

# OUTLOOK

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## **Hormonal Contraception, IUDs, and HIV Risk**

**M**any contraceptive users are at risk of sexually transmitted diseases (STDs), including human immunodeficiency virus (HIV). Women at highest risk for STDs (such as sex workers) should always be counseled to use condoms. (Male condoms provide effective protection against STDs if used consistently and correctly; limited data suggest that female condoms also provide effective prevention.) Women who are married or in seemingly stable relationships also can be at risk, often because of their partner's sexual behavior. In many regions, multiple sexual relationships for men are common (and often condoned or expected), putting their partners at risk. For example, of 400 selected women attending STD clinics in Pune, India, all tested positive for at least one STD and 13.6 percent had HIV, although 91 percent of them reported that they had never had sex with anyone but their husbands.<sup>1</sup> Social norms may make it difficult for a woman to discuss sexual matters with her partner or to control her fertility. The previous issue of *Outlook* (Volume 16, Number 4) discussed the complex issues surrounding gender and women's control of their health and fertility.

Most women, especially those who are married or in stable relationships, use methods to prevent pregnancy rather than to prevent STD transmission. Hormonal contraceptives, such as oral contraceptive pills (OCs), injectables, and contraceptive implants, are used by over 100 million women worldwide;<sup>2</sup> intrauterine devices (IUDs) are used by over 106 million women;<sup>3</sup> and surgical sterilization is used by 150 million women.<sup>4</sup> Many women need or prefer to practice contraception without their partner's knowledge. For many others, suggesting condom use is difficult since condoms often are associated with commercial rather than marital sex.<sup>5</sup>

Investigators are working to determine if certain modern contraceptive methods—primarily hormonal methods and IUDs—might increase a woman's risk of HIV infection. Some studies have suggested that contraceptives containing high levels of progestins, including injectables and some oral contraceptives, may increase a woman's risk of HIV infection by promoting certain physiological changes. Other studies have found no association or have been inconclusive due to various methodological concerns (for example, differences in the populations being studied, loss of participants in follow-up, and difficulty in acquiring accurate information from study participants about sexual history and condom use). Concerns also have been raised about possible links between IUD use and

HIV risk, in part because of the recognized effect of IUDs on risk of pelvic inflammatory disease around the time of insertion.

## Hormonal Methods: No Clear Evidence of Increased Risk

Hormonal contraceptives, such as OCs, injectables, and contraceptive implants, all contain progestins, synthetic versions of the hormone progesterone, and may contain estrogen as well. Progesterone has been found to cause endometrial, cervical mucus, and bleeding changes that may affect STD/HIV risk. Estrogen produces other changes, including changes in the degree of cervical ectropion, which may affect users' susceptibility to certain infections. One Kenyan study of HIV-positive women found that use of oral contraceptives and the three-month injectable, DMPA, may be associated with increased endocervical shedding of HIV.<sup>6</sup>

A recent study investigated the effects of reproductive hormones on HIV susceptibility in rhesus monkeys and found cause for concern, although the extent to which the results apply to humans is unclear. The monkeys were treated with progesterone and exposed vaginally to simian immunodeficiency virus (SIV). The hormone-treated monkeys were more likely to become infected with SIV than monkeys in the non-treated control group: 14 of 18 treated monkeys became infected, versus one of 10 monkeys in the control group. The study authors suggested that the increased infection rate was due to thinning of vaginal epithelium caused by the hormones.<sup>7</sup> While the results of the study are compelling, they are not necessarily helpful in determining human risks. The effects of hormonal contraceptives on the vaginal epithelium of humans are not as well known, but existing data suggest that the thinning is not as pronounced as was observed in monkeys.<sup>8</sup>

In humans, some studies carried out among women at high risk of HIV have suggested there may be a link, although methodological questions make it difficult to interpret results. In 1990, a study of prostitutes in Nairobi, Kenya, concluded that OCs may increase the risk of HIV infection,<sup>9</sup> but the results of subsequent studies have been less clear. For example, a 1994 prospective study, also conducted among prostitutes in Nairobi, found no increased risk of HIV infection among OC users.<sup>10</sup> Another prospective study conducted among sex workers in Mombasa, Kenya, found several factors associated with increased HIV seroconversion, including the use of some hormonal contraceptives. Women using DMPA (a

progestin-only injectable) were found to be twice as likely to become infected with HIV as women not using contraception or women who had been surgically sterilized (hazard ratio 2.0; 95% CI 1.3–3.1). Women using high-dose OCs appeared to be at a higher risk of infection than women using low-dose OCs, although the associations were not statistically significant.<sup>11</sup>

