

Network

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Barrier Methods

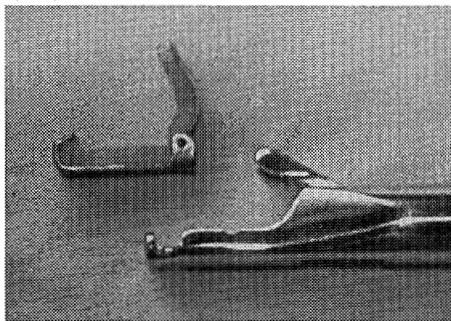


News Briefs

FILSHIE CLIP

PASSES FDA PANEL

An advisory panel of the U.S. Food and Drug Administration (FDA) has recommended that the FDA approve the Filshie Clip, a device used in female sterilization. Manufactured by Femcare Limited of the United Kingdom, the clinical trials used to support the panel's decision were conducted by FHI.



FILSHIE CLIP AND APPLICATOR

Sterilization, the most widely used birth control method, is achieved in women by cutting or blocking the fallopian tubes, thus preventing a woman's egg from becoming fertilized. The Filshie Clip, about the size of a small fingernail, blocks the fallopian tube by clamping. It is designed to cause less damage to the tube compared with other widely-used sterilization procedures.

Because of this, it is hoped that the clip will improve the prospects for surgical reversal among women who later regret their sterilization and want to become pregnant. However, no data on reversal were submitted to FDA. Sterilization should be considered permanent since reversal operations are expensive, difficult and do not guarantee success.

In a February hearing before the advisory panel, FHI scientists said their studies show the Filshie Clip is both a safe and effective method for voluntary female sterilization. FHI began clinical trials on the clip in 1984 and has completed 11 studies in 20

countries involving more than 6,000 women who volunteered to be sterilized with Filshie Clips. They were compared with nearly 4,000 women using other sterilization techniques, including two other devices that block tubes: the Tubal Ring (also known as the Falope or Yoon Ring) and the Wolf Clip (also known as the Hulka Clip).

Femcare, based in Nottingham, England, distributes gynecological and urological devices to more than 40 countries. The FHI studies were supported in part by the U.S. Agency for International Development (USAID). Because of USAID assistance, the Filshie Clip will be available at a lower price to governmental and intergovernment agencies, as well as to national and international humanitarian aid organizations.

SIX-DAY WINDOW OF FERTILITY

A recent study shows women can only conceive if they have sexual intercourse during the six days that lead up to ovulation (including the day they ovulate).

Although scientists have known for some time that the period of fertility is limited, the new research more precisely identifies when a woman can get pregnant. Previously, estimates ranged from two days a month just prior to ovulation, to a total of 10 days before and after ovulation.

Women attempting to avoid this short period of fertility as a means of preventing pregnancy will need to know precisely when they ovulate each month — something that is still hard to predict.

"We came one step closer to understanding the fertility window," says Dr. Allen Wilcox, chief of epidemiology at the National Institute for Environmental Health Sciences (NIEHS), a U.S. government agency, located in Research Triangle Park, NC.

"For that to be translated into couples' practices, they'd have to have a very good measure of when ovulation occurs," he says.

"Couples trying to avoid pregnancy by abstinence or natural family planning should still abstain for longer than six days, because we have no good way to predict ovulation accurately."

Dr. Wilcox, who headed the study, analyzed the menstrual cycles, urine samples, and sexual behaviors of 221 U.S. women who volunteered for a pregnancy

study. By comparing women's reports of when they had sex with hormonal evidence of ovulation and pregnancy, his team was able to identify when most women got pregnant. All 192 conceptions experienced by women in the study occurred during the six-day period ending on the day of ovulation. The study was published in the December 1995 issue of *The New England Journal of Medicine*.

NEW AIDS

THERAPY DRUGS

The U.S. Food and Drug Administration (FDA) has approved three AIDS therapy drugs to reduce symptoms and increase the lifespan of people afflicted with the disease.

The new class of drugs, called protease inhibitors, attack the AIDS virus by blocking the enzyme, protease, which is crucial for the maturation and spread of the virus. Most previously available AIDS therapy drugs work by inhibiting a different enzyme, called the reverse transcriptase enzyme, which the human immunodeficiency virus (HIV) needs to reproduce itself.

The new drugs are saquinavir, made by Hoffman-LaRoche Inc., zidovudine, produced by Abbott Laboratories, and indinavir, made by Merck & Co., all U.S.-based pharmaceutical companies. The relatively expensive drugs are not expected to become widely available in developing countries.

Saquinavir, sold under the brand name Invirase, was approved by the FDA in December 1995. Trials showed that Invirase alleviated symptoms of AIDS when prescribed in combination with a more commonly used AIDS therapy, zidovudine (AZT).

In a ritonavir clinical trial involving 1,090 AIDS patients at 67 hospitals in the United States, Canada, Europe and Australia, the death rate after six months was 5.8 percent among patients receiving ritonavir, and 10.1 percent in a comparison group receiving a placebo. Ritonavir was approved by the FDA in February.

Indinavir, marketed as Crixivan, was approved by FDA in March. In clinical trials lasting 24 weeks, indinavir reduced HIV in blood levels by 90 percent in all 58 patients taking indinavir in combination with AZT, compared to a 45 percent reduction in 62 patients taking AZT alone.

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Cover photo of a couple in Caracas, Venezuela by Beryl Goldberg

The Dual Goals of Reproductive Health

By Willard Cates Jr., MD, MPH
FHI Corporate Director of Medical Affairs

In today's global health village, the term "reproductive health" involves preventing not only unintended pregnancy, but also sexually transmitted diseases (STDs). The specter of HIV infection has made protection from genital tract infection a high priority on the world's reproductive health agenda.

As awareness of HIV and other STDs has grown, decisions about contraceptive use have begun to involve the need to prevent STDs. This became most obvious at the United Nations 1994 International Conference on Population and Development in Cairo, which defined a reproductive health agenda that encourages family planning programs to add STD prevention services. However, the only contraceptives currently recommended for STD/HIV prevention are barrier methods, making them important for ensuring one's reproductive health.

Nonetheless, many in family planning programs are hesitant to recommend barrier methods because their record in preventing unintended pregnancies is less reliable than other contraceptives. Some family planning clinicians worry that reliance on barrier methods alone will produce higher rates of both unintended pregnancy and STD/HIV. Are their fears justified?

What do we currently know about the efficacy of barrier methods in preventing STD/HIV? Four key questions dominate the barrier contraceptive method research agenda. Let us consider them in order.

Question: Do condoms (male and female) really work to prevent STD and unplanned pregnancy?

Answer: The simple answer is yes, if used consistently and correctly. When used consistently, condoms are effective in preventing both STDs and unplanned pregnancy. Thus, the method itself is effective against both conditions.

Several convincing studies demonstrate the effectiveness of condoms when used consistently. One intriguing study involved U.S. Navy seamen on shore leave in a "high-risk" port city: None of the 29 men who reported using condoms with commercial sex workers became infected with gonorrhea or nongonococcal urethritis, but 14 percent of the nonusers became infected (71 of the 499 nonusers). A second excellent study of condom use occurred among HIV-discordant couples in Europe. None of the 123 seronegative partners prospectively reporting consistent condom use became infected. Thus, used regularly and correctly, condoms work effectively.

The problem is that condoms — whether male or female devices — are typically used sporadically or incorrectly. Effectiveness rates must take this into account. Using a public health model, sexual abstinence will obviously prevent all of the risk of unprotected sex. However, intercourse using barrier methods of contraception, while not perfect, also provides a large measure of protection against the risk of STD or unintended pregnancy. In fact, plotting both abstinence and condom use on the same curve, sex protected by barrier methods reduces 70

percent of the total risk between unprotected sex and complete sexual abstinence. Thus, at the policy level, condoms must continue to be emphasized and made available.

Question: How effective are spermicidal nonoxynol-9 (N-9) agents against HIV and the other STDs?

Answer: Based on data from well-conducted randomized controlled trials, spermicides containing N-9 show a measurable protective effect against specific STDs — gonorrhea, chlamydia, trichomoniasis, and bacterial vaginosis. In Cameroon, Thailand and the United States, the regular use of N-9 by women attending either STD or family planning clinics reduced cervical gonorrhea and chlamydia infections by 20 percent to 50 percent.

