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*New Developments in
Intrauterine Contraception*

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ASSOCIATION OF REPRODUCTIVE HEALTH PROFESSIONALS



September 2004

New Developments in Intrauterine Contraception

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Intrauterine Contraception: Filling an Unmet Need

Intrauterine contraception (IUC), which includes the use of various intrauterine devices (IUDs) and the levonorgestrel intrauterine system (LNG IUS), is as effective as sterilization, is not dependent on user motivation for effectiveness, and, according to a July 2004 ARHP survey, is one of the highest-rated methods for patient satisfaction. Millions of women throughout the world use IUC. In the United States, IUC use has been hampered by several factors, including limitations to access and persistent myths about associated adverse events. While fading, these myths still exist, restricting more widespread adoption of IUC.

With this issue of *Clinical Proceedings*[®], we hope to educate providers so they can feel more comfortable offering intrauterine contraception as a useful and effective option for their patients.

My sincere thanks to the members of our advisory committee for their investment of time and expertise: David Grimes, MD; Kirtly Parker Jones, MD; Susan Wysocki, RN-C, NP; and Chris Knutson, MN, ANP.

Wayne C. Shields
ARHP President and CEO

LEARNING OBJECTIVES

After completing this *Clinical Proceedings*, participants will be able to:

1. Describe the mechanisms of action and effectiveness of the two intrauterine contraceptives available in the United States.
2. Compare and contrast the copper-T IUD and the LNG IUS.
3. List seven myths regarding IUC and identify correct information.
4. Identify appropriate candidates for IUC.
5. List eight counseling topics to discuss with patients considering IUC.
6. Discuss the steps and timing of IUC insertion, recommended follow-up, and the management of associated complications and side effects.

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INTRODUCTION

Almost 50 percent of pregnancies in the United States are unintended and about half of these end in elective abortion.¹ The proportion of unintended pregnancies is high not only among adolescents but also among older women—over 40 percent in those aged 35 to 39.¹ Due to these high rates, the Association of Reproductive Health Professionals (ARHP) advocates for the availability of as many safe and effective contraceptive methods as possible. For many women, oral contraceptives are an excellent choice for pregnancy prevention. But the misuse or discontinuation of oral contraceptives—a method for which effectiveness is dependent on the degree to which it is used correctly and consistently—leads to over 1 million unwanted or mistimed pregnancies each year in the United States.² One study found that 30 percent to 51 percent of women missed taking their oral contraceptives at least three days per month.³ Clearly there is an unmet need for highly effective contraceptive methods that are “forgettable,” for which the default option is pregnancy

prevention. Examples of such methods include intrauterine contraception, hormonal implants, and surgical and transcervical sterilization. With these methods, action is required to discontinue or reverse protection but not to continue it. This monograph features the latest information regarding IUC in an effort to increase understanding of its use as a contraceptive option.

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USE OF INTRAUTERINE CONTRACEPTION IN THE UNITED STATES

Intrauterine devices (IUDs) were originally developed in Germany in the 19th century as vaginal pessaries. These rigid metal devices, introduced in the pre-antibiotic era, were associated with significant discomfort and serious infection. The design was improved over several decades, but it was not until 1959 that a report by Ishihama and Oppenheimer on their clinical experience with IUDs inspired interest in the devices and sparked the creation of several different types of IUDs.¹

For a variety of reasons, the demand for IUDs has waned over the past three decades in the United States, and fewer providers have been trained in the insertion and management of IUDs. Thirty years ago, nearly 10 percent of US women used intrauterine contraception (IUC) but less than one percent currently do, as shown in Figures 1 and 2.²

Meanwhile, intrauterine contraception is an important contraceptive method in many parts of the world outside the US, and research to develop better device designs is ongoing. As shown in Figure 3, worldwide use of IUC is much higher in Asia, Europe, and Latin America than in North America. In Germany and Denmark over 20 percent of women use IUC. In Mexico, about the same proportion of women use IUC, and the continuation rate

is 75 percent at one year.² In Vietnam and Kazakhstan over 60 percent of married women use IUC.⁵ Currently, there are over 100 million IUC users in the world.⁵

Several factors are responsible for the lower use of IUC in the United States than in other countries, including provider and patient misconceptions, a paucity of trained and willing providers able to insert the devices, provider concerns about litigation, and restrictions imposed by product labeling.

FIGURE 1. Use of Different Contraceptive Methods by Age Groups in the US³

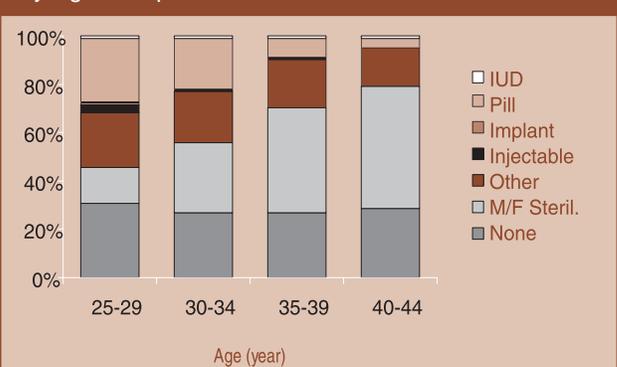
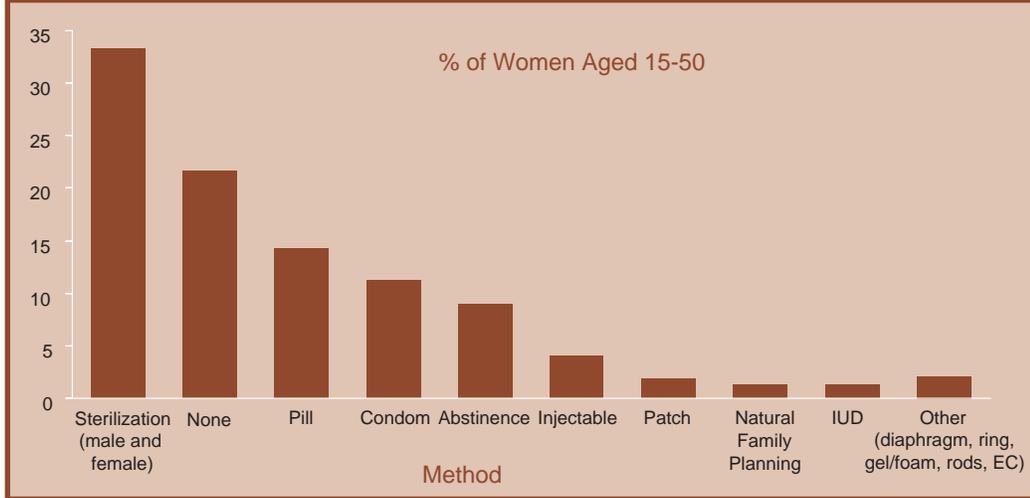




FIGURE 2. Contraceptive Use and Nonuse in the United States, 2003⁴



United Kingdom found that many exaggerated the disadvantages and understated the advantages of the IUD.⁶ In addition, a majority of the US texts inaccurately reported an increased risk of pelvic inflammatory disease (PID) and ectopic pregnancy associated with the device. There is also evidence that information obtained

PROVIDER AND PATIENT MISCONCEPTIONS ABOUT INTRAUTERINE CONTRACEPTION

In the past there were many misconceptions about the safety of IUC that significantly limited its use. These myths, some of which are listed in Table 1, have become somewhat less powerful over the past two to three years, but they still affect IUC use. This monograph will provide data disproving these myths.