Several factors may have affected infection rates in these studies. For example, study participants reported varying levels of condom use, and among those who tested positive for HIV, over 80 percent had had a recent STD or other reproductive tract infection or abnormality.<sup>11</sup> In Thailand, injectable contraceptives were associated with higher incidence of HIV among sex workers compared to OCs and IUDs, but the use of unsterilized needles or decreases in condom use among injectable users may have been a factor in these findings.<sup>12</sup>

Studies conducted in lower-risk and more diverse populations have not found an increased risk of HIV among women using hormonal contraceptives. Among women attending family planning clinics in Nairobi, Kenya, for example, researchers found no significant association between OC use and HIV risk.<sup>10</sup> A study of women attending prenatal and pediatric clinics in Rwanda (with an overall HIV-positive rate of 32 percent) also found no significant association between contraceptive method and HIV status.<sup>13</sup> In all studies, factors such as multiple partners, alcohol consumption, inconsistent condom use, and a history of STDs were consistently associated with increased risk.<sup>10,11,13,14</sup>

Hormonal contraceptives, IUDs, and other long-term methods do not provide protection against HIV and other STDs. Many women are at risk of HIV and should be advised to use male condoms or an appropriate female barrier method to protect themselves and their families.

## IUDs Do Not Appear to Increase Overall Risk

There have been concerns that increased menstrual bleeding and possible increases in upper genital tract infections might put IUD users at higher risk of HIV infection. While some cross-sectional studies have suggested a link between IUD use and HIV risk,<sup>14</sup> others have not.<sup>10</sup> No statistically significant association between IUD use and HIV risk was observed in the Mombasa, Kenya, study of sex workers described above.<sup>11</sup> A prospective study in Italy, which examined contraceptive practices among couples in which the man was HIV-positive and the woman was not, found that women who used an IUD as their only contraceptive method were not at an overall increased risk of becoming infected. Women who had the device inserted or removed during the time they were at risk were *four times more likely to become infected*, however.<sup>15</sup> These results mirror the increased risk of pelvic inflammatory disease observed among IUD

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## Emergency Contraception Update

**E**mergency contraception is safe and effective and can help prevent unintended pregnancy if used within 72 hours of unprotected intercourse (see *Outlook*, Volume 14, Number 2). Emergency contraceptive pills (ECPs) containing only levonorgestrel are more effective and have fewer side effects than combined ECPs, according to a recent study by the World Health Organization (WHO). Another study found that the availability of emergency contraception, including advance prescriptions, does not encourage women to abandon other methods of contraception.

The WHO study involved 1,998 women at 21 centers worldwide and found that levonorgestrel-only ECPs have fewer side effects and are more effective than combined ECPs (see Table 1).<sup>1</sup> Overall, women taking the levonorgestrel regimen had only about one-third the risk of pregnancy compared to women taking a combined estrogen-progestin regimen (relative risk 0.36; 95% CI 0.18–0.70). The levonorgestrel-only regimen consists of 0.75 mg levonorgestrel taken within 72 hours of unprotected intercourse followed by another 0.75 mg dose 12 hours later. The combined emergency contraception regimen—also known as the Yuzpe regimen—consists of 100 mcg ethinyl estradiol plus 0.5 mg levonorgestrel (two “high-dose” oral contraceptive pills) taken within 72 hours of unprotected intercourse, followed by the same dose 12 hours later. The women were randomly assigned to a treatment regimen. The analysis excluded 43 women for whom the outcome of treatment was unknown. The WHO study also found that the effectiveness of both emergency contraception regimens declined with increasing time since



Postinor-2™, the first available levonorgestrel-only ECP product, is being introduced in Kenya, Sri Lanka, and several other countries.

unprotected intercourse. This result reinforces the importance of advising women to start emergency contraception treatment as soon as possible after unprotected intercourse.