However, the effect of N-9 agents on HIV transmission remains uncertain. Despite the *in vitro* activity of N-9 against HIV, and its protective effect against the simian immunodeficiency virus in Rhesus monkeys, published data are unclear about the impact of N-9 on humans *in vivo*. Among commercial sex workers in Nairobi, women who were randomly assigned to use a contraceptive sponge with N-9 had higher levels of vaginitis, genital ulcers, and HIV infection than those using a placebo. However, other observational studies in Africa and Asia show more favorable results — HIV infection was reduced among N-9 users. Thus, these data inconsistencies mean the jury is still out on the scientific verdict regarding N-9 and HIV.

Carefully controlled studies are also needed to assess the relative value of the different formulations of N-9 in preventing the transmission of STDs, especially HIV. Ongoing studies of N-9 film in Cameroon, and N-9 gel in Kenya and other parts of the world, will help resolve the question of which formulation, if any, works best.

Question: How close are we to having another female-controlled chemical barrier method?

Answer: Because of the uncertainties about N-9, and the desire to have a microbicide without spermicidal properties, developmental research is under way to discover new microbicidal agents (see article on page 15). Research is addressing not only new chemical methods, but also new physical barrier methods that protect the cervix.

New chemical methods under study include a buffer gel that maintains a low vaginal pH and does not disturb the normal vaginal flora; sulfated polysaccharides

designed to prevent adherence of HIV and chlamydia to cells in a woman's reproductive tract, yet are not spermicidal; N-docosanol, an antiviral product that works by inhibiting lipid-enveloped viruses; C31G, an amphiphilic surfactant that disrupts cellular membranes but causes less irritation to the epithelium than N-9; and squalamine, a steroid-based compound that affects cell growth. These and other agents will undergo phased clinical studies over the next several years.

Question: Why not emphasize two methods, one for preventing unintended pregnancy and the other for preventing STD/HIV?

Answer: Clinicians promoting dual contraceptive use must weigh the interacting factors of extra cost and effect on user compliance. Clients usually attach different priorities to preventing either pregnancies or infections, and these priorities may change over time and among relationships.

Studies on dual-method use are limited and have focused on the use of the male condom added to the mix of other methods of contraception. In general, based on investigations where participants were using primary methods other than the condom, the more effective the primary contraceptive was in preventing pregnancy, the lower the level of consistent condom use. For example, a study in the U.S. city of Baltimore showed only 6 percent of the women who were sterilized were also using condoms consistently to prevent STDs.

Several reasons can explain why condom use may be low among people already using an effective contraceptive method. First, many people — even those with sexual behaviors putting them at risk of STD — see pregnancy as a greater immediate threat. Thus, having taken precautions against unintended pregnancy, they may be less motivated to undergo the extra effort and expense of using condoms.

Second, those who are sterilized or who are using implants, injectable contraceptives, or IUDs do not have frequent reminders to use contraception. People who depend upon barrier methods or the daily schedule

of taking oral contraceptives may be more aware of, and prepared for, prophylactic needs. Without regular reminders of the need to protect against both pregnancy and STDs, individuals may be less likely to have condoms available.

The way in which counselors and clinicians encourage dual methods can influence whether the message is effective. With spermicides as the primary contraceptive method, the percentage of consistent condom users varied dramatically among three small clinic-based studies in Mexico, the Dominican Republic, and Kenya. This indicates factors other than the method itself affect levels of concurrent use.

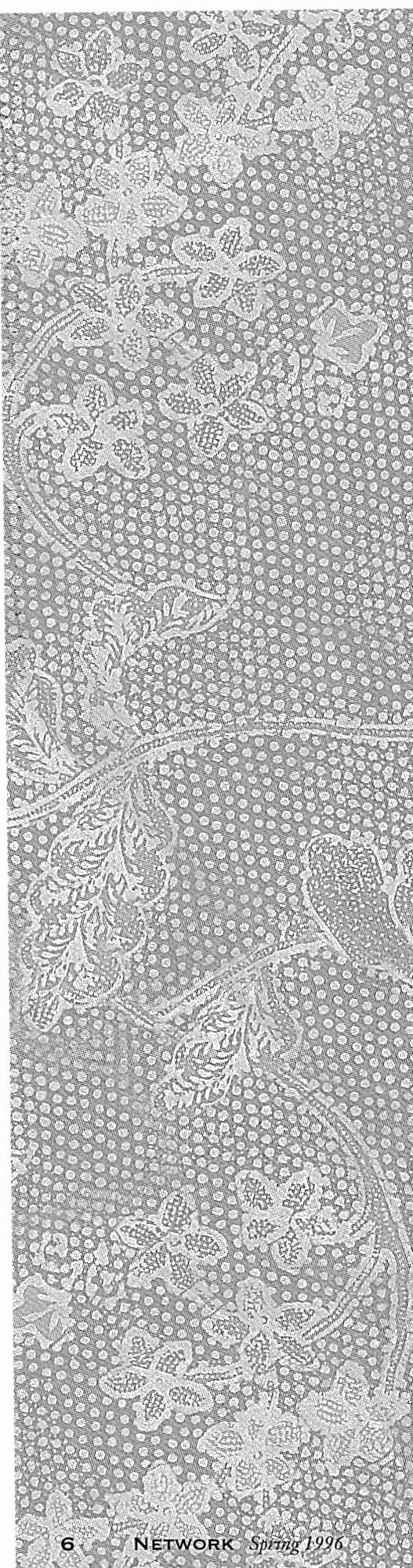
In addition, among Colombian commercial sex workers, women counseled to use spermicides as a backup method if their clients were unwilling to use condoms were less likely to use condoms consistently than women encouraged only to use male condoms. More research is clearly needed on the best mix of contraceptives. Studies that examine the use of the female condom, diaphragm, or spermicides in conjunction with long-term methods will help clarify this issue.

What are the key messages regarding use of barrier contraceptive methods to achieve better reproductive health? First, encourage correct and consistent use of condoms. Second, maintain hope (albeit with appropriate scientific skepticism) that research will show N-9 can be used effectively against HIV. Third, support developmental research of other female-controlled contraceptive barrier methods and microbicides. Fourth, evaluate ways to increase dual-method use to prevent both unplanned pregnancies and STD/HIV.

Dr. Cates, FHI's corporate director for medical affairs, is an epidemiologist. He previously directed the Division of STD/HIV Prevention at the U.S. Centers for Disease Control and Prevention.



DR. WILLARD CATES



Barrier Methods Require Consistent Use

Correct, consistent use improves contraception and is essential for achieving good STD protection.

For barrier methods to be most effective against both pregnancy and disease, they should be used during every act of intercourse and be used correctly.

Barrier methods are the only contraceptive methods that have been shown to protect against sexually transmitted diseases (STDs). The best scientific data available suggest that the level of STD protection from condoms or spermicides is closely linked with consistent use.

Two recent studies found that condoms must be used with every act of intercourse to achieve dependable protection against HIV from an infected partner. The studies tracked monogamous couples in which one partner was infected with HIV and the other was not.

One study followed couples an average of 20 months. Among 124 couples who used condoms during every act of intercourse, covering some 15,000 episodes of intercourse, no new HIV cases occurred. Among the 121 couples who used condoms inconsistently, there were 12 new HIV cases, a yearly rate of 4.8 per 100 person-years. Moreover, the study found that the couples who used condoms more than half the time had about the same number of new HIV cases as did those couples who used condoms less than half the time.¹

A study of 343 steady partners of infected men found similar results, with a new HIV incidence rate of 7.2 per 100 person-years among those who did not always use condoms, compared to a rate of 1.1 per 100 person-years among those who always used condoms.²

"In these studies, because one partner was infected, every act of intercourse involved the possibility of HIV transmission," explains Dr. Paul Feldblum of FHI, an epidemiologist who studies barrier methods. "That's why even using condoms half of the time did not make a significant difference over time. Similarly, during a woman's fertile period, the condom must be used every time for pregnancy prevention. In these situations, inconsistent condom use does not provide protection."