The persistence of such myths stems in part from misinformation presented in the professional and the lay print and electronic media. A 2002 review of the accuracy of information about copper-containing IUDs in obstetrics and gynecology textbooks from the United States and the

from the Internet is misleading or inaccurate. A review of consumer-oriented websites that provide information about contraceptive options found that over half stated that IUC increases the risk of PID; about 40 percent of these websites reported that the risk of ectopic pregnancy is increased with IUC.⁷ Data from a survey of provider-oriented sites, which are less likely to present this misinformation, indicated that about 27 percent stated an association between IUC and PID and 23 percent an association between IUC and ectopic pregnancy.⁷

Misinformation is also present in the lay press. In one study, the characteristics deemed most important by the women interviewed—safety, ease and convenience, and effectiveness—were generally not seen to be characteristics of IUC; only 21 percent, 46 percent, and 31 percent of respondents, respectively, felt that these features closely describe IUC.⁸ Interestingly, younger subjects and Hispanic subjects, especially those born outside the US, were more likely to be interested in future IUC use than other groups. These negative patient perceptions exist despite the fact that IUC use is associated with very high user satisfaction ratings, as shown in Table 2.

FIGURE 3. Worldwide Use of Intrauterine Contraception

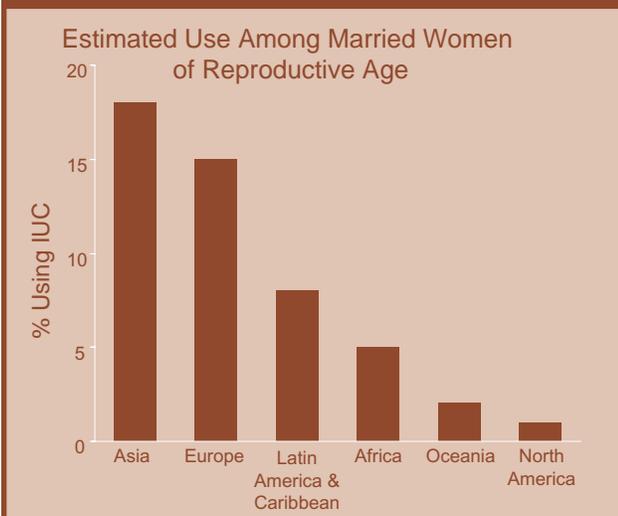


TABLE 1. Myths About Intrauterine Contraception

- Acts as an abortifacient
- Causes ectopic pregnancies
- Causes pelvic inflammatory disease (PID)
- Causes infertility
- Cannot be used in nulliparous women
- Needs to be removed for PID treatment
- Needs to be removed if actinomyces-like organisms are seen on Pap test



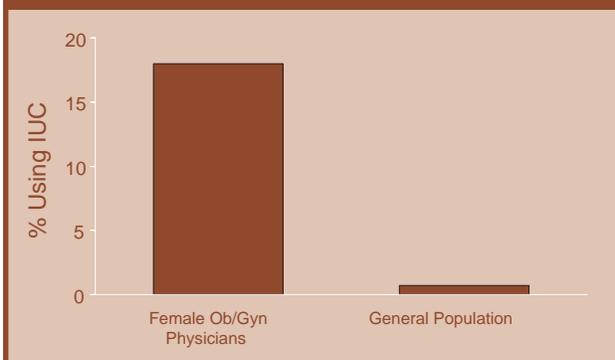
TABLE 2. Myths About Intrauterine Contraception

Method	Percentage of Women Who Reported Being “Very Satisfied” or “Somewhat Satisfied” with Current Contraceptive Method
IUDs	99%
Implants	92%
Oral contraceptives	91%
Cervical cap	90%
Male/female sterilization	85–89%
Diaphragm	78–84%

PAUCITY OF TRAINED AND WILLING PROVIDERS TO INSERT DEVICES

Despite the persistence of misinformation, providers generally have a positive perception of IUC. On a personal level, female obstetrician/gynecologists are more likely than the general population of US women to use IUC, as shown in Figure 4.¹⁰ In addition, a 2002 survey of members of the American College of Obstetricians and Gynecologists (ACOG) documented a positive attitude about IUC, with 95 percent agreeing the method is safe and 98 percent that it is effective.¹⁰ However, even though 80 percent of respondents had inserted IUC in the past year, only 21 percent of those providers had inserted more than 10 devices.¹⁰ The average number of devices inserted per provider was just seven. Thirteen percent of respondents reported they had never inserted a device during training. There was no correlation between the number of IUC devices inserted during training and the number inserted in the last year. The authors of the study believed that IUC underuse was related more to overly restrictive selection criteria than to lack of training in insertion technique.

FIGURE 4. Use of IUC by Female Ob/Gyns and by All Women in the United States^{11,12}



PROVIDER CONCERNS ABOUT LITIGATION

The 2002 survey of ACOG members found a correlation between the degree to which respondents believed that IUC is associated with PID and a lower rate of insertion.¹⁰ There also was a statistically significant correlation between fear of litigation and a lower number of IUC insertions in the previous year. The study authors suggest that a persistent belief that IUC causes PID and thus increases litigation risk is a primary reason that IUC is underused in the United States. This concern has not been substantiated by reviews of litigation experience—most lawsuits regarding IUC have been product liability suits against manufacturers rather than professional liability suits against providers.^{13,14} Between 1988 and 1996 the Planned Parenthood Risk Management Group was notified of approximately 125 events per year that were involved IUC, the majority of which were minor problems.¹⁵ An analysis of earlier claims against Planned Parenthood found that only 18 (10 percent) involved IUC and only two of those resulted in unfavorable settlements that were related to failure to diagnose and treat PID rather than to IUC use itself.¹⁶ Providers can reduce the risk of litigation by providing thorough patient counseling, discussing the risks and benefits, ensuring proper insertion and follow-up, and obtaining written informed consent.