Another recent study found that advance provision of ECPs does not appear to adversely affect use of regular contraception or encourage repeated use of emergency contraception. This Scottish study compared the contraceptive use patterns of two groups of about 500 women: one group received only information about emergency contraception, and the other received both information and an advance ECP supply. After one year, use of regular contraceptive methods did not vary significantly between the two groups. Furthermore, women who received advance supplies were not more likely to use ECPs repeatedly. The study also suggested that providing advance supplies of ECPs may contribute to lower unintended pregnancy rates, but further research will be required to confirm this.<sup>2</sup>

Making emergency contraception more widely available can be an important step in preventing unintended pregnancies. Programs can encourage correct use of emergency contraception by informing women of their availability and appropriate use during routine reproductive health care visits, and by providing ECPs in advance of the need for them. While combined ECPs remain an option for emergency contraception, the levonorgestrel-only regimen should be the product of choice where available.

**Table 1. Effectiveness and Side Effects of Two Emergency Contraceptive Pill Regimens†**

	Levonorgestrel-only Regimen	Combined Regimen
<b>Effectiveness</b>		
Crude pregnancy rate (%)	1.1	3.2
Proportion of pregnancies prevented (%)††	85.0	57.0
<b>Side effects</b>		
Nausea (%)	23.1	50.5
Vomiting (%)	5.6	18.8
Dizziness (%)	11.2	16.7
Fatigue (%)	16.9	28.5

†All differences were statistically significant.

††Compared with the expected number without treatment.

Source: WHO, 1998.

1. WHO/HRP Task Force on Postovulatory Methods of Fertility Regulation. Randomised controlled trial of levonorgestrel versus the Yuzpe regimen of combined oral contraceptives for emergency contraception. *Lancet* 352(9126): 428-433 (August 8, 1998).
2. Glasier, A. and Baird, D. The effects of self-administering emergency contraception. *New England Journal of Medicine* 339(1):1-4 (July 2, 1998).

## Quinacrine Sterilization: The Controversy Heightens

Since the mid-1960s, researchers have tried to identify safe, simple, and inexpensive methods of non-surgical female sterilization. Surgical sterilization, while safe and effective, is not accessible to all women who want it, especially those in rural or remote areas where trained staff and facilities are largely unavailable. A large unmet need for sterilization services therefore persists in many developing countries throughout the world.

The non-surgical method that has received the most attention—and has caused the most controversy—is intrauterine application of quinacrine hydrochloride. Proponents of this method hail it as a medical breakthrough that could save thousands of women's lives by enabling them to avoid unwanted pregnancies safely, easily, and cheaply. Critics argue that potential long-term risks have not been sufficiently evaluated, nor have other safety concerns such as ectopic pregnancy and the possibility that women may be sterilized without their consent.

To date, approximately 104,500 women in over 20 countries have been sterilized using this method, mainly in Viet Nam (50,000), India (26,000), and Pakistan (15,000). In the last year, however, serious concerns have been raised about broadening quinacrine sterilization use. The method has been banned in two countries, and the only manufacturer of quinacrine pellets for sterilization has stopped production. This article describes recent events related to quinacrine sterilization and discusses future prospects for the method. (For more information, see *Outlook*, Volume 11, Number 4.)

### Background

Administered orally, quinacrine was used for over 50 years to prevent and treat malaria. It is no longer marketed for this purpose in the U.S., but it is still used in oral form to treat several parasitic diseases, as well as symptoms of the autoimmune disorder, lupus. Investigation into quinacrine's potential for female sterilization began in the 1960s in Chile and continued in collaboration with Family Health International throughout the 1970s and 1980s. *In vitro* studies showed that quinacrine caused cell mutation in bacteria; carcinogenicity was never established, however. In 1991, the World Health Organization (WHO) Toxicology Panel reviewed the *in vitro* studies and confirmed that conclusions could not be made about the carcinogenicity of quinacrine sterilization. Further toxicology studies were recommended.<sup>1</sup>

United States Food and Drug Administration (USFDA) regulatory standards have become more rigorous since

the 1970s, including requirements for evaluating the potential cancer risk of new drugs. Therefore, most of the animal tests needed to evaluate the safety of intrauterine quinacrine have never been conducted.<sup>2</sup> Proponents of quinacrine sterilization suggest that any cancer risk associated with the method must be negligible or nonexistent since no increased cancer risk has been observed in the millions of people who have taken the drug orally.