However, people who have multiple sexual partners, a minority of whom are HIV infected, will achieve some protection even with inconsistent condom use. For these people, "50 percent condom use will reduce the probability of contact with an infected partner by half," Dr. Feldblum and his colleagues wrote in a review of the effectiveness of barrier methods in preventing HIV.³

Incidence rates of gonorrhea and chlamydial infection, two STDs that can enhance the possibility of HIV transmission, have been found to decrease as spermicides are used more consistently.⁴ Hence, there could be less chance of HIV transmission. Using hypothetical scenarios involving multiple factors, an FHI computer analysis also

predicts that HIV infections in a high-risk group would be reduced if the overall proportion of coital acts protected by condom or spermicide use increased.⁵

"The key is the proportion of unprotected coital acts," explains Dr. Feldblum. "We must reduce that proportion. A method of limited efficacy, such as spermicides or the diaphragm, may offer some protection against HIV for women in situations where men do not use condoms consistently."

COUNSELING

Counseling can help people assess their own risk of STD infection or unintended pregnancy, as well as gain the necessary skills to assure consistent and correct use of barrier methods. Just saying "use it every time" does not help a client to understand the problem or help alter his or her behavior.

The risk of STD transmission varies depending on the number of partners involved (including partners of partners), prevalence rates of STDs in the region, demographic issues and other factors. To avoid unintended pregnancy while using barrier methods, a woman needs to understand her fertile period.

While most family planning associations offer barrier methods, many providers feel that they are not as effective as other methods and they should promote injectables or IUDs or some other highly effective contraceptive method. "At the same time, there has been more emphasis on counseling in the clinic for all methods," says Marc Okunnu, African regional director for the International Planned Parenthood Federation. "Counseling is seen as very important, and the trend to emphasize counseling will increase."

In most cases, using a barrier method consistently requires a change in sexual behavior. As with other personal matters, such as changing a diet, this involves moving through several stages: a

person considers making the change, may use the new behavior on a sporadic basis, and finally may continue the change over time.

To sustain behavior change, counseling needs to help people assess the stage they are in and move toward the maintenance stage. "The main point of counseling is to bring into cognitive awareness the specific behaviors needed to begin and maintain their contraceptive intentions; not to say, 'use a condom every time,'" explains Dr. Deborah Oakley of the University of Michigan, who has studied the effectiveness of counseling on barrier method use.

"The user, not the counselor, has responsibility for the behavior change," she says. "Counseling should go beyond the traditional notion of simply providing information. The main messages need to be: What is important in your life? How do you solve a problem? What behaviors do you want to use for your life? For people at risk, the most important counseling message is to bring them into awareness of how they even know that they have a problem."

In a study of consistent condom use for contraceptive purposes, Dr. Oakley and her colleagues identified groups of women who needed intensive counseling to achieve consistent use.⁶ "People who use condoms as a

backup method — for example, when a pill was missed — are highly motivated," says Dr. Oakley. "However, those who choose condoms as their contraceptive method may have underestimated how hard it is to use them every time."

Counseling appears to increase condom use when being done with both partners in a monogamous situation and when focusing on skill building. In a project that counseled heterosexual HIV discordant couples every six months over six years, there were no HIV seroconversions. Over time, condom use and abstinence increased.⁷ Another study compared women who received four, 90-minute group sessions and a one-month follow-up session in skill training with women who received only general health prevention messages. Three months later, the group receiving the training had increased condom use from 26 percent to 56 percent while the control group only increased marginally, from 26 percent to 32 percent.⁸

A less intensive approach did not prove successful. In 1991, a study in Kenya informed all HIV-infected women of their HIV test results and counseled them about the potential risks of transmission to future

RICHARD LORD



A FAMILY PLANNING COUNSELOR VISITS A SHOP IN HO CHI MINH CITY, VIETNAM, TO EXPLAIN THE CORRECT USE OF BARRIER METHODS.



A PROVIDER IN THE DOMINICAN REPUBLIC EXPLAINS THE CORRECT WAY TO USE CONDOMS.

children, giving special emphasis to using condoms. A year later, the same group was surveyed and compared to an HIV-negative control group. "Counseling women did not seem to influence their decisions on condom use and family planning," the researchers found. "More effective ways of informing and counseling women are urgently needed."⁹

To assess risk for STD infection, a counselor must ask confidential questions about sexual behaviors. Risk assessment checklists can help guide a counselor. Another approach is self assessment, in which the client is given materials to help evaluate his or her own risk.

Family planning agencies might consider using strategies that AIDS prevention campaigns have found successful. For example, rather than relying on professionals for counseling, a clinic could use peer counseling, where members of a group work with their peers.

Successful AIDS prevention projects have used peer education widely, especially among adolescents, commercial sex workers, truck drivers and other targeted groups. In Abidjan, capital of Côte d'Ivoire in West Africa, Population Services International (PSI) sponsors about 20 kiosks where young men and women sell condoms, hand out information and demonstrate correct condom use. Kiosks are located at high traffic areas such as taxi stands and market areas, and can be moved for use at community events.

COMMUNITY FACTORS

Consistent use of barrier methods is influenced by a variety of cultural or community factors. "Two of the most important predictors of condom use in the developing world are availability and affordability," says Michael Sweat, who works with FHI's AIDS Control

and Prevention (AIDSCAP) project. "If people can't afford condoms they will not use them no matter what interventions you design."

From the beginning of the AIDS epidemic, promoting condoms and their use has been a primary strategy. Social marketing projects, which use mass media, entertainment and other commercial marketing approaches,

"DUAL-METHOD" APPROACH AFFECTS CONSISTENT USE

Consistent use of barrier methods may decline when clients employ the "dual-method" approach, using a barrier method for protection against sexually transmitted diseases (STDs) but another method for contraception.

In an analysis of dual-use studies, Dr. Willard Cates of FHI found that "the more effective the primary contraceptive method was in preventing pregnancy, the lower the level of consistent use of the male condom."¹ For example, a U.S. study in Baltimore, MD found that among 92 adolescent women who were using oral contraceptives and were at high risk for STDs, only 10 percent used condoms consistently.²

But factors other than the method itself appear to affect levels of concurrent condom use, says Dr. Cates, FHI's corporate director of medical affairs. In a multisite study where spermicides were the primary contraceptive method, wide variations were found in the degree of consistent condom use, from 75 percent in Mexico to only 4 percent in the Dominican Republic.³

FHI is conducting a study of dual method acceptability, where women using oral contraceptives are given the choice of spermicide film or male condoms for disease protection. "Preliminary data indicate that giving the women a choice for disease prevention increases the degree of consistent use," says Markus Steiner of FHI, study coordinator.

— William R. Finger

FOOTNOTES

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have led to large-scale changes in condom use, particularly in Africa. Just a few years ago, there were less than a million condoms used annually in all of Africa. Today, there are nearly 20 million condoms sold a year in Ethiopia alone, with similar levels in several other African countries. "This pattern in condom sales across sub-Saharan Africa indicates a major behavioral change among African men," says Dr. Godfrey Sikipa, African regional director for AIDSCAP.

For counseling condom use among women to be effective, men have to be willing to use condoms. "Because women in many countries are not in a position to insist on condom use for cultural and economic reasons, men should be specifically targeted in AIDS prevention programs," concluded a study on condom promotion in Africa.¹⁰

"You've got to get to the men," says William Schellstede, FHI executive vice-president, who has worked with condom distribution for more than 20 years. "Counseling is a good, worthwhile thing. But the mass media approach is much more cost effective in reaching people who need to be using condoms but are not. You've got to do what the toothpaste industry did. 'Brush your teeth twice a day.' That jingle is what sells toothpaste, not individual counseling."

When possible, social marketing projects promote condoms for both disease and pregnancy prevention. "This double message allows women to bring up pregnancy prevention as a reason for using condoms, hence avoiding the issue of disease prevention or unfaithfulness," says Judith Timyan of PSI, the world's largest social marketing condom distributor. Entertainers, rock groups and others get people talking about condoms, helping to remove the stigma, she says.

PSI and other AIDS prevention efforts have used many tools to take the mass media message to a personal level. Illustrated brochures on correct condom use are usually distributed with condoms. Some programs have wooden penis models and demonstrate

proper condom use. Ideally, various barrier methods would be available for people to see and handle, at a clinic or from a community-based provider. Drawings, flipcharts, and wallcharts can be used to show correct placement of female methods. Also, women should have the opportunity to practice putting the diaphragm or cervical cap in place while at the clinic. Informational pamphlets or booklets to take home can be helpful.