RESTRICTIONS IMPOSED BY PRODUCT LABELING

Product labeling for IUC may restrict more widespread usage. The prescribing information for the two types of IUC available in the United States recommends use only in women who have at least one child, no history of PID, and no history of ectopic pregnancy.^{17,18} However, based on current evidence, nulliparous women should not be excluded from IUC use based on their parity alone.^{19,20,21} Clinicians, particularly nurse practitioners or others practicing with protocols, may feel hesitant about or be restricted from providing “off-label” prescriptions for IUC devices to nulliparous women, when IUC may be the best choice for a particular patient. The prescribing information incorrectly implies that use in nulliparous women is unsafe and therefore imposes unnecessary restrictions that prevent some clinicians from offering this method to appropriate candidates.

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CHARACTERISTICS OF INTRAUTERINE CONTRACEPTION

Intrauterine contraception (IUC) is a contraceptive method that provides safe long-term protection, is immediately and highly effective, and allows for rapid return of fertility. Users are very satisfied with IUC. However, IUC affects menses—which may be a problem for some women—involves an initial cost, and requires provider insertion and removal. This section will discuss these advantages and disadvantages, as well as the features, mechanisms of action, noncontraceptive health benefits, and cost-effectiveness of the IUC available in the United States.

METHODS AVAILABLE WORLDWIDE

A variety of IUC products are available for use outside the United States, as shown in Figure 5, including copper-containing devices in a range of shapes and sizes, a nonmedicated polyethylene device, a progesterone-releasing device, and a levonorgestrel-releasing device.¹

METHODS AVAILABLE IN THE US

Only two types of IUC are currently available in the United States: the copper-T intrauterine device (IUD) and the levonorgestrel-releasing intrauterine system (LNG IUS), which are shown in Figure 6. The copper-T IUD is marketed as ParaGard® T 380A by FEI Women's Health LLC. It was approved by the Food and Drug Administration (FDA) in 1984 and became available for use in 1988. The device consists of a T-shaped polyethylene frame that is wound with copper wire around the vertical stem and has copper bands on the lateral arms. It is equipped with a monofilament polyethylene thread that is tied through the bulb, with the two ends of the thread available for use during removal. The device also contains barium sulfate to make it radiopaque. The ParaGard T 380A is approved for up to 10 years of use, although limited data support its effectiveness for at least 12 years.^{2,3}

The LNG IUS, marketed by Berlex Laboratories as Mirena®, consists of a T-shaped polyethylene frame with a reservoir around the vertical stem that contains levonorgestrel. It was approved for use by the FDA in 2000. Initially the LNG IUS releases levonorgestrel at a rate of 20 µg per day. This rate decreases to approximately half that rate by five years. A monofilament thread is attached to a loop at the end of the vertical stem, with two ends of the thread available for use during removal. The device also contains barium sulfate to make it radiopaque.

It is indicated for up to five years of use, although limited data support its effectiveness for at least seven years.^{4,5}

MECHANISMS OF ACTION

Despite lingering myths to the contrary, IUC does not act as an abortifacient.⁶ Instead, IUC acts primarily prior to fertilization by affecting sperm motility and ova development. Two types of studies substantiate this mechanism of action: assays for serum human chorionic gonadotropin (hCG) levels and evaluations of washings from the vagina and endocervix. In one study, the serum beta hCG levels in 30 IUC users were monitored for 30 months; there were no changes in these levels suggesting early pregnancy.⁷ In another study, washings from the uterus and uterine tubes of women undergoing surgical sterilization were examined at midcycle.⁸ Ova were recovered from the uterine tubes of 39% of IUC users (30% of copper-containing IUD users) and 56% of the women who were not using IUC. Of the eggs recovered from women who had intercourse prior to the procedure, 64 percent showed a lack of normal preimplantation development, compared with 19 percent of the eggs from women not using a device.⁸

These findings undermine the theory that the primary effect of IUC is creation of an inflammatory endometrial environment that prevents implantation. Instead, inhibition of implantation appears to be a secondary mechanism of IUC, one that may explain why copper-containing IUDs are so effective when used as emergency contraception.⁹ According to established guidelines, women should be informed that the primary mechanism of action of IUC is prevention of fertilization.¹⁰

Copper-containing IUDs reduce the motility and the viability of sperm and the development of ova. Research has shown that sperm counts found in the cervical mucus and uterine tube are much lower in women using IUDs than those in nonusers.¹¹ Regular midcycle contractions are important for the rapid transport of sperm. A clinical study found that women using copper-containing IUDs had uncoordinated contractions, which suggests that the device may act by hindering sperm transport.¹² In addition to its primary actions on the sperm and ova, the copper-containing IUD also produces an inflammatory environment in the endometrium.¹¹

The primary mechanisms of action of the LNG IUS are thickening of the cervical mucus, which prevents the sperm from gaining access to the uterus and uterine tubes,

FIGURE 5. Methods of IUC Outside the United States



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



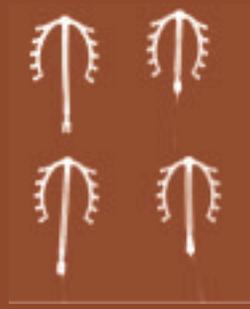
**TCu-200 and T
Cu-200B**



**Nova T and
CuNovaT**



Lippes Loop



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



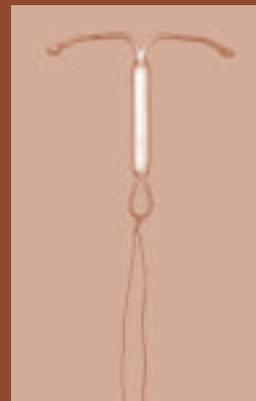
TCu-220C

Photos provided by the Population Council

FIGURE 6. Intrauterine Contraception Devices Available in the United States



Copper T 380A



LNG IUS

Photos provided by the Population Council



and inhibition of sperm mobility and function. One study found that the cervical mucus weight increased significantly in women using the LNG IUS.¹³ In addition, the endometrium in users of the LNG IUS shows glandular atrophy, decidualized stroma, and inflammatory changes. As with copper-containing IUDs, inhibition of implantation appears to be a secondary mechanism of action of the LNG IUS.¹⁴ Indeed, the low ectopic pregnancy rate relative to intrauterine pregnancy rate suggests that an anti-implantation effect is not the primary contraceptive mechanism of action of the device.