### Ongoing Research: An Update

To sterilize women, quinacrine pellets are inserted directly into the uterus with a modified Copper T intrauterine device (IUD) inserter 5–10 days following onset of menses. The quinacrine pellets (each containing 36 mg of quinacrine) dissolve in about 30 minutes. The liquefied drug then flows into the fallopian tubes and causes scarring. Within 6–12 weeks, the scar tissue blocks entry to the tubes, resulting in sterilization. Newer protocols call for two insertions (one month apart) of seven pellets each. Each procedure is reported to take only a few minutes to perform and not to require anesthesia.

Since the 1980s, quinacrine has been championed by the Center for Research on Population and Security headed by Dr. Stephen Mumford, and the International Federation for Family Health, headed by Dr. Elton Kessel. Until recently, these organizations procured the drug from a Swiss manufacturer and distributed quantities free of charge to countries expressing an interest in the method. The organizations also provided financial, technical, and material assistance to some countries for additional human trials of quinacrine sterilization. Results of a large study in Viet Nam, published in 1993, prompted official reviews of all existing quinacrine data because of concerns about methodology, follow-up, and other issues. These reviews led to calls from several agencies, including the International Planned Parenthood Federation and WHO, to establish the long-term safety of quinacrine sterilization before further human trials are conducted.

In the Viet Nam study, 31,781 women in 24 provinces underwent quinacrine sterilization between 1989 and 1992. One-year failure rates, based on a subsample of about 11,700 women, ranged from 2.6 percent in women receiving two doses to 5.2 percent in women receiving just one dose. The ectopic pregnancy rate among a subsample of 4,500 women was less than 1 per 1,000 years of woman use after two years. Few major, persistent side effects were recorded and no deaths were observed. One fetal anomaly was

reported, but the researchers did not believe it was attributable to quinacrine sterilization because conception occurred more than 30 days after quinacrine administration.<sup>3</sup> Although the researchers concluded that quinacrine sterilization was safe and effective, the study's methodology was criticized because many of its conclusions were based on small subsamples of women, follow-up was variable, and dose and insertion protocols were inconsistent.<sup>4</sup>

A retrospective study of Vietnamese women who received quinacrine sterilization, however, found that 86 percent said that the method was a good choice for them. The study also found that service delivery points were not able to effectively manage the demand, which was quite high (surgical sterilization was not available).<sup>5</sup> Although the Vietnamese quinacrine program has been discontinued because of WHO's concerns about long-term safety, follow-up of sterilized women continues to assess intrauterine and ectopic pregnancy rates, the effect of administering other drugs in conjunction with quinacrine, and complications. Results are expected in 1999.<sup>6</sup>

Another important follow-up study currently is being conducted by Family Health International in Chile. In an early evaluation of 572 Chilean women receiving quinacrine sterilization from 1977–1981, eight cancers were observed during follow-up. Further analysis of almost 1,500 women who had received quinacrine sterilization between 1977 and 1989 did not find increased cancer rates, although one case of uterine cancer was identified.<sup>7,8</sup> This cohort of women is still being followed to determine whether quinacrine may be associated with an elevated cancer risk. Results are expected in 2000. Another study of 1,000 women in Pakistan, funded by Marie Stopes International, is still ongoing.

Other recent international studies involving far fewer women also have concluded that quinacrine sterilization is safe, effective, and acceptable. Again, however, protocols differ among studies, making comparisons of efficacy and safety extremely difficult, and most studies do not have the potential to clarify long-term risks.

