexually transmitted disease, you should use condoms along with your IUD. Also, think about switching to a different family planning method. The IUD does not prevent sexually transmitted diseases including AIDS.

Please come back...

...For a routine checkup after your next menstrual period, 3 to 6 weeks after the IUD is put in. The IUD is most likely to come out in the first month of use.

...If you have very heavy bleeding or bad pain in the belly, especially with fever, or if you might get or have an STD, if you might be pregnant, or if the IUD might be out of place.

...Any time you have any questions, problems, or concerns. Your family planning provider is always happy to help.

...Any time you want the IUD taken out, for any reason.

You can keep your IUD for at least 10 years.

Your TCu-380A IUD may become less effective after 10 years. It needs to be taken out in _____ _____ [month, year]. A trained family planning provider can take out your IUD. You can get a new IUD at the same time if you want.

Source: Hatcher et al. 1996 (597)

The GATHER Approach

There are six steps to family planning counseling (see **Population Reports**, *Counseling Guide*, J-36, December 1987). The provider can remember the steps using the English word "GATHER."

G—**Greet clients.** The provider greets clients politely and gives them full attention.

A—**Ask clients about themselves.** The provider asks clients about their family planning needs and obtains information that will help the provider advise and inform each client individually.

T—**Tell clients about family planning methods.** The provider lists the available family planning methods and clearly describes those that interest the client—how they work, advantages and disadvantages, and possible side effects. Even clients who immediately express a preference for the IUD or some other method should know of other available methods for future reference and so they can inform friends and family members.

H—**Help clients choose a method.** Some women may have already decided that they want an IUD. Others may want advice and guidance from the provider. In either case the provider helps the woman decide on a safe method that suits her needs and plans. If the method is not appropriate, the provider explains why and helps the client select another method. If there are reasons that another method would be preferable, the provider and client compare the risks and benefits of the IUD and of other contraceptive methods and consider the risks of an unintended pregnancy. The final decision to use an IUD—or any other method—must be an informed choice made by the client. If possible, involving the husband in counseling is a good idea. In an African study husbands' wishes accounted for many IUD removals after postpartum insertion (592).

E—**Explain how to use the IUD.** Once a woman decides to use an IUD, the provider explains:

- When, where, and how it will be inserted,
- The common side effects,
- The slight chance of more serious complications, expulsion, or unintended pregnancy,
- Reasons to return to the clinic or see another provider;
- When a copper or hormone-releasing IUD should be replaced.

Women who understand that mild cramping and bleeding in the days following insertion and heavier menstrual periods while using an IUD are common and usually harmless will be less likely to have their IUDs removed unnecessarily (184, 353). A study in Sri Lanka, for example, found that women who were counseled by specially trained midwives and satisfied IUD users had side effects similar to those among women who received no special counseling. Nevertheless, the women who received special counseling kept their IUDs longer (353). In Egypt women who received counseling were less likely to report common IUD side effects, more likely to seek immediate help when needed, and more likely to use the IUD longer (512). Programs may be able to tailor counseling to help their clients decide about IUD use and to use IUDs with greater satisfaction if they keep track of personal reasons that IUD users give for having their IUDs removed (619).

It is helpful to give clients printed material to take home, particularly a card with the name and picture of the IUD, noting the date of insertion and time for removal (398). (Printed materials can help providers, too. During counseling and screening, flip charts, wall charts, cue cards, and checklists

Health care providers must be familiar with the medical conditions that make another method preferable or that rule out IUD use altogether (see box, pp. 28–29). The health care provider should question the client to find out if she has any of these conditions and, if not, perform a pelvic exam. All clients should be carefully evaluated for clinical signs of sexually transmitted diseases (395, 398) (see box, p. 21). When clients are at low risk of exposure to such diseases, routine lab tests are not necessary (634). If a woman shows signs of STDs, examining fluids under a microscope can help determine appropriate treatment quickly (614).

As part of the counseling process (see above), the health care provider also should seek to find out from the client whether she and her partner have a mutually faithful sexual relationship (to assess her potential exposure to STDs). Since women may find it difficult to speak openly about their sexual behavior or that of their sexual partners, family planning programs need to look for other ways to tell women about STD risk before they meet one-on-one with a provider to choose a method. Then women can decide for themselves whether an IUD suits them. For example, in the clinic a provider can address a group of clients to describe family planning methods, or radio broadcasts can describe who are good candidates for different methods.