EFFECTIVENESS

IUC requires little patient action for its effect, so typical failure rates and failure correct and consistent use failure rates are similar.¹⁵ The copper-T IUD has a failure rate of 0.6 to 0.8 per 100 women per year.¹⁵ The LNG IUS also is highly effective at preventing pregnancy, with a failure rate of about 0.6 per 100 women per year.¹⁶ IUC is as effective as female sterilization, which has a failure rate of about 0.5 per 100 women in the first year and a cumulative rate of about 2.0 per 100 women at 10 years.^{17,18} Thus, IUC can be considered “reversible sterilization.”

DISCONTINUATION RATE

Pooled data of an international World Health Organization (WHO) study and a US industry-sponsored study showed that about 92 percent of women using the ParaGard T380A continued use at one year.² The most common reasons for discontinuation were bleeding and/or pain (3.4 percent) and expulsion (2.3 percent). A 2002 study reported a continuation rate for the LNG IUS of about 66 percent at two years.¹⁶ Expulsion (6.6 percent), oligomenorrhea or amenorrhea (9.3 percent), pain (6.6 percent), and personal reasons (10.8 percent) were the most common causes of discontinuation. A longer-term comparison study found that the cumulative continuation rate at seven years was slightly higher for the copper-containing IUD than for the LNG IUS (29.4 percent versus 24.9 percent).⁵ The most common reason for discontinuation was amenorrhea. Other sources list similar one-year continuation rates for the LNG IUS and the copper-containing IUD at 81 percent and 78 percent, respectively.¹⁷

SAFETY

Adverse events associated with IUC use include menstrual effects, expulsion, and uterine perforation. Other potential risks previously thought to be associated with IUC use include pelvic inflammatory disease (PID), ectopic pregnancy, and infertility. Concerns about these risks are largely unwarranted, however, because they were based on

the data found in outdated, poorly designed studies.

Concerns about the use of IUC by nulliparous women or by those who have human immunodeficiency virus (HIV) infection may need to be reexamined.

Menstrual effects. The two types of IUC available in the United States have significantly different effects on menstrual flow. The copper-containing IUD increases the duration and amount of menstrual flow, which increases the amount of blood loss by about 50 percent.^{19,20} In fact, the most common reason for removal of copper-containing IUDs is menstrual abnormalities.¹⁰ In contrast, the LNG IUS reduces menstrual flow, often leading to amenorrhea, which may be considered an advantage by some women. During the first three to six months after insertion of the LNG IUS, bleeding may be irregular and the number of days with bleeding or spotting may increase from baseline. Thereafter, bleeding generally decreases, to the extent that about 50 percent of users have developed amenorrhea by 12 months after insertion.¹⁶

Expulsion. Expulsion is rare, occurring in only 5% of users, but the most likely cause of IUC failure. Expulsion is most common within the first three months after insertion.¹⁰ The risk increases with nulliparity, severe dysmenorrhea, and abnormal menstrual flow.²¹ The risk of expulsion is also higher—in the range of 11 percent to 25 percent after 12 months of use—after immediate postpartum insertion, defined as insertion that occurs more than 10 minutes but less than 48 hours after the delivery of the placenta.²² Immediate postpartum insertion is associated with a higher risk of expulsion than the risk for insertion at times unrelated to pregnancy, but it is associated with a lower risk than for cases of delayed postpartum insertion.²³ The risk of expulsion is also high after second-trimester abortions—in the range of 20 percent to 50 percent, depending on the device.²⁴ In addition, first-trimester abortion is associated with a risk of expulsion similar to the baseline risk of about 5 percent.²⁴ Women may not notice an expulsion, leaving them at risk for unintended pregnancy.

Uterine perforation. Uterine perforation is a rare complication of IUC, occurring approximately once every 770 to 1600 insertions.¹¹ Perforation generally occurs at insertion, when a portion of the device becomes embedded in the uterine wall. Available evidence suggests that the risk of serious complications from perforation is low and that surgical intervention is rarely required.¹⁰

Pelvic inflammatory disease. Early observational studies reported a link between intrauterine contraception and PID. These studies were flawed, however, by use of inappropriate comparison groups, diagnostic bias in the form of overdiagnosis of infection in IUD users, and lack of controls for confounding factors (such as the number of sexual partners). One study found a tenfold increase in

risk of salpingitis among IUD users.²⁵ When these data were reanalyzed using an appropriate comparison group and excluding users of the Dalkon Shield, which had a design flaw associated with increased infection risk, the relative risk of PID dropped to 1.8, a level that could be explained by residual bias and confounding.²⁶

More recent and better designed studies have not confirmed any large increase in PID risk in IUC users. Research by WHO has shown a small increase in PID risk that is confined to the first 20 days after insertion which most likely is caused by endometrial contamination at the time of insertion.²⁷ Substantial evidence from trials of various device designs suggests that any increase in risk after the first month is small.²⁸ Other research has established that the risk of PID is associated with a woman's underlying risk of sexually transmitted infection (STI), not with IUC use.²⁹ More specifically, women who have multiple sexual partners have a higher risk of infection associated with the insertion but not with the prolonged use of IUDs, and populations with a low risk of STI have a low incidence of upper genital tract infection.³⁰

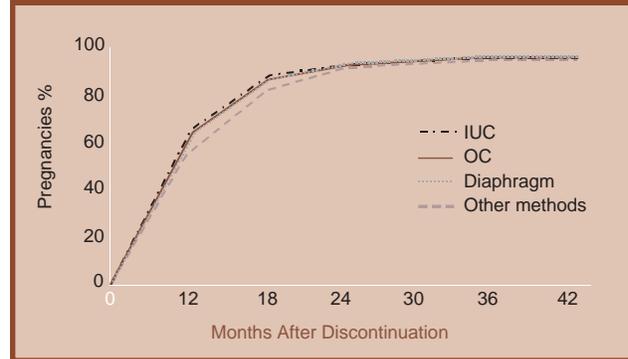
Ectopic pregnancy. IUC does not increase the risk of ectopic pregnancy; it actually reduces the risk of both intrauterine and ectopic pregnancy.¹⁰ However, a higher proportion of pregnancies are ectopic for IUC users than for nonusers because IUC offers less protection against ectopic than intrauterine pregnancies.¹¹ A long-term study of women using copper-containing IUDs found an ectopic pregnancy rate of 0.09 per 100 women at one year and a cumulative 10-year ectopic pregnancy rate of 0.89 per 100 women.³¹ One study of LNG IUS users found an ectopic pregnancy rate of 0.045 per 100 women at one year and 0.22 per 100 women at five years.³²

Infertility. In the past, the presumed association between IUC and PID led to a concern about an increased risk of infertility. This concern appears to be unfounded. A case-control study found that tubal infertility in nulliparous women was not linked to a history of IUC use but was highly associated with the presence of antibodies to chlamydia.³³ After a review of the available evidence, the WHO reported that the majority of studies investigating return to fertility after IUD use have been reassuring.³⁴ A study of women using copper-containing IUDs found that 89 percent of the women who desired pregnancy had become pregnant by one year after removal.³⁵

Return to fertility appears to be unaffected by IUC use. A prospective study in Norway examined the conception rate after five years of use and subsequent removal of copper-containing IUDs.³⁶ Within 24 months, 72 women had conceived, one woman needed an infertility evaluation, and 74 women did not desire pregnancy or had not conceived. Within 39 months, all 97 women who

desired pregnancy had conceived. As shown in Figure 7, the rate of fertility return after discontinuation of IUC is similar to the rate after discontinuation of other forms of contraception.