Political decisions can affect condom use. In Thailand, political leaders approved a nationwide "100 percent condom" program, which has led to a sharp decrease in STD rates as condom use increased. "We concentrated the program on a limited goal, the use of condoms in commercial sex," explains Dr. Wiwat Rojanapithayakorn of the Thailand Ministry of Health. If a man came to an STD clinic with an infection, the clinic asked him which sex establishment he has used and enforced the rule at that establishment, closing it if necessary. Condom use has increased from about 14 percent when the program began in 1989 to 90 percent in 1994, and STDs in the country have decreased by 85 percent.¹¹

— William R. Finger

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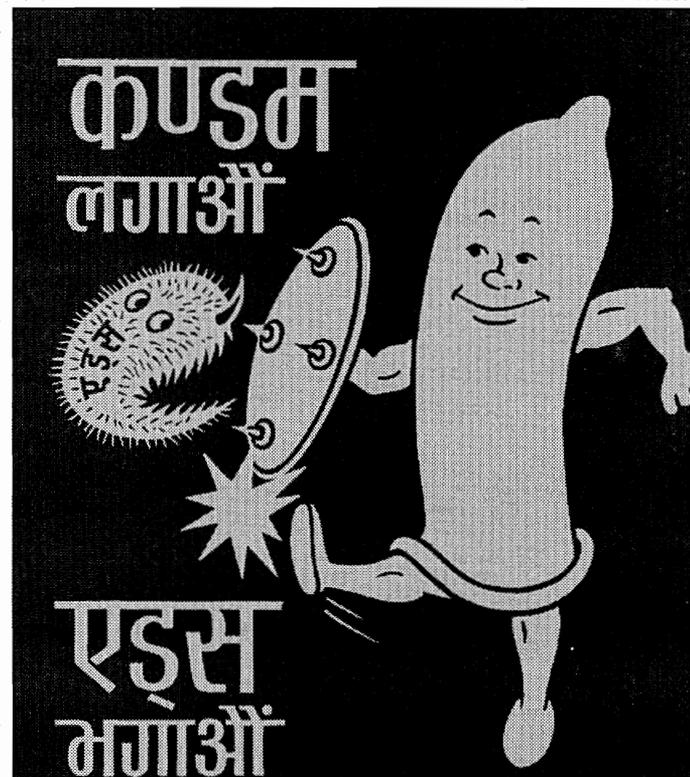
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AN AIDS PREVENTION POSTER FOR NEPAL, PRODUCED BY
FHI'S AIDS CONTROL AND PREVENTION (AIDSCAP) PROJECT,
PROMOTES CONDOM USE.



Methods Work Better when Couples Talk

Communication between partners about sexual concerns, risks and fears leads to better contraception and safer sex.

Communication between partners is a key factor in achieving correct and consistent use of barrier methods. Yet, in many societies, few couples ever talk to each other about reproductive health issues.¹

The couples who do not talk are at a greater risk for sexually transmitted disease and unintended pregnancy.² Providers who counsel clients on how to negotiate with partners and how to talk openly about sexual fears, risks and concerns will help clients achieve better contraception and safer sex.

While many AIDS prevention programs have explored ways to improve couple communication in order to promote effective condom use, family planning clinics have focused less on this issue.

"Most family planning programs offer methods women can use without involving their partners — such as pills and injectables," says Laurie Fox, who specializes in family planning and STD integration research at FHI. "The issue of correct and consistent barrier contraceptive use can be difficult because it requires something new — teaching partner cooperation." Some family planning providers criticize barrier methods because they are less effective in typical use than many other contraceptive options. The effectiveness of barrier methods would probably improve, however, with greater emphasis on couple communication.

"If family planning programs can counsel which method is best and how to use it, why can't they counsel clients on how to talk to their partners?" says FHI's Carol Joanis, who conducts research on the acceptability of contraceptive methods. "Certainly, we have enough experience with AIDS to know that communication is needed. Why is it such a radical notion? You ask if your client feels comfortable talking to her partner about condoms. Very simple questions lead to talking."

BUILDING CONFIDENCE

Ultimately, the effectiveness of communication about sexual issues depends on a person's self-esteem and sense of self-worth, says Joanis. The more confidence a woman has, the more she will be able to communicate about her needs, about sex, and her feelings, even in cultures where such communication is considered taboo.

Strengthening a woman's confidence in being able to manage her own sexual relationship may improve condom use, according to FHI's Dr. Priscilla Ulin, who conducted focus groups on safe sex in Haiti. Discussion groups among women, or among women and men, can promote a dialogue about sex, barrier methods and sexual risks.

Some women prefer gently encouraging a man to wear a condom, while others think they should convince a man rationally and appeal to his sense of duty to protect the family from AIDS. If communication does not work, women sometimes withhold sex, although

such a tactic can be risky.³ Counselors should consider asking clients what types of threats, reactions, and consequences they face.

In 1993 and 1994, the Washington-based International Center for Research on Women, an independent research group, organized 240 female factory workers into small discussion groups in Chiang Mai, Thailand, in collaboration with Chiang Mai University. After the sessions, the number of women who said they felt confident talking to a partner about STD risks increased from 60 percent to 90 percent. The portion of women who said they would not be embarrassed to give a partner a condom jumped from 36 percent before the sessions to 82 percent.⁴

Educational background may improve prospects for couple communication and contraceptive use, suggests a survey of 1,022 Nigerian men. The survey showed that among educated men who communicated about family planning with their partners, 60 percent used contraceptives. Among the educated men who did not discuss sexual matters with partners, only 10 percent used contraception. Among uneducated men in the survey, 27 percent who talked about family planning were using contraception, compared with only 4 percent who did not communicate with partners.⁵

Couple communication among adolescents should be encouraged. A University of Minnesota study looked at 550 adolescent women in the United States who used school and community-based clinics. Women who said they communicate openly with their partners had the lowest risks of pregnancy and sexually transmitted diseases (STDs). Nontalkers were five times more likely to have multiple partners and twice as likely to have sex with a partner infected with an STD.⁶

Among married couples, communication seems to improve contraceptive use. The U.S.-based Demographic and Health Surveys (DHS) analyzed reports from 7,150 married women in its 1988 Kenya survey, finding that 36 percent of couples who communicated frequently about sex used contraception, compared with only 12 percent of women who did not communicate with their spouses.⁷

LEARNING TO TALK

Teaching women to talk about STD risks with their partners may require approaches that are different from the interventions used with men.

BERYL GOLDBERG



STUDENTS IN AVEQUIPA, PERU TALK AFTER CLASSES.

An STD education campaign in the Dominican Republic in 1995 improved condom use among men, but failed to address the needs of women. When surveyed, women said they did not like the idea of discussing sexual issues with men present. Consequently, the Coordinadora de Animación Socio-Cultural (CASCO), a non-profit STD prevention organization in Santo Domingo, and FHI's AIDSCAP project, revised their approach. In female discussion groups, women felt more comfortable talking about the challenges of encouraging condom use.

"We needed to think of a new strategy exclusively for women," said Betaña Betances, a CASCO social psychologist. The Santo Domingo discussion groups involved 185 young women, ages 15 to 24. Women said they understood condoms would help protect them from HIV and other STDs, but they feared insisting on condom use. They thought condoms would make them look promiscuous. Women with

multiple partners were more likely to use condoms, while those with monogamous relationships were less likely to do so.

When asked what type of sexual education they would most like to receive, the women were divided about whether they preferred talking to peers or experienced counselors. The women suggested having a resident female counselor in their communities with whom they could discuss sexual matters at any time.

In 1993, Brazil's family planning organization, Sociedade Civil Bem-Estar Familiar no Brasil (BEMFAM), began offering peer discussion groups to women attending BEMFAM clinics for routine medical services. By 1996, more than 2,500 women across the country had participated in the one-hour discussions, designed to teach communication

Continued on page 14

Typical One-year
Contraceptive
Effectiveness*

Male Condom

88%

Female Condom

79%

Spermicides

79%

Effect on STDs

Latex condoms provide substantial protection against STDs including HIV, if used consistently and correctly and are the recommended method for STD protection

Probably protects against STDs, including HIV, if used consistently and correctly; under study

Some protection against bacterial STDs such as gonorrhea and chlamydia; effect against viral STDs such as HIV is uncertain

Health and
Other Concerns

Irritation and allergic reactions to latex (rare); may interrupt sexual activity and may reduce sensation

Irritation possible (very rare); can be inserted prior to sexual activity; may be difficult to learn to insert; relatively expensive

Can cause irritation with frequent use; may cause minor discomfort or allergic reaction; can lead to yeast infections

How to Use
Correctly

Used correctly, condoms rarely break or slip. Studies have found that only a small portion of condom users break them during use, and these people can be identified by good screening.