IUDs can be inserted postpartum within 48 hours or postabortion within seven days or, after four weeks postpartum, at any time the provider can be reasonably sure that the woman is not pregnant. There are several additional situations in which postpartum or postabortion IUD insertion is not appropriate, however:

- Prolonged rupture of membranes (greater than 24 hours);
- Signs of abdominal or pelvic infection, including fever;
- Intrapartum or postpartum hemorrhage that continues after complete emptying of the uterus;
- Bleeding problems; or
- Trauma to the genital organs (487, 634).

Counseling

Counseling is an essential part of every family planning provider's role. Informative and empathetic counseling

To Counseling About IUDs

help providers maintain accuracy and remember what to cover, and they help clients understand.)

The client should be told if and how she will be notified when it is time for the IUD to be replaced. The family planning program should keep records for each IUD user showing the type of IUD and when it was inserted. These records should be used to answer questions from women who have forgotten when to have their IUDs replaced and to follow up users when the time for replacement approaches.

R—Return for follow-up. When a woman has an IUD inserted, she and the provider should plan for a follow-up visit three to six weeks later, after her next menses. While no further scheduled follow-up visits are required for the safe use of the IUD, the woman should be strongly encouraged to return whenever she has questions or problems or if she wants the IUD removed (319, 398). Also, she should return as soon as possible if she notices any warning signs (see box, p. 25). The provider should be sure that the woman knows both when and where to seek medical care (164).

At the follow-up visit three to six weeks after IUD insertion, the provider should ask about any menstrual problems, pain, or expulsion. A pelvic examination can be performed not only to check for the IUD strings but also to look for signs of pelvic infection, which is most likely to occur within the first weeks after insertion (see p. 16) (7, 82, 436). The provider also should reassure the client about any common side effects, remind her of the warning signs of IUD complications, and address any other concerns or questions she might have.

Research has demonstrated that there is no reason to *require* IUD users to return to the clinic repeatedly at regular intervals when they are having no problems. In a study of more than 11,700 routine follow-up clinic visits by IUD users, only 72 visits detected a need for IUD removal that the clients themselves would not have recognized (601). Avoiding unnecessary routine visits saves resources to provide important services to other clients. IUD users are likely to benefit more if they are made to feel welcome to return at any time that they have problems, questions, or concerns.

To handle serious complications, programs should make arrangements with a referral medical center. The center should be staffed with surgeons and gynecologists and have facilities for diagnostic and surgical procedures (436).

Health care providers should remove copper-bearing and hormonal IUDs when the IUD reaches the end of its approved lifespan if it has not been removed sooner at the woman's request or for medical reasons. A new IUD can be inserted immediately afterwards, without any waiting period, if a woman wants to continue using an IUD. If a woman is having no problems, the *Lippes Loop* and other nonmedicated IUDs do not need to be removed until menopause (7, 162). After menopause removal may be difficult because the uterus shrinks and narrows (179). Of course, removal should be available promptly whenever a woman requests it and whatever her reason.

When a new IUD is being introduced, women using a different IUD may want to replace it with the new one. Because most IUD complications and pregnancies are most common just after insertion, changing IUDs unnecessarily should be discouraged. A woman should be encouraged to wait until her current IUD reaches the end of its approved lifespan or until it must be removed for other reasons.

helps clients make the best choice of a contraceptive method and helps them use the method safely, effectively, and with satisfaction (see **Population Reports**, *Counseling Makes a Difference*, J-35, November 1987). For IUD users, good counseling is as important as careful screening. As with every other family planning method, new users need to know what problems they might encounter. In particular, women using IUDs should understand that menstrual bleeding is likely to increase but this is seldom dangerous. Good counseling is the key to satisfied use.

Where postpartum insertion of IUDs is available, it should ideally be discussed, along with other family planning options, during the woman's prenatal care. Then, if she chooses an IUD, an experienced provider can place the IUD in the uterus immediately after delivery of the placenta. Some programs counsel women about postpartum IUD insertion and perform the insertion during the first 48 hours after delivery (535). Providers should not try to counsel women or expect them to decide on a contraceptive method during labor.

Training for Health Care Providers

Safe and effective IUD use requires competent, well-trained health care providers. Training must cover how to insert and remove IUDs and how to communicate with clients.

Clinical training. To be effective, training must include practical experience in performing pelvic exams, IUD insertions, and removals (319, 436). The World Health Organization (WHO) advises that most trainees need to perform at least 50 to 60 pelvic examinations and 10 to 15 IUD insertions under supervision before they have the skill and self-confidence to practice alone (126). The training should be flexible, however, to allow for as many insertions as needed. Training also should emphasize the management of side effects. Practical training should be done in small groups to assure adequate supervision (126, 287). Special training is needed for postpartum IUD insertion. When health care providers return to their jobs, they need to continue inserting and removing IUDs regularly in order to maintain their skills (287, 319).