FIGURE 7. Fertility Rates After Discontinuation of Contraception³⁷



Use in nulliparous women. As discussed above, in years past it was believed that IUC use by nulliparous women was associated with an increased risk of infertility. Indeed, the current product labeling for the devices available in the United States continues to recommend use only by women who have had at least one child.^{4,2} However, recent studies suggest that this restriction may be unnecessary. A four-year study of copper-containing IUD users found that the failure and expulsion rates were lower for nulliparous than for parous women. The Pearl index for pregnancy among nulliparous women was 1.55 per 100 women-years compared with 2.55 per 100 women-years for parous women. The Pearl index for expulsion among nulliparous women was 2.15 per 100 women-years; for parous women the Pearl index was 2.55 per 100 women-years.³⁸ There were no cases of PID or infertility among the nulliparous women. According to the medical eligibility criteria that the WHO has established for contraceptive use, nulliparity is considered a condition for which the advantages of using IUC generally outweigh the theoretical or proven risks.¹⁵

Use by HIV-positive women. In the past, use of IUC by women who have been diagnosed with HIV infection was not recommended because of theoretical concerns about increased rates of PID and female-to-male HIV transmission.¹⁰ However, recent research suggests that IUC may be safe for use by carefully screened HIV-positive women. Researchers followed women who were at low risk for STIs after IUC insertion at two family-planning clinics in Kenya.³⁹ There was no difference in overall or infection-related complications among women who had been diagnosed with HIV infection and those without infection. A follow-up study found no difference between the rate of cervical shedding of HIV DNA at the



time of IUC insertion and at evaluation four months later.⁴⁰ Prospective studies have shown no increase in female-to-male transmission or increase in viral shedding with IUC use.⁴¹ Clinical guidelines from the Faculty of Family Planning and Reproductive Health Care Clinical Effectiveness Unit recommend that HIV-positive women be offered IUC after ruling out bacterial STIs.¹⁰ This option may be especially important because women with HIV infection need a highly effective form of contraception that is unaffected by liver enzymes.

NONCONTRACEPTIVE BENEFITS

In addition to its efficacy in preventing pregnancy, IUC is associated with a number of noncontraceptive benefits. Several studies have reported a reduced risk of endometrial cancer in previous users of copper-containing and nonmedicated IUDs.⁴² Some studies also have suggested a reduction in cervical cancer risk, although this association was not statistically significant.⁴²

Use of the LNG IUS is associated with several noncontraceptive benefits. The device decreases menstrual blood loss and has been shown to be effective in treating idiopathic menorrhagia and increasing hemoglobin levels.⁴² It has been used as an alternative to endometrial ablation or hysterectomy in the treatment of menorrhagia. One clinical trial found that the LNG IUS was as effective as endometrial ablation at reducing blood loss when assessed one year after insertion.⁴³ A five-year study found that the hysterectomy cancellation rate was much higher for users of the LNG IUS than for other patients (80 percent versus 9 percent).⁴⁴ The LNG IUS is approved for the treatment of menorrhagia in many countries and may be approved in the United States for this indication in the near future. The LNG IUS also has been investigated for use as a substitute for oral progestin in hormone therapy for postmenopausal women and is approved for this indication in many countries. One study followed

postmenopausal women who used oral or transdermal estrogen with the LNG IUS continuously for five years.⁴⁵ Histological examination demonstrated that the LNG IUS protected the women against endometrial hyperplasia.

COST-EFFECTIVENESS

Contraception that requires a larger initial outlay of cash, such as IUC, may pose a challenge for women who do not have adequate health insurance or financial resources. However, over the long run, the devices are more cost-effective than many other forms of contraception. A 2003 study analyzed costs to the health care services payer of a variety of contraceptive methods, including the LNG IUS, copper-T IUD, oral contraceptives, injectable contraception, cervical cap, tubal ligation, and diaphragm.⁴⁶ The two forms of IUC had the lowest five-year costs, at about \$1600 for each.

The LNG IUS may also be cost-effective for noncontraceptive uses. One study comparing outcomes for treatment of menorrhagia among women who ultimately had a hysterectomy and those who used the LNG IUS found similar rates of satisfaction.⁴⁴ Despite the fact that 42 percent of those starting with IUC eventually underwent hysterectomy, the average direct costs and indirect costs for the IUC group were lower than the average costs for the hysterectomy group.

DIFFERENCES BETWEEN THE COPPER-T IUD AND THE LNG IUS

Both forms of IUC available in the United States are highly effective, safe, and cost-effective. They differ in some important respects, and knowledge of these distinctions can aid in the selection of the most appropriate option for a patient. Table 3 lists the key differences between the copper-T IUD and the LNG IUS.

TABLE 3. Key Differences Between the Copper-T IUD and the LNG IUS

	Copper-T IUD	LNG IUS
Active components	Copper	Levonorgestrel
Noncontraceptive benefits	Reduced risk of endometrial cancer	Reduced menstrual bleeding and dysmenorrhea Treatment of menorrhagia Protection of the endometrium during postmenopausal estrogen therapy ⁴⁴
Duration of use	10 years	5 years
Menstrual effects	Increased bleeding	Decreased bleeding



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SCREENING AND COUNSELING PATIENTS

GOALS FOR PROVIDERS

There are a number of goals that providers need to consider during the process of screening and counseling patients for intrauterine contraception (IUC) use. They include reviewing the range of contraceptive options with their patients, promoting the successful use of the chosen method, allowing time for questions, and providing written materials in the language and literacy level their patients require.

CANDIDATES FOR INTRAUTERINE CONTRACEPTION

In the past, overly restrictive protocols for selecting IUC candidates prevented many women from accessing this form of contraception. Appropriate candidates potentially include all women of reproductive age who are seeking a long-term, highly effective contraceptive method. IUC is especially suited for women who are at low risk for sexually transmitted infections because they are in a mutually

monogamous relationship or because their partners correctly and consistently use condoms, those seeking a convenient method, or those considering sterilization.