To use correctly:

- open package carefully to avoid tearing condom, especially with sharp objects like fingernails, teeth or scissors
- roll condom directly onto the erect penis all the way to the base of the shaft (do not unroll before putting it on)
- pinch the end of the condom while unrolling it to leave room for the semen
- after ejaculation, hold rim of condom and pull penis out of vagina before penis gets soft, to prevent condom from slipping off
- slide condom off penis without spilling semen
- dispose of properly after use

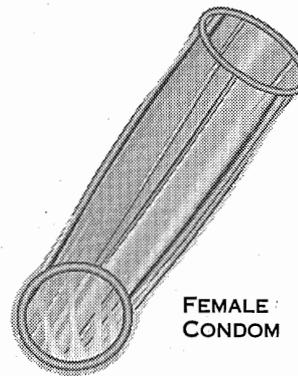
Other considerations:

- avoid genital contact before condom is put on
- use a separate condom for each act of intercourse, never reuse a condom
- use only water based lubricants such as K-Y jelly, spermicidal gels or creams or saliva; oil-based lubricants such as hand lotions and mineral or vegetable oils weaken condoms in just a few minutes, making them more likely to break
- if the package has been torn or damaged or if the condom feels brittle or dry or has changed color, do not use the condom.

To avoid tearing the female condom, the package should be opened carefully, especially when using sharp objects like fingernails, teeth or scissors.

To use correctly:

- insert inner ring high in the vagina, against the cervix
- place the outer ring properly outside the vagina
- during intercourse, be sure the penis is placed inside the female condom



Other considerations:

- avoid genital contact before condom is put in and after it is removed
- can be used by a woman who is pregnant or menstruating, but not by a woman who has a tampon inserted
- is pre-lubricated with silicone, and a vial of lubricant is provided to allow adding more lubrication to meet a couple's preference; adding lubricant also reduces noise during use
- dispose of properly after use

Spermicides should be placed high in the vagina near the cervix shortly before intercourse, and reinserted for each act of intercourse. Foams, jellies and creams are effective as soon as inserted.

Suppositories, tablets and films require five to 15 minutes to dissolve before intercourse.

To use correctly:

- use clean hands and a clean applicator when inserting
- for foams, shake container vigorously just before insertion
- for jelly or cream, fill applicator and insert far into vagina (near cervix); push applicator plunger to release spermicide; after each use, wash applicator with soap and water
- film must be folded in half and inserted with dry fingers near the cervix, or the film will stick to the fingers and not the cervix



Other considerations:

- once inserted, spermicides are effective for one to two hours
- for maximum effectiveness, a spermicide should be used with another barrier method, such as a diaphragm or condom
- after intercourse, wait at least six hours before douching

* Methods are more effective if used correctly during every act of intercourse — about 97 percent for the condom and 94 percent for spermicides. "Typical use" includes people who do not always use the method correctly, or who use it inconsistently.

ER METHODS AND DISEASE PREVENTION

Diaphragm

82% (with spermicide)

Some protection against bacterial STDs such as gonorrhea and chlamydia; effect against viral STDs, such as HIV, is uncertain

Not recommended for those with allergy to latex or spermicides or history of toxic shock syndrome; may lead to urinary tract infection

A diaphragm must be fitted initially by a trained provider and is not recommended for women with cervical or vaginal abnormalities or during the first six weeks after childbirth.

DIAPHRAGM



To use correctly:

- before inserting, check for holes or tears by holding it up to the light; if defective, use a backup method
- spread spermicidal jelly or cream on the inside portion of the dome and rim with clean, washed hands
- put the device all the way back against the cervix with the cavity containing the spermicide covering the cervical opening; feel around the edge to be sure the cervix is completely covered
- if intercourse occurs more than an hour after inserting a diaphragm, or if multiple acts occur, spermicide should be added without removing the diaphragm
- leave in place for at least six hours after the last act of intercourse, but no more than 24 hours
- after use, wash with soap and water, dry it, and store it in a cool, dry, dark place

Other considerations:

- after intercourse, wait at least six hours before douching
- when removing, care should be taken not to damage it with fingernails
- refitting may be necessary following weight change, full-term pregnancy or late-term abortion

Cervical Cap

82% (nulliparous women)

May protect against gonorrhea and chlamydia, but not studied

Not recommended for those with allergy to latex or spermicides or with history of toxic shock syndrome

Cervical caps are inserted before intercourse and can remain in place up to 48 hours. They are effective for multiple acts of intercourse.

They must be fitted initially by a trained provider and are not recommended for women with cervical or vaginal abnormalities or during the first six weeks after childbirth.

To use correctly:

- before inserting, check for holes or tears by holding it up to the light; if defective, use a backup method
- fill one-third to one-half of cap with spermicidal jelly or cream
- insert by squeezing cap between thumb and index finger, sliding into vagina and pressing rim around cervix; feel around the edge to be sure the cervix is completely covered
- to remove, press on rim until seal on cervix is broken, tilt cap, then hook fingers under rim and pull sideways out of vagina
- after use, wash with mild soap and water, and dry thoroughly; store in a cool, dry, dark place

Other considerations:

- although it can stay in place for up to 48 hours, this may lead to a bad odor
- after intercourse, wait at least six hours before douching
- when removing, care should be taken not to damage it with fingernails
- refitting may be necessary following weight change, full-term pregnancy or late-term abortion

Sponge

82% (nulliparous women)

Probably protects against bacterial STDs, such as gonorrhea and chlamydia; only study done on HIV did not show any protection

Irritation and allergic reactions (rare); limited availability; may be less effective among parous women

A sponge is effective for multiple acts of intercourse and, depending upon brand, may be used up to 12 hours or up to 24 hours. It should be left in place for several hours after intercourse.

Specific instructions vary by product. The sponge is currently marketed only in France (benzalkonium product) and Canada (a product containing sodium cholate, benzalkonium chloride and nonoxynol-9). A U.S. nonoxynol-9 product, the Today sponge, is no longer manufactured.

To use properly:

- insert deep into the vagina so it rests against the cervix
- check placement before and after intercourse
- follow other brand-specific instructions provided in the labeling
- dispose of properly after use

Other considerations:

- use only once
- no fitting needed
- consider using with condom to increase effectiveness

CERVICAL CAP





A COUPLE AT A FAMILY PLANNING CLINIC IN LIMA, PERU. BETTER COMMUNICATION BETWEEN PARTNERS HELPS ACHIEVE CORRECT AND CONSISTENT USE OF BARRIER METHODS.

Continued from page 11

skills about safe sex. Comic strip stories about HIV risk were used to open up the group conversations, and penis models were used to teach women how to use condoms.⁸

In 1994, International Planned Parenthood Federation (IPPF) helped train counselors at the Jamaican Family Planning Association on partner negotiation and how to prompt clients to think about partners' sexual habits and STD risk. Training included role plays in condom negotiation strategies with a reluctant partner. The role playing helped counselors appreciate the complexity of trying to convince a partner to do something in the middle of a sexual act, says IPPF's Julie Becker.

A project by AIDS Technical Support: Public Health Communication Component (AIDSCOM) in Brazil, Tanzania and Indonesia asked women to talk about the reactions or consequences they might encounter if they tried to talk to their partners about sexual risks, or insisted on condom use. In

focus groups of 40 women in each country, women were asked to indicate the advantages and disadvantages of discussing safe sex.

Advantages included protection from AIDS and other STDs, protection from pregnancy, convincing a partner to have only one partner, and strengthening the relationship. But several disadvantages also were listed, including the potential for instilling distrust and suspicion.⁹

"It's a really tricky issue," says FHI's Donna Flanagan, who specializes in behavior change communication to help prevent AIDS. "You have to teach someone how to convince somebody else to do something, like wear a condom. That requires skills. Not only skills in communication, but it also requires self-confidence and assertiveness."