WHO Scientific Group Updates Eligibility Guidelines for Copper IUDs

A World Health Organization (WHO) scientific working group recently developed up-to-date recommended eligibility criteria for all major contraceptive methods including IUDs (565). The group based its recommendations on an assessment of research findings. To date, lists of eligibility criteria, or contraindications, in IUD training protocols have differed widely (574). The consensus reached by the WHO group of scientists from around the world should help resolve these conflicts.

The WHO scientific group classified medical conditions into four categories. In situations where doctors and nurses are not available to assess specific cases, these four categories can be simplified into two categories—conditions in which the method is safe and effective, and conditions in which the method should not be used.

These criteria refer to a client's characteristics or known preexisting medical conditions. For the most part, these characteristics or conditions can be detected by asking the client questions or, in the case of IUDs, making observations during the pelvic examination. Other physical examination or laboratory tests generally are not necessary.

Eligibility criteria for *starting* use of a copper-bearing IUD, as categorized by the WHO scientific working group, are as follows:

Safe and Effective to Use Copper-Bearing IUD

WHO Category 1:

*These conditions **do not restrict** use of copper-bearing IUDs:*

1. Had pelvic inflammatory disease (PID) in the past, has been pregnant since, and is not now at risk of STDs.
2. Past ectopic pregnancy.
3. Irregular menstrual patterns *without* heavy bleeding.
4. Just had an IUD removed because its period of effectiveness had ended.
5. IUD was expelled and client wants to try again.
6. Just had first-trimester abortion or miscarriage and no infection or risk of infection.
7. Breastfeeding.
8. Previous cesarian section.
9. Diabetes.
10. Current or past cardiovascular diseases or cardiovascular problems caused by diabetes; high blood pressure; stroke; deep or superficial venous thrombosis; pulmonary embolism; valvular heart disease without complications; ischemic heart disease; hyperlipidemia.
11. Headaches, including severe headaches and migraines.
12. Current or past breast cancer or benign breast disease.
13. Current or past liver or gallbladder disease.
14. Malaria; schistosomiasis; tuberculosis (other than pelvic tuberculosis); viral hepatitis.
15. Obesity.
16. Smoking.
17. Epilepsy.
18. Cervical intraepithelial neoplasia or cervical ectropion.
19. Thyroid conditions.
20. History of preeclampsia.
21. Benign ovarian tumors including cysts.

WHO Category 2:

*Advantages generally outweigh theoretical or proven disadvantages, and copper-bearing IUDs **generally can be provided** without restriction in these conditions:*

1. Less than 48 hours postpartum.
2. Had pelvic inflammatory disease in the past, has *not* been pregnant since, and is not now at risk of STDs.
3. Childless or age 20 or younger. IUD expulsion more likely than in older women or women with children.
4. Heavy or prolonged menstrual bleeding *without clinical signs of anemia.*
5. Severe menstrual cramps.
6. Iron-deficiency anemia.
7. Uterine fibroids, very narrow cervical canal, cervical lacerations, or other anatomical abnormality that does *not* distort the uterus.
8. Vaginitis *without* purulent cervicitis.
9. Endometriosis.
10. Valvular heart disease *with complications*. (The woman should take antibiotics before IUD insertion.)
11. Sickle cell disease.
12. Thalassemia.
13. Just had a second-trimester abortion.

Should Not Use Copper-Bearing IUD

WHO Category 3:

*Conditions in which copper-bearing IUDs are **usually not recommended**, but a doctor or nurse may make an exception in individual cases:*

1. High risk for STDs (that is, currently has or likely will have more than one sexual partner or a partner who has more than one partner).
2. Heavy menstrual bleeding *with* clinical signs of anemia.
3. Between 48 hours and four weeks postpartum.
4. HIV infection or AIDS or high risk for HIV infection.
5. Benign trophoblast disease.

WHO Category 4:

*Conditions that **rule out use** of copper-bearing IUDs:*

1. Pregnancy.
2. Active STD (including purulent cervicitis) or PID now or in the last three months.
3. Sepsis following childbirth or abortion.
4. Until evaluated, abnormal vaginal bleeding that suggests a serious medical condition.
5. Severely distorted uterine cavity that prevents proper IUD insertion.
6. Cervical, endometrial, or ovarian cancer awaiting treatment; malignant trophoblast disease.
7. Pelvic tuberculosis.