There are few absolute contraindications to IUC use. Table 4 lists conditions designated as category 4 according to the medical eligibility criteria that the WHO has established for contraceptive use.¹ Conditions assigned to category 4 are those that represent an unacceptable health risk if the contraceptive method is used. For complete information about relative contraindications, see the WHO criteria, available at: http://www.who.int/reproductive_health/publications/RHR_00_2_medical_eligibility_criteria_second_edition/.

In helping women choose between the IUC devices available in the United States, providers should consider that the copper-T IUD can be left in place five years longer than the LNG IUS and that it may be preferred by women who do not want to use a hormone-releasing IUD. The LNG IUS is better suited for women with menorrhagia or those who would find amenorrhea an advantage.

TABLE 4. Contraindications to Intrauterine Contraception Use, According to the World Health Organization¹

Category 4 Condition*	Comments
Pregnancy	
Puerperal sepsis	
Use immediately after septic abortion	
Distorted uterine cavity	
Unexplained vaginal bleeding	For initiation; continuation of IUC is designated category 2
Malignant trophoblastic disease	
Cervical cancer (awaiting treatment)	For initiation; continuation of IUC is designated category 2
Endometrial cancer	For initiation; continuation of IUC is designated category 2
Breast disease (current)	For LNG IUS only
Uterine fibroids that distort uterine cavity	
Pelvic inflammatory disease (current or within past three months)	For initiation; continuation of IUC is designated category 3
STIs (current or within past three months) including purulent cervicitis	
Known pelvic tuberculosis	For initiation; continuation of IUC is designated category 3

*Category descriptions:

Category 1: A condition for which there is no restriction for the use of the contraceptive method.

Category 2: A condition where the advantages of using the method generally outweigh the theoretical or proven risks.

Category 3: A condition where the theoretical or proven risks usually outweigh the advantages of using the method.

Category 4: A condition that represents an unacceptable health risk if the contraceptive method is used.



COUNSELING TOPICS

Providers need to counsel women who are considering IUC to ensure they have sufficient and accurate information to make an informed choice. Providers need to ask patients about their current understanding and dispel any myths they may have about IUC or other forms of contraception. Providers should discuss the topics listed in Table 5, and then ask patients if they have any additional questions.

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TABLE 5. Myths About Intrauterine Contraception

- Effectiveness
- Mechanisms of action
- Description of devices
- Insertion and removal procedures
- Possible adverse events, including menstrual changes
- Possible complications
- Instructions for checking string, follow-up visits, and warning signs
- Noncontraceptive benefits

INSERTION AND MANAGEMENT OF INTRAUTERINE CONTRACEPTION

With appropriate training and experience, a range of providers, including nurse practitioners, nurse-midwives, and physician assistants, can safely insert intrauterine contraception (IUC) devices. The professional criterion for all providers should be competency in insertion and removal in a variety of clinical scenarios (such as different uterine positions), rather than a requirement based on absolute clinical hours spent on insertion or number of insertions performed. Before inserting the devices independently, potential providers should practice on models and demonstrate proficiency with insertion and removal while supervised.

Prior to insertion, the provider needs to obtain a medical history and discuss contraceptive choices with the patient. Many providers recommend that patients take a nonsteroidal anti-inflammatory drug 30 to 60 minutes before insertion to help reduce discomfort. Alternatively, some providers offer patients misoprostol or a paracervical block. It is important that providers obtain familiarity and experience with IUC insertion prior to inserting the devices.

STEPS FOR INSERTION

Providers need to carefully read the manufacturer's instructions on insertion since the specific steps differ slightly for each the type of IUC. The basic steps are:

1. Perform a bimanual examination, checking the shape, position, and size of the uterus.
2. Apply an antiseptic solution to the cervix and load the device into the inserter under sterile conditions.

3. Apply the tenaculum, grasping the anterior lip of the cervix about 2.0 centimeters from the os.
4. Straighten the axis of the uterus by applying traction to the tenaculum.
5. Sound the uterus slowly and gently and place the device, based on distance measured during sounding.
6. Withdraw the inserter.
7. Cut the threads. Leave about one inch and note the length of the visible strings in the patient records. Instruct the patient to feel for the strings before she leaves the examination room.

TIMING OF INSERTION

IUC can be inserted at any time during the menstrual cycle, as long as the provider is reasonably certain the woman is not pregnant. The practice of inserting IUC only during menses is unnecessary and inconvenient for the patient. WHO criteria for insertion after delivery or abortion are reviewed in Table 6; the criteria are available at: http://www.who.int/reproductive-health/publications/RHR_00_2_medical_eligibility_criteria_second_edition.

USE OF PROPHYLACTIC ANTIBIOTICS

Prophylactic antibiotics to prevent pelvic infection are not recommended.^{2,3} Data from several studies have shown no benefit from prophylactic antibiotics given at the time of insertion. One study found no difference between the treatment group and the placebo group in the



TABLE 6. Contraindications to Intrauterine Contraception Use, According to the World Health Organization¹

Timing	WHO CATEGORY*		Comments
	Copper-containing IUD	LNG IUS	
Postpartum (<48 hours)	2	3	Increased risk of expulsion
Postpartum (48 hours to <4 weeks)	3	3	Increased risk of perforation; lack of data on local effects of the LNG IUS on uterine involution; concern for neonate's exposure to steroid hormones during first six weeks postpartum
Postpartum (>4 weeks)	1	1	If breastfeeding, the LNG IUS is considered category 3 until six weeks postpartum
Postabortion (first trimester)	1	1	
Postabortion (second trimester)	2	2	Some concern about risk of expulsion; lack of data on local effects of the LNG IUS on uterine

likelihood a woman would retain the intrauterine device (IUD) at 90 days or in the frequency of the need for medical attention after insertion.⁴ A meta-analysis of six study reports (four studies, two of which had pilot phases) found a reduced frequency of unscheduled return visits for patients who used prophylactic antibiotics at the time of insertion but no statistically significant difference in protection against pelvic inflammatory disease (PID) or premature discontinuation rates.⁵

FOLLOW-UP SCHEDULE

Clinical guidelines recommend a follow-up visit after the patient's next menstrual period, within three weeks to six weeks after IUC insertion.^{2,3} It is recommended that providers check IUC placement and evaluate for any signs of infection at this visit. Further routine visits are not required. A 2003 study found no difference in discontinuations, pregnancies, or expulsions among women who received a follow-up visit at six weeks and then annually and those who had more frequent routine visits.⁶ Women should be counseled to return if they develop any warning symptoms (such as fever, severe bleeding, or pain with intercourse) or if they have any questions or concerns.