— Sarah Keller

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Microbicide Research Aims to Prevent STDs

Polysaccharides, buffer gels and a variety of plant and animal extracts are among promising candidates.

One of the newer areas of barrier method research is the development of microbicides — substances that destroy or incapacitate infection-causing organisms, including bacteria, viruses and parasites.

Microbicides may offer a female-controlled method of STD prevention that does not require partner knowledge or cooperation. Also, microbicides may or may not have spermicidal properties, allowing women to prevent disease but not pregnancy — an option that is not available to condom or spermicide users.

While couples may want to prevent pregnancy at certain times in their lives, “the desire to prevent infection is consistent throughout your life,” says Dr. Penelope J. Hitchcock, chief of the STD branch of the National Institute of Allergy and Infectious Diseases (NIAID) in the United States. “Program managers have been focusing on family planning and limiting the number of children, but we also have to realize that preservation of fertility is an important component of reproductive health.”

NIAID is one of several organizations working to develop microbicides. With NIAID funding, the University of Pittsburgh will soon begin safety and efficacy studies of microbicides containing lactobacilli, bacteria that occur naturally in the vagina. Lactobacilli produce hydrogen peroxide, which scientists believe prevents the spread of infections. The University of Pittsburgh study will examine the use of lactobacilli suppositories among adolescents.

“Adolescents have typically been excluded from research,” says Dr. Sharon L. Hillier, the study’s principal investigator. “If we are going to think of solutions that will work in preventing STDs, we will have to target the group that is most at risk. We have to determine whether they will use an intervention, and how they will use it. We can benefit from knowledge of their behaviors.”

The study will follow more than 900 adolescent women at an urban health clinic for one year. Researchers will try to determine whether use of the lactobacilli suppositories alters microorganisms that normally occur in the vagina, whether the suppositories decrease the incidence of bacterial vaginosis and gonorrhea compared to use of a placebo, and whether use of the suppository has any effect on acquisition of other STDs.

The U.S.-based Population Council also is conducting research to develop new microbicides and has completed safety trials among women on microbicides containing sulfated polysaccharides. These substances occur naturally in the human body, coating the cells and connective tissues. Scientists believe that polysaccharides, which have been shown *in vitro* to inhibit HIV, may coat the epithelial surface of the vagina with a film that repels HIV and HIV-infected cells. Polysaccharides, which are used as food additives, are non-detergents and may produce less irritation than currently available spermicides.

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SPERMICIDE RESEARCH EXAMINES HIV PREVENTION

Spermicides, already available for contraception without prescriptions in many countries, are being studied for their ability to prevent HIV. FHI researchers, for example, are working with the Ministère de la Santé Publique in Cameroon to examine the effects of the vaginal contraceptive film containing the spermicide nonoxynol-9 (N-9) in preventing HIV.

Study participants include approximately 1,300 female sex workers in Yaoundé and Douala, who are HIV-negative. Participants are divided into two groups — those who use male condoms and N-9 film and those who use condoms and a placebo film. They will be followed for one year.

decrease in HIV infection, gonorrhea and genital ulcers.¹ A second analysis of the Cameroon data, which separated the effects of condom use and N-9 use, found HIV incidence declined as N-9 use increased.² FHI research in Zambia found that among 110 HIV-discordant couples who consistently used N-9 spermicide, there was a slightly lower incidence of seroconversion than among couples who did not use N-9 consistently. However, the study is not conclusive, and it remains unclear whether N-9 reduces HIV risks.³

The conflicting findings may be due to different doses of spermicide. FHI studies in Thailand and the Dominican Republic have

HIV, and because studies in humans demonstrate that spermicides reduce the incidence of gonorrhea and chlamydia, some health organizations have recommended spermicides as a choice for STD protection. In the United States, the New York State Public Health Department recommends a hierarchy of protective measures women can use against STDs. Male latex condoms are the first choice, followed by female condoms with spermicide, diaphragm with spermicide, and spermicide alone. "This is risky," a health department brochure says about using spermicide alone for protection, "but it's better than doing nothing."



NASH HERNDON/FHI

Researchers will also examine the effects of N-9 use on genital ulcers, as well as its effects on normal microorganisms in the vagina. The study is funded by the National Institutes of Health (NIH) in the United States.

Previous studies have shown that low levels of nonoxynol-9 inactivate HIV *in vitro*. But studies in humans have shown conflicting results. One study of female sex workers in Kenya found that sponges containing N-9 did not protect against HIV, while an FHI study of N-9 suppository use among sex workers in Cameroon showed a

shown that high, frequent doses of N-9 cause irritation and disrupt the cell surface of the vagina.⁴ The World Health Organization (WHO) conducted a study on effects of the spermicide menfegol, and found similar results.⁵ These effects on the vaginal mucosa may enhance the transmission of HIV and bacterial STDs.

Because *in vitro* studies show that the detergent spermicides N-9, benzalkonium chloride (BZK) and menfegol can inactivate

In addition to studies on the ability of current spermicides to prevent STDs, research is under way to develop new spermicides and delivery systems. Advantage 24, a spermicide that may be effective for 24 hours, is being studied for its microbicidal properties. Researchers have investigated the spermicidal effects of mandelic acid,

which is extracted from peach leaves and has been shown *in vitro* to kill both sperm and trichomonas; crassulaceae, a family of herbs used by rural women for contraception; carrageenan, a component of seaweed; synthetic magainins, peptides isolated from the skin of the African clawed frog; and extract from seeds of *Abrus precatorius*, commonly called Indian licorice.

ACCEPTABILITY

Researchers are examining ways to improve acceptability, including evaluations of the systems used to deliver spermicides and microbicides. An FHI-sponsored study of family planning clients in Kenya and Mexico found that women preferred spermicides delivered in contraceptive film rather than foaming tablets.⁶ Another FHI-sponsored study among STD clients in Zambia found that foam was the least popular delivery system while suppositories and foaming tablets were more acceptable.⁷ A study of 260 women in Scotland examined the acceptability of the diaphragm with contraceptive film and found that many women preferred the film but experienced some irritation and discharge not common among users of spermicide gel.⁸

PROFAM in Mexico has studied the delivery of spermicides through soft capsules that dissolve in the vagina. The University of Kentucky in the United States is exploring the use of slow-releasing pellets for spermicides and microbicides, and Biotek, a U.S. company, is working on a spermicide that turns into a gel when it comes in contact with vaginal secretions. A vaginal ring, which would release spermicide for up to 30 days, also is under study.

— Barbara Barnett



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"What we want is something that is not absorbed when it gets into the vagina," says Dr. David Phillips, who is conducting the research at the Population Council. "Since these compounds are very large in size, they're not easily absorbed by the body. They are generally found throughout nature, so they would be an inexpensive and stable source for microbicides."

The Population Council's studies have examined women's preferences about delivery systems, including film, gels, and suppositories. "One of the take-home messages is that any kind of vaginal product is going to have to be formulated in multiple ways," said Christa Coggins of the Population Council. "There is not going to be one product that will meet every woman's needs."

FHI, NIAID, National Institute of Child Health and Human Development, ReProtect Llc., and Johns Hopkins University are working to evaluate a buffer gel that would offer

protection against STDs, including HIV. This product, which would contain substances similar to some of the gel agents found in shampoos and soaps, would maintain the pH levels in the vagina even in the presence of semen, which normally neutralizes the vagina's acidity.

A buffer gel that maintains the acidity in the vagina could have numerous benefits, researchers say. Many types of enveloped viruses, including a strain of HIV, are inactivated by increases in acidity. Bacteria, including the type that causes gonorrhea, are killed when acid levels increase. "Trojan Horse" leukocytes — the HIV-infected cells in semen and cervical mucus that may enhance the transmission of HIV — appear to lose motility and viability and stop producing HIV when exposed to an acidic environment. And sperm are rapidly killed by mild acidity. The buffer gel is odorless, colorless and inexpensive, and it does not eliminate the lactobacilli, which help produce the acidity in the vagina.

Plant extracts, including gossypol (cottonseed oil) and neem, have been investigated for their microbicidal effects by the South to South Cooperation in Reproductive Health, based in Brazil. With gossypol, researchers are trying to develop a way to contain the substance in a gelatin capsule that could be inserted into the vagina. Creams and pessaries made from neem, which grows abundantly in the tropics, have been shown to be both spermicidal and microbicidal. However, initial safety studies among humans were discontinued because the odor was unacceptable to users and because it took too long for neem products to dissolve in the vagina. New formulations, with reduced odor, are being tested.