In addition to long-term safety issues, many important questions about quinacrine sterilization still remain, such as: determining the optimal dose and insertion protocols; clarifying the need for interim contraception after insertion; and assessing the ability of concurrent intrauterine administration of other drugs, such as analgesics or smooth muscle relaxants, to enhance effectiveness. WHO and others also have recommended that if long-term safety issues are ultimately resolved, future studies must examine whether age and parity affect efficacy, and whether the

drug is linked to upper genital tract infections, including pelvic inflammatory disease.<sup>9</sup>

## Recent Developments

The efforts of Drs. Mumford and Kessel to increase use of quinacrine sterilization have prompted several serious actions over the past year. The USFDA has ordered Drs. Kessel and Mumford to discontinue export of quinacrine because of safety concerns and because it is not approved for use as a contraceptive in any country. Furthermore, the USFDA ordered that the organizations destroy existing supplies of quinacrine because of concerns about the drug's effect on reproductive-tract cancers, development of abnormal uterine lesions, ectopic pregnancy, and fetal anomalies.<sup>10</sup> In addition, in mid-1998, the Swiss pharmaceutical company producing the drug, Sipharm Sissein AG, decided to discontinue production.

It is unclear what, if any, effect these actions will have on distribution of quinacrine, since Drs. Mumford and Kessel have indicated that arrangements already have been made to manufacture and distribute the drug outside the U.S. They also currently are working to make

“The information available to the FDA indicates that the product at issue does not meet even the threshold requirement for export in that it is not approved for use in non-surgical female sterilization in any country.”  
U.S. Food and Drug Administration<sup>10</sup>

the compound available to several U.S. physicians interested in providing quinacrine sterilization through their private practices. Whether or not the USFDA would take action against this unapproved use of the drug remains unclear.

Several other countries also are taking action to prevent quinacrine sterilization. In August 1998, India, after significant pressure from women's groups, banned the manufacture, sale, distribution, or use of quinacrine pellets. Chile also has banned quinacrine, spurred by pressure from women's groups as well as by negative U.S. media reports regarding the method.

## Future Prospects

The potential benefits of non-surgical sterilization are indisputable: such methods would be cheaper than surgical sterilization (quinacrine costs about \$1 per dose) and significantly easier to provide. Based on available data, quinacrine sterilization appears to be at least as safe in the short-term as surgical sterilization, although not as effective.<sup>11</sup> Proponents argue that where the risks associated with unwanted pregnancy and birth are high, the benefits of quinacrine sterilization far outweigh the risks. They recommend that risk-benefit analyses be done at national and local levels to determine the appropriateness of quinacrine sterilization in a given setting. WHO has rejected this approach: in 1994, the director of

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# IUDs: Do New Devices Reduce Bleeding and Expulsion Rates?

Intrauterine devices (IUDs) can provide safe and effective contraception for women at low risk of sexually transmitted diseases. The modern generation of medicated IUDs—the Copper T (TCu) 380A, the Copper T 220C, the Multiload-375, and the levonorgestrel-releasing (LNG-20) IUD—provide effective contraception for long periods of time, with reported pregnancy rates from less than one to three per 100 women per year.<sup>1</sup> Of these, the TCu 380A and the LNG-20 IUD are the most effective. Among typical users, IUDs are more effective than oral contraceptives, and about as effective as injectables, implants, and voluntary sterilization. Since IUDs already are very effective at preventing pregnancy, researchers have sought to improve them by reducing side effects and complications, primarily bleeding, pain, and expulsion.

Increased menstrual bleeding, often with pain, is the most common concern among IUD users, and the most common medical reason for IUD removals. In clinical trials, as many as 15 percent of women stopped using IUDs within the first year after insertion due to bleeding and pain; younger and nulliparous women generally experienced the highest rates of removal for these reasons. Reported expulsion rates vary from about one to eight per 100 women in the first year of use.<sup>1</sup> Most expulsions occur within one year of insertion, especially in the first three months. Factors that appear to influence expulsion include younger age, never having been pregnant or given birth, and provider skill in insertion technique.

Within the past decade, several modified IUDs have been designed to reduce bleeding, pain, and expulsions while maintaining high efficacy. While few data are available about the performance of most of these devices, recent studies have compared the performance of the Cu-Safe 300<sup>®</sup> and the Cu-Fix to the TCu 380A.