REMOVAL

IUC may be removed for a number of reasons, including expiration of the device, the patient's desire to become pregnant, patient request, or development of a side effect that cannot be otherwise treated. Women who are

perimenopausal should wait until one year after menopause for IUC removal. Since IUC prevents fertilization, women who have intercourse within seven days before IUC removal are at risk for pregnancy, and should be advised to refrain from intercourse or to use condoms during that week. This precaution applies even if IUC reinsertion is planned, in case reinsertion is delayed. Removal may occur at any time in the menstrual cycle, but it may be easiest during menses or midcycle.

To remove an IUD, the provider should apply steady, gentle traction on the string. If gentle traction is not effective, the provider can straighten the anteversion or retroversion of the uterus with a tenaculum and then pull on the string.

USE OF INTRAUTERINE CONTRACEPTION AS EMERGENCY CONTRACEPTION

Emergency contraception, defined as methods used after intercourse to prevent pregnancy, offers women a "second chance to avoid unintended pregnancy."⁷ Copper-containing IUDs are an effective and safe method of emergency contraception. When used as emergency contraception, the most likely mechanism of action of the copper-containing IUD is interference with implantation due to the effect of the copper ions or the presence of the IUD itself.⁷ One study documented a high effectiveness with this form of emergency contraception, with an estimated failure rate of less than 0.1 percent.⁸ The devices can be inserted up to the time of implantation, which is about five days to seven days after ovulation. However, most providers limit insertion to



within five days of intercourse rather than ovulation, since it is often difficult to estimate the day of ovulation. Side effects seen after postcoital IUD insertion are similar to those seen after insertion at other times. The levonorgestrel-releasing intrauterine system (LNG IUS) should not be used as emergency contraception.

MANAGEMENT OF COMPLICATIONS AND SIDE EFFECTS

Despite the infrequency of complications with IUC, it is important for providers to be familiar with the signs of possible complications, which are shown in Table 7. Recommendations for managing these complications are discussed in the following sections.

Perforation. Providers need to be familiar with the recommended management of this rare complication. Signs suggestive of perforation include a sudden loss of resistance to the uterine sound or insertion device, a uterine depth greater than expected on bimanual examination, and unexplained pain.⁹ The procedure should be halted, and the patient's vital signs and level of discomfort should be monitored until the patient is stable. Urgent follow-up, including an ultrasound examination or abdominal x-ray to locate the device, may be needed. If the patient continues to experience pain or shows any evidence of blood loss or bowel damage, emergency surgery may be required. However, evidence suggests that surgical intervention is rarely needed and conservative management is appropriate.²

Expulsion. Expulsion can occur without the woman's knowledge, leaving her at risk for unintended pregnancy. Expulsion or partial expulsion can present as irregular bleeding or pregnancy. If expulsion is suspected, as a result of a missing string, missed menses, or irregular bleeding, it is important to rule out pregnancy and obtain an ultrasound to verify expulsion.

Heavy bleeding or cramping. Heavy bleeding may signal pregnancy or device expulsion, but it is more commonly simply a side effect of IUC use. Heavy bleeding or cramping is more likely to occur with the copper-T IUD than with the LNG IUS. Use of prophylactic nonsteroidal anti-inflammatory drugs (NSAIDs) can help reduce the symptoms. For women who experience heavy bleeding that lasts more than three months to six months, providers should check for infection or fibroids, treat for anemia if indicated, and then prescribe NSAIDs. If heavy bleeding cannot be managed or is unacceptable to the patient, the device should be removed.

Missing string. IUC strings may not be visible for a variety of reasons, including IUC expulsion or perforation, twisting of the strings in the endocervical canal, or excessive trimming of the strings. Providers need to first rule out pregnancy, then probe for the strings in the cervical canal with an endocervical brush or uterine sound. If this maneuver is not effective, the provider can use a thread retractor to try to snag the strings. If this action is not effective, the provider can use alligator forceps to search within the endometrial cavity and remove the device, using a tenaculum to stabilize the uterus before intrauterine manipulation.⁹ If the strings cannot be located, the provider needs to prescribe back-up contraception and obtain an ultrasound examination or x-ray to locate the device. Devices that have migrated to the abdomen should be removed promptly, since copper-containing IUDs can cause adhesions in the peritoneal cavity.

Sexually transmitted infections and pelvic inflammatory disease. IUC users who develop sexually transmitted infections (STIs) or PID should be tested for relevant organisms and treated with appropriate therapy. Clinical guidelines state that removal of the IUC is not necessary unless symptoms fail to improve within 72 hours of treatment initiation.^{2,3} Follow-up is needed to ensure resolution of symptoms and adherence with

TABLE 7. Signs of Complications Associated with IUC

Sign/Symptom	Possible Complication
Severe bleeding or abdominal cramping three to five days after insertion	Perforation and/or infection
Irregular bleeding or pain every menstrual cycle	Dislocation or perforation
Fever, chills, unusual vaginal discharge	Infection
Pain during intercourse	Infection, perforation, and/or partial expulsion
Missed period, other signs of pregnancy, expulsion	Pregnancy (uterine or ectopic)
Shorter, longer, or missing string	Partial or complete expulsion and/or perforation



therapy, to provide counseling about safer sex practices, and, if indicated, to notify and treat the woman's sexual partner. The patient's risk profile for STIs then should be reevaluated to ensure that she remains a candidate for IUC.

Actinomyces-like organisms (ALO) normally exist in the female genital tract and are sometimes identified on Pap test. Their presence appears to be more likely as time of IUC use increases.⁹ Upper genital tract infection is rare but can be serious, with symptoms such as irregular bleeding, pelvic pain, and pain with intercourse.⁹ The identification of ALO in asymptomatic women is not predictive of disease.¹⁰ Current recommendations state that symptomatic women with a finding of ALO on Pap test or by other testing should be treated with appropriate therapy and the IUC removed (after the patient has begun treatment).² Asymptomatic women require neither IUC removal nor therapy.

Pregnancy. Pregnancy with IUC in situ is uncommon because of the associated low failure rate. Most pregnancies that occur are intrauterine, but ectopic placement must be ruled out because of the increased risk of ectopic pregnancies with IUC use.² Women who become pregnant while using IUC must be advised, if the device remains in place, of the increased risk of second-trimester abortion, preterm delivery, and infection.¹¹ In addition, women should be advised that removal of the device will reduce these risks but is associated with a slightly higher risk of miscarriage.²

Providers need to ascertain whether the patient wishes to continue the pregnancy. If she does and the IUD strings are visible, the device should be removed as gently as possible and as soon as pregnancy has been confirmed. If the strings are not visible, an ultrasound examination should be obtained to locate the device. If the device is outside the uterus, the pregnancy should be addressed first, then the device located. If the device is retained in the uterus, it should be located and retrieved at delivery or abortion.²

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THE FUTURE OF IUC

Worldwide, there are several intrauterine contraception (IUC) designs new to the market or under development. The goals of these design modifications are to facilitate easier insertion and removal, decrease the number of expulsions, and reduce the pain or bleeding associated with some devices that can lead to discontinuation. Some of the new devices are smaller, some are frameless, and some combine copper and hormone components. None of the new devices is currently available in the United States.