Other substances that are being studied as potential vaginal microbicides are synthetic protegrins, small proteins that occur in the white blood cells and have been shown *in vitro* to inactivate HIV, herpes, gonorrhea, chlamydia and other bacterial STDs; C31G, a substance in mouthwash that is both spermicidal and microbicidal; N-docosanol, an alcohol that blocks some enveloped viruses; and squalamine, a steroid-based compound that may be effective against bacterial and viral STDs.

Also, a modified version of beta-lactoglobulin, a protein found in the dairy product called whey, has blocked HIV transmission in human cells in test tube experiments at the New York Blood Center. The modified protein, called B69, does not seem to affect sperm.

The interest in microbicides has been fostered, in part, by the need for a female-controlled method that offers women protection against STDs. The best protection currently available is latex condoms, which men control. Yet, while microbicides have been discussed as a method that will benefit women, the development of these products may protect men from contracting STDs as well, Dr. Hitchcock suggests. And they may be more appealing than condoms to use.

— Barbara Barnett

BERYL GOLDBERG



IDEAL MICROBICIDES WOULD NOT HAVE CONTRACEPTIVE PROPERTIES, ALLOWING WOMEN TO PREVENT DISEASE BUT NOT PREGNANCY. WOMEN IN MONTEVIDEO, URUGUAY WAIT TO SEE A DOCTOR AT A MOBILE CLINIC.

DEVELOPING NEW DIAPHRAGMS, CONDOMS AND SIMILAR DEVICES

Efforts are under way to improve condoms, diaphragms and similar devices that work by providing a physical barrier between sperm and egg.

Research organizations, including FHI and the World Health Organization, and private industry are exploring the use of new materials for male condoms, such as polyurethane (plastic) instead of latex, and new designs, such as loose-fitting condoms instead of the snug fit currently used. The first plastic condom was introduced last year in Europe and the United States. Plastic condoms have several advantages, including possibly a longer shelf-life than the latex condom, possibly improved sensation during sexual intercourse, and compatibility with oil-based lubricants, which destroy latex.

The polyurethane female condom, which can be used for contraception and STD prevention, is being studied to determine whether it can be used more than once. Being able to clean the device and reuse it safely and effectively could lower the cost to users. Additional FHI studies to evaluate the method's acceptability, including male partners' attitudes, are under way in Mexico. New types of female condoms are being studied, including the Bikini Condom, which is worn like a panty, and another product called Women's Choice, which is inserted with an applicator.

The contraceptive sponge, which is not widely available in many countries, is undergoing refinements. A new sponge, Protectaid, is available in Canada. Made of polyurethane, the device contains F-5 gel, a combination of three spermicides (nonoxynol-9, benzalkonium chloride and sodium cholate) in

low doses. Manufacturers believe these lower concentrations of spermicides will reduce irritation to the vaginal mucosa. A sponge containing benzalkonium chloride (BZK) is available in Europe. However, the Today sponge, which contains nonoxynol-9 (N-9) and was sold in the United States, is no longer manufactured.

The diaphragm has the advantage of being a female-controlled method that prevents pregnancy and appears to reduce the risks of some STDs, including gonorrhea and chlamydia, as well as pelvic inflammatory disease. Yet,

many women find the device inconvenient, since it must be inserted prior to intercourse, and messy, since it must be used with a spermicide gel or cream. Researchers are exploring ways to make this device easier and more appealing to use.

In Brazil, women from three clinics participated in a study to compare contraceptive effectiveness of the diaphragm when used with spermicide during time of intercourse, and when not used with a spermicide but worn continuously. Spermicide use did not significantly improve effectiveness, researchers found, and the cost and messiness of spermicide may have discouraged

correct use.¹ Yet, because spermicides also act as microbicides, many researchers suggest that diaphragms without spermicide may offer little protection against STDs. A study in London found relatively high pregnancy rates, but promising continuation rates, among 110 women who continuously used a fit-free diaphragm (one that did not require fitting by a doctor) without spermicide. The 12-month accidental pregnancy rate was 24.1 pregnancies per 100 women.²

A new type of diaphragm — one made of silicone rather than latex — has been developed, and a study of this device's effectiveness and acceptability is now under way in Brazil. According to Dr. Carlos Petta of Centro de Pesquisas e Controle das Doencas Materno-Infantis de Campinas (CEMICAMP), the diaphragm, used without spermicide and worn continuously by women in the study, is re-

moved only for washing. This diaphragm comes in different colors, which researchers think may be more attractive to women.

Another new method, Lea's Shield, is a cup-shaped barrier that covers the cervix. This device has a valve that allows the draining of cervical secretions and menstrual flow, and has a U-shaped loop for easy removal. Made of silicone rubber, it can be worn up to 48 hours. The U.S.-based Contraceptive Development and Research program (CONRAD) has conducted safety and efficacy studies of this device, which eventually may be available without a visit to a health provider.

The Gynaeseal diaphragm tampon, available in Australia, has an inner chamber and an outer pouch. The inner chamber has a one-way valve that allows menstrual fluids to pass

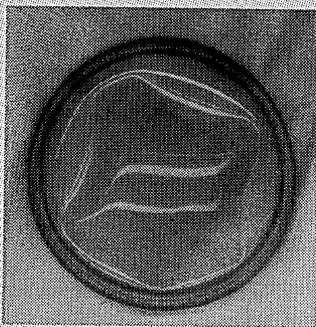
through, and cervical secretions are collected in the outer pouch.

Cervical caps, available primarily in the United States and Europe, also are being refined. Shaped like a small dome, the cap is used with spermicide and can

be inserted 40 hours prior to intercourse, and must not be removed for at least eight hours following intercourse. Side effects include vaginal odor and discharge, vaginal tears and cervical irritation. Also, some cervical cap users report increased rates of urinary tract infections, as do diaphragm users.

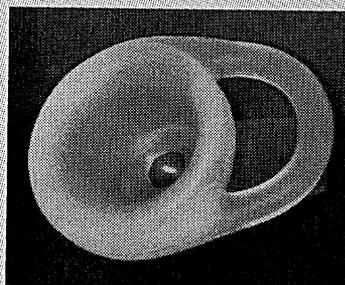
The safety and efficacy of a new type of cervical cap are being evaluated in the United States by FHI and CONRAD. Femcap, which is made of silicone rubber, is a device shaped like a hat with a wide, upturned brim. It fits over the cervix, is designed to be worn for up to 48 hours, and may be effective without spermicide.

— Barbara Barnett



FHI

SILICONE DIAPHRAGM



YAMA INC.

LEA'S SHIELD



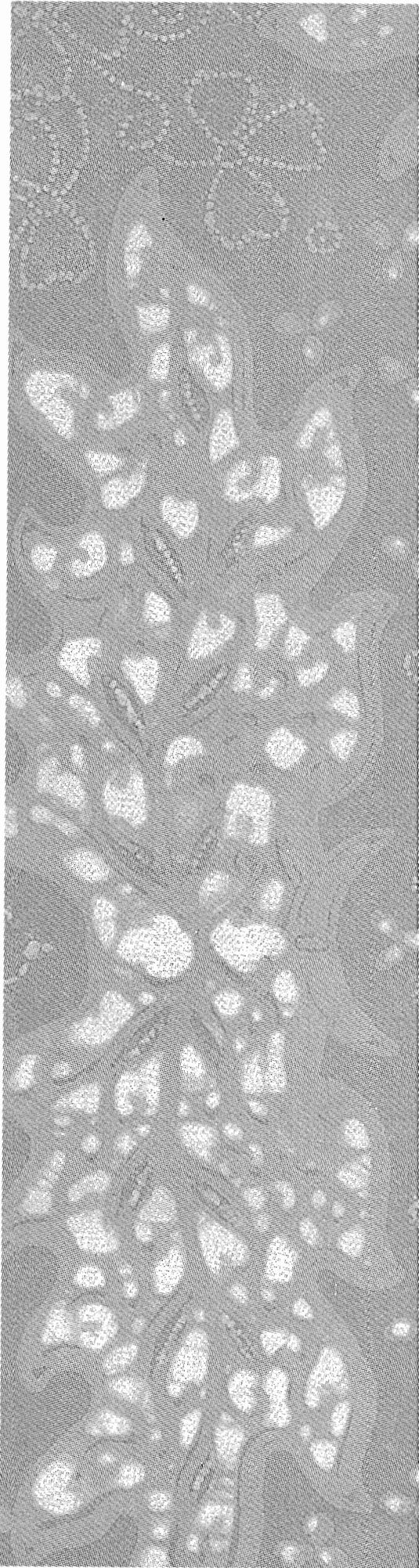
NASH HERNDON/FHI

PROTECTAID SPONGE

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STD Protection after Intercourse

Emergency protection after STD exposure has limitations and should be used for specific situations.