In general, any woman who does *not* have a condition in WHO Categories 3 or 4 can use a copper-bearing IUD.

The best training is competency-based—that is, each trainee is trained until competent to provide IUD services. The competency-based approach recognizes that different providers will need differing amounts of practice before they are competent. The approach also requires training programs to recognize that some providers will not achieve competence during a training course and therefore cannot be certified as competent (571).

The value of the competency-based approach for training in IUD insertion has been demonstrated. The Johns Hopkins Program for International Education in Reproductive Health (JHPIEGO) has developed competency-based training for trainers of IUD insertion (614). In a comparative study in Thailand, a higher percentage of the midwives who learned from these trainers achieved competency during the training course than midwives whose trainers were trained by conventional techniques. Also, the clients of these midwives were more satisfied with the services that they received, and the training cost less. Among the key elements of the JHPIEGO approach are standardization of the way the trainers themselves provide IUD services, practicing insertion on a pelvic model until competent before practicing with actual clients, and assessing clinical skills before the course to ascertain where each trainee needs to improve. Even with the conventional training, the Thai midwives needed an average of just 6.5 practices with clients. With the new training approach, however, midwives were competent after an average of only 1.6 practices with clients, and 98% of the midwives achieved competence after only three practices with clients (571).

Thorough training in IUD insertion along with careful counseling and follow-up lead to longer IUD use. In areas of Sri Lanka where doctors and public health midwives received refresher training that emphasized insertion technique, counseling, and follow-up, rates of discontinuation due to expulsion or complications were significantly lower than where there was no special training (107, 353).

Training in communication. As noted, family planning providers who offer IUDs must be able to counsel clients accurately and empathetically. To do so, they themselves need both training in counseling techniques and accurate information about IUDs. Providers themselves may believe some of the false rumors about IUDs—that the IUD can travel to the heart or brain, or that the IUD string can become wrapped around a man's penis during intercourse, for example. Effective training identifies trainees' misperceptions and addresses then directly. The result can be a new and positive attitude toward IUDs (593). Program managers, ministry officials, and other decision-makers also need updates on IUDs. Without such updates, they may not be aware that recent scientific findings show the modern IUD to be a safe, highly effective, and comfortable method for many women.

The role of nurses, midwives, and paramedics. In Chile, China, Ecuador, Ghana, Indonesia, Nigeria, Sweden, Thailand, Turkey, the US, and many other countries, nurses, midwives, or paramedical workers routinely insert IUDs (51, 203, 268, 270, 351, 429, 436, 448, 482). Studies in a number of countries have found that with appropriate training these health care personnel provide safe and effective IUD services (18, 35, 268, 293, 313, 353, 436, 439, 448, 482, 484). A WHO study in the Philippines and Turkey, for example, found that assistant nurse-midwives and doctors

Beryl Goldberg

When providers are well trained in clinical skills and counseling, IUD effectiveness and safety are maximized, and clients are most satisfied.

inserting IUDs were equally able to identify eligibility criteria and complications of IUD use. Furthermore, rates of expulsion, pregnancy, medical removal, and continuation were similar in the clients of the two types of providers (439). A Brazilian study also found no significant differences in complication or continuation rates between women randomly assigned for IUD insertion to a doctor or to a nurse (35). Where nurses, midwives, or paramedical workers provide IUD services, doctors should be readily available for supervision, consultation, and, when necessary, diagnosis and treatment of complications.

Community health workers, trained traditional midwives, and other briefly trained health care personnel also can play an important role in IUD services. With appropriate training they can tell women about IUDs and other methods and help in counseling about routine side effects, recognizing complications, and referring women for medical care when necessary (125, 436). Satisfied IUD users also can be helpful in spreading the word about IUDs. In Sri Lanka, where midwives were teamed with satisfied IUD users, they recruited an average of two-thirds more new clients than midwives alone (107, 353).

Now that long-lasting second-generation copper IUDs have become available and research has identified the appropriate users, attention is focusing more on improving the way that programs provide IUDs. As with all family planning methods, it is essential to help the client decide whether the IUD suits her needs or, if the IUD is not medically appropriate, to encourage her to choose another method. At the same time, well-trained providers are needed to insert and remove IUDs properly and to help whenever the user has a problem. When the right women are using IUDs with the right program support, the result is effective, safe contraception and satisfied users.

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