There is a great deal of clinical experience worldwide with the frameless GyneFix® device, which consists of copper sleeves clamped onto a string-like suture material.¹ The device is anchored via a knot that is pierced about one centimeter into the myometrium. It has a smaller total surface area than standard IUC devices, which is believed to minimize menstrual bleeding.² The device is associated with few expulsions and high rates of continuation due to a low incidence of bleeding or pain.²

In addition to new devices, the use of IUC may shift in the future to include a wider range of users. Greater numbers

of nulliparous women, interested in reversible, long-term, highly effective contraception may choose the device, especially if overly strict selection criteria are revised. IUC also may be used increasingly in the future for noncontraceptive purposes, such as treatment of menorrhagia and provision of endometrial protection during estrogen replacement therapy.

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CONCLUSIONS

There is an unmet need in the United States for effective contraceptive methods that can be used consistently, correctly, and on an ongoing basis. Intrauterine contraception (IUC) is as effective as sterilization, is not dependent on user motivation for effectiveness, and has high user satisfaction rates. IUC use in the United States has been limited by several factors, including limitations to access and persistent myths about the devices.

Two forms of IUC are available in the United States: the copper-containing ParaGard T 380A intrauterine device (IUD) and the levonorgestrel-releasing intrauterine system (LNG IUS). The two have similar effectiveness rates but differ in side-effect profiles: the copper-T IUD increases menstrual blood flow, whereas the LNG IUS is associated with a reduction in flow that often results in amenorrhea.

The primary mechanism of action of IUC is prevention of fertilization. IUC does not cause or increase rates of pelvic inflammatory disease (PID), infertility, or ectopic pregnancy. The most common side effects associated with

IUC use are menstrual changes, heavy bleeding, and cramping. Complications with IUC use are rare but include uterine perforation, expulsion, and missing strings. Providers need to be aware of the recommended management of these side effects and complications, and need to know how to manage sexually transmitted infections, PID, and pregnancy in IUC users.

Candidates for IUC should be selected based on current recommendations; in the past, overly restrictive protocols unnecessarily prevented many women from accessing IUC. Prophylactic antibiotics are not needed at insertion. Providers need to become familiar with issues surrounding the timing of IUC insertion and insertion techniques.

IUC is a safe, highly effective form of contraception, the use of which has been unnecessarily limited in the United States. Providers need to receive accurate information about IUC and become willing to provide insertion, management, and removal services to increase access to this contraceptive method in this country.



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New Developments in Intrauterine Contraception

POST-TEST

Please circle the single most appropriate answer below.

1. Which is the primary mechanism of action of intrauterine contraception (IUC)?
 - a. Postimplantation effects
 - b. Pregnancy interruption
 - c. Abortifacient effects
 - d. Prevention of fertilization
2. Which of the following statements about the effectiveness of IUC is true?
 - a. Both types of IUC available in the United States have been proven effective for at least ten years of use.
 - b. The copper-T intrauterine device (IUD) is significantly more effective than the levonorgestrel intrauterine system (LNG IUS).
 - c. The typical failure rate is much higher than the failure rate for correct and consistent use.
 - d. IUC is as effective as sterilization.
3. The copper-T IUD:
 - a. Commonly induces amenorrhea.
 - b. Contains the hormone progesterone.
 - c. Is associated with increased menstrual blood loss.
 - d. Can be used as an alternative to endometrial ablation in the treatment of menorrhagia.
4. The LNG IUS:
 - a. Commonly induces amenorrhea.
 - b. Contains the hormone progesterone.
 - c. Is associated with increased menstrual blood loss.
 - d. Can be used for emergency contraception.
5. IUC is associated with a higher risk of pelvic inflammatory disease (PID):
 - a. That is confined to the first 20 days after insertion.
 - b. Almost exclusively in nulliparous women.
 - c. Only when nonmedicated devices are used.
 - d. Primarily after postabortion insertion.
6. IUC:
 - a. Must be removed for PID treatment or if actinomyces-like organisms are seen on Pap test.
 - b. Is more cost-effective over time than other contraceptive methods.
 - c. Is associated with a higher rate of tubal infertility than other contraceptives.
 - d. Should be inserted only during the menses.
7. Which of the following statements about the timing of IUC insertion is true?
 - a. Insertion of the LNG IUS generally should be delayed until six week postpartum in women who are breastfeeding.
 - b. The risk of expulsion is higher when IUC is placed more than 48 hours postpartum.
 - c. The risk of perforation is higher when IUC is placed less than 48 hours postpartum.
 - d. IUC should not be inserted immediately after a first-trimester abortion.
8. All of the following are contraindications to IUC use EXCEPT:
 - a. Severely distorted uterine cavity
 - b. Nulliparity
 - c. Suspected pregnancy
 - d. Insertion immediately after septic abortion
9. Which of the following statements about pregnancy and fertility in users of IUC is true?
 - a. IUC reduces the rate of intrauterine but not ectopic pregnancy.
 - b. Tubal infertility is associated with a history of IUC use.
 - c. The risk of preterm delivery is higher if the device remains in place.
 - d. Removal of the device should be delayed until the last trimester of pregnancy.
10. Which of the following statements about IUC is FALSE?
 - a. Prophylactic antibiotics at the time of insertion to prevent pelvic infection are not recommended.
 - b. Clinical guidelines recommend a follow-up visit at two weeks, six weeks, and six months after insertion.
 - c. Removal can occur at any time in the menstrual cycle but may be easiest during the menses.
 - d. Copper-containing IUDs are an effective form of emergency contraception.



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1. Extent to which stated program objectives are met.
 - a. Describe the mechanisms of action and effectiveness of the two intrauterine contraceptives available in the United States.
5 4 3 2 1
 - b. Compare and contrast the copper-T IUD and the LNG IUS.
5 4 3 2 1
 - c. List seven myths regarding IUC and identify correct information.
5 4 3 2 1
 - d. Identify appropriate candidates for IUC.
5 4 3 2 1
 - e. List eight counseling topics to discuss with patients considering IUC.
5 4 3 2 1
 - f. Discuss the steps and timing of IUC insertion, recommended follow-up, and the management of associated complications and side effects.
5 4 3 2 1
2. Relevance to clinical practice
5 4 3 2 1
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