The Cu-Safe 300<sup>®</sup> IUD looks like other T-shaped devices, but the arms and stem are thinner and more flexible. Also, the ends of the arms are bent down and in

toward the stem of the device in an effort to reduce uterine irritation and to help prevent expulsions (see illustration, page 7). The flexibility of the device allows it to be inserted with a gentle “push-in” technique—no plunger is required. The inserter also is thinner than the TCu 380A inserter (3 mm vs. 4 mm), making insertion less uncomfortable. Results of a randomized comparative study of Cu-Safe 300<sup>®</sup> and TCu 380A use among 600 women aged 18–45 years<sup>2</sup> found the Cu-Safe produced a slightly—but not statistically significant—higher pregnancy rate and more expulsions. However, removals for bleeding and pain were significantly lower (see Table 1). Physicians participating in this trial reported that insertion and removal of Cu-Safe 300<sup>®</sup> was easier than with the TCu 380A. The device was approved for marketing in all European Community countries in 1996 for use for up to five years.

The Cu-Fix frameless IUD (also known as the Flexigard 330 and the GyneFix<sup>®</sup>) uses a different design approach. This device consists of six copper collars (each 5 mm long and 2.2 mm wide) on a surgical polypropylene thread that is knotted at the proximal end (closest to the uterine fundus). Using a special inserter, the knot is embedded into the fundus to a depth of 1 cm to implant the device into the uterine muscle. A randomized, multicenter, two-year study compared the performance of the Cu-Fix to the TCu 380A in 989 parous women between the ages of 18–40 years. The study found that both devices were highly effective at preventing pregnancy<sup>3</sup> (see Table 1); the Cu-Fix had significantly higher expulsion rates at 13 and 25 months, however. These findings contrast with a Belgian study<sup>4</sup> involving 1,039 insertions of the Cu-Fix in nulliparous and parous women aged 16–48. In that study, only six expulsions were reported during the study period—a rate of 0.7 expulsions at 36 months. The Belgian study used investigators with previous experience inserting the Cu-Fix, suggesting that provider skill and experience in insertion technique may influence expulsion rates. This

**Table 1. Comparison of a Copper T IUD with Modified IUDs: Results of Three Studies<sup>†</sup>**

	TCu 380A		Cu-Safe 300 <sup>®</sup>		Cu-Fix	
	1 year	2 years	1 year	2 years	1 year	2 years
Pregnancy <sup>††</sup>	≤0.8 <sup>2,3</sup>	≤0.8 <sup>2,3</sup>	1.5 <sup>2</sup>	1.9 <sup>2</sup>	≤1.0 <sup>3,4</sup>	≤0.1 <sup>4</sup> ; 1.5 <sup>3</sup>
Expulsion <sup>††</sup>	2.0 <sup>3</sup> ; 2.7 <sup>2</sup>	2.0 <sup>3</sup> ; 2.7 <sup>2</sup>	3.6 <sup>2</sup>	6.2 <sup>2</sup>	0.5 <sup>4</sup> ; 9.8 <sup>3</sup>	0.7 <sup>4</sup> ; 11.4 <sup>3</sup>
Bleeding/pain <sup>††</sup>	6.9 <sup>3</sup> ; 7.3 <sup>2</sup>	11.4 <sup>3</sup> ; 12.9 <sup>2</sup>	3.8 <sup>2</sup>	7.4 <sup>2</sup>	1.9 <sup>4</sup> ; 5.6 <sup>3</sup>	2.7 <sup>4</sup> ; 8.3 <sup>3</sup>

<sup>†</sup>It is important to note that two studies evaluated nulliparous and parous women,<sup>2,4</sup> and one study evaluated parous women only.<sup>3</sup>

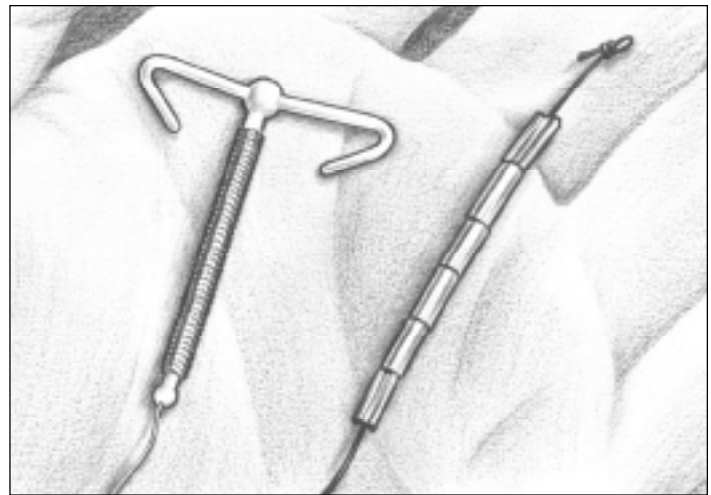
<sup>††</sup>Gross cumulative rates per 100 women.

Source: Van Kets et al., 1995;<sup>2</sup> Rosenberg et al., 1996;<sup>3</sup> and Van Kets et al., 1995.<sup>4</sup>

device also is approved for marketing in European Community countries for up to five years of use.

These limited data suggest that modified devices provide comparable pregnancy protection to the Copper T 380A, and may provide an alternative for women who have experienced difficulty with bleeding and pain with other copper-bearing IUDs. Once providers have mastered the insertion technique, use of the Cu-Fix may result in fewer expulsions compared to the Copper T 380A, but more studies are needed to confirm these conclusions. The costs of providing the modified devices also must be compared with the cost of providing commonly used devices.

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3. Rosenberg, M. et al. Performance of the TCU 380A and Cu-Fix IUDs in an international randomized trial. *Contraception* 53(4):197-203 (April 1996).
4. Van Kets, H. et al. The frameless GyneFix intrauterine implant: a major improvement in efficacy, expulsion and tolerance. *Advances in Contraception* 11(2):131-142 (June 1995).



The Cu-Safe 300® and the Cu-Fix frameless IUD, shown at approximately 150% of actual size. These IUDs may reduce pain and bleeding complaints, particularly in nulliparous women.

## Hormonal Contraception *from page 2*

users within the first 20 days of insertion, and this may account for the higher HIV rates among these women.

## Program Implications

What should reproductive health programs tell providers and clients about commonly used contraceptives and HIV risk? Most importantly, they should know that hormonal contraceptives, IUDs, and other long-term methods do not provide protection against infection. More data are required before any conclusions can be made regarding whether the use of various hormonal methods may increase HIV risk, although some studies suggest that methods with higher progestin levels may increase risk to some extent. IUDs generally are not a recommended method for women at risk of any STD, including HIV.

All women at risk of STD/HIV should be counseled to use a method that protects them against infection. Male condoms provide the best STD protection; female barrier methods, such as the female condom, diaphragm, and cervical cap, provide varying levels of protection (see *Outlook*, Volume 11, Number 4). Dual method use (for example, use of condoms in conjunction with hormonal) has been recommended for women who prefer certain methods for prevention of pregnancy, but also are at risk of HIV and other STDs. Limited experience with dual method use suggests that many factors influence whether couples will use two methods consistently, including costs, STD history, and couples' decision-making processes (which include women's power in relationships).

A key program emphasis should be to ensure that providers understand that many married or monogamous women are at risk of STDs, including HIV, and require protection. Providers need to understand clients' personal

situations, including clients' risk of contracting STDs from their partners, and then help them to determine appropriate contraceptive methods. Risk assessment questionnaires may help health care providers discuss these issues with their patients. Above all, providers should work to create a comfortable and confidential environment in which clients feel comfortable discussing difficult or personal topics.

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## Quinacrine Sterilization *from page 5*

WHO's Special Programme of Research, Development, and Research Training on Human Reproduction wrote that "the high standards of safety demanded in the testing and use of contraceptives should apply whether the subjects who are recruited to the studies are from the developed or developing world."<sup>9</sup>

It is clear that the future of non-surgical sterilization will depend upon various organizations working together to ensure that decisions regarding the use of quinacrine sterilization ultimately rest on science, not politics. Development and/or confirmation of a safe and effective method of non-surgical sterilization would ultimately benefit millions of women worldwide.

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In addition to selected members of *Outlook's* Advisory Board, the following individuals reviewed this issue: Ms. M. Cabral, Dr. J. Kreiss, Dr. S. Mumford, Dr. P. Rowe, Dr. D. Sokal, and Dr. P.F.A. Van Look. *Outlook* appreciates their comments and suggestions.

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