For couples to prevent unintended pregnancy after unprotected intercourse, emergency contraception offers a means. Yet unprotected intercourse also increases the risks of contracting a sexually transmitted disease (STD). Are there emergency measures that can be taken to reduce this risk after exposure?

Yes, experts say. However, these measures have limitations and are recommended only for certain groups of people, such as women who are victims of sexual assault. Emergency treatment of STDs is not recommended for routine use.

“The principal problem [with emergency treatment] is the multitude of STDs,” says Dr. Robert Johnson, a medical epidemiologist with the Division of STD Prevention at the U.S. Centers for Disease Control and Prevention (CDC). “There isn’t a single drug that can treat all STDs. The viral agents cannot be treated. Coming up with a regimen is problematic.”

There are more than 20 types of sexually transmitted diseases. While latex condoms, used consistently and correctly, can reduce the risks of all of them, no single drug can successfully treat all of them.

Combinations of antibiotics may be used to reduce a woman’s risks of infection from some bacterial STDs following sexual assault. Genital washing and medications have shown some effectiveness in preventing STDs among men serving in the military. Douches, used by many women to cleanse

the vagina, may not help prevent STDs and may actually promote infection in cases where contamination is introduced.

Worldwide, an estimated 250 million new cases of STDs occur annually.¹ Most scientists now agree that STD infection increases an individual’s risk of contracting HIV, the virus that causes AIDS. There is evidence that STDs that cause genital sores, such as herpes, chancroid and syphilis, can enhance the risks of HIV transmission by creating a site of entry for the AIDS virus. Other STDs, which do not produce ulcers but do produce inflammation, may also increase susceptibility to HIV.²

Because latex condoms can prevent transmission of both bacterial and viral STDs, and because antibiotics can successfully treat bacterial STDs once a diagnosis has been made, research to find a method of emergency STD prevention — one that could be used after unprotected sexual intercourse but before symptoms develop — has been limited.

However, research is under way to develop microbicides, which would kill both bacterial and viral STD pathogens. Some researchers have speculated that these products, designed for use prior to sexual intercourse to prevent infection, might also be used for postcoital or emergency STD prevention. (See related article, page 15.)

“The need for such a product is evidenced by emerging data concerning the widespread prevalence of non-consensual and coercive sex in women’s lives, even within married and consensual unions,” write Christopher Elias of the Population

Council and Lori Heise of the Health and Development Policy Project. "A postcoital method might also have some utility for women, especially adolescents, in communities where 'planning' to have sex is unacceptable."³

Postcoital STD treatment could also be helpful for couples who use condoms as a means of STD prevention but experience condom breakage or slippage, much as emergency contraception is used to prevent pregnancy when a couple experiences condom failure.

SEXUAL ASSAULT

For women who are the victims of sexual assault or non-consensual sex, the CDC has developed guidelines for emergency STD treatment. The guidelines recommend a combination of antibiotics, given within hours after sexual intercourse. This combination is designed to prevent the infections most commonly diagnosed after sexual assault — trichomoniasis, chlamydia, gonorrhea and vaginal bacteriosis.

The CDC recommends: 125 milligrams of ceftriaxone injected intramuscularly in a single dose; two grams of metronidazole orally in a single dose; and 100 milligrams of doxycycline taken orally twice a day for seven days.⁴

The CDC also recommends that health-care providers counsel the client about symptoms of STDs and the need for her to return to the clinic if these occur. Providers should counsel the client to use condoms until the antibiotic treatment is complete, to prevent the possibility of any STD transmission to her partner.

If available, clients should be given a vaccine to protect against Hepatitis B. If laboratory tests are available for STDs, the client should return for follow-up examinations at two weeks and 12 weeks after the sexual assault.

The likelihood of contracting an STD after sexual intercourse is less than the risk of becoming pregnant. Fewer than one in five people are infected with an STD at any given time, while nine out of 10 women under age 35 are fertile and could become pregnant.⁵ The use of antibiotics as a preventive measure is often done for psychological reasons as well as biological ones. The client, who has already undergone the physical and emotional trauma of assault, may have one less consequence to worry about if she takes antibiotics.



NASH HERNDON/FHI

WHILE LATEX CONDOMS CAN REDUCE THE RISKS OF ALL KNOWN STDs, NO SINGLE DRUG CAN SUCCESSFULLY TREAT ALL OF THEM.

There is some risk a woman will acquire HIV infection after sexual assault, but the CDC says the risks are very low. There are no emergency measures a health-care provider can take to reduce a woman's risk of HIV in this situation. Providers should offer HIV counseling and testing to clients, but some experts recommend that this be done during a return visit to the clinic, not during the initial visit when the client is frightened and upset.

Outside of use to prevent the development of STDs among sexual assault victims, the use of antibiotics for emergency STD prevention in the larger population is regarded by most experts as an unnecessary and an expensive use of scarce medical resources. "Emergency treatment will result in the overtreatment of people who are not infected," says Dr. Jonathan Zenilman, associate professor of medicine in the Infectious Disease Division of Johns Hopkins University in the United States. Given that some STDs have developed a resistance to certain antibiotics, treatment before diagnosis is not recommended.

MILITARY EXPERIENCE

The use of postcoital emergency treatment for STDs has had some success in the U.S. military. During World War I, military officials tried to reduce the incidence of STDs through educational campaigns that emphasized the need for servicemen to be "100 percent efficient to win the war." Mili-

tary personnel were encouraged to practice abstinence to prevent sexually transmitted diseases.

Servicemen who did engage in sexual activity with prostitutes were told to return to their military base and report for emergency treatment within three hours after sexual intercourse. The procedure involved several steps. First, the soldier urinated, then washed his genitals with soap and water, followed by bichloride of mercury. A medical attendant inspected the soldier's genital area, then injected Protargol, which contains silver protein, into the penis. The soldier would urinate five minutes later. Finally, calomel ointment was rubbed onto the penis, and the penis was wrapped in wax paper. The soldier was not to urinate for at least four to five hours after treatment.

To further reduce the incidence of sexually transmitted disease during World War I, U.S. soldiers were given an emergency treatment packet they could administer themselves. This was done on an experimental basis for soldiers who did not have access to a health clinic. The packet contained calomel ointment, carbolic acid and camphor.

Military health officials estimated this treatment could be 99.6 percent effective in preventing syphilis, gonorrhea and chancroid. Statistics on the success of military efforts to reduce STDs were not published.

However, military officials estimate that several million men received emergency STD treatment.

During World War II, the U.S. military sought to reduce the incidence of STDs by offering educational programs, emergency STD treatment and condoms for STD prevention. With the discovery that antibiotics could effectively treat bacterial STDs, and the knowledge that condoms could prevent STD transmission, the use of emergency STD clinics diminished.⁶

In the 1970s, a study among some 500 U.S. male sailors who had sexual intercourse with women while on shore leave in the western Pacific concluded that STD infection rates did not decrease significantly if a man urinated within 30 minutes after intercourse or if he washed his genitals within an hour.⁷ Another study among 1,000 male sailors found that 200 mg of minocycline, taken orally a few hours after intercourse, offered some protection against the subsequent development of gonorrhea. However, researchers did not recommend widespread use of the antibiotic because drug-resistant strains of gonorrhea could develop.⁸

VAGINAL DOUCHING

Because many women practice routine vaginal douching for hygienic purposes, there has been speculation that postcoital douching might reduce the incidence of STDs. Studies have shown that douching may not offer any type of protection against STDs. In fact, it may promote some types of reproductive tract infections.

While vaginal douching may decrease the risks of gonorrhea, it may increase the risks of pelvic inflammatory disease and ectopic pregnancy.⁹ A study of more than 600 women in the United States found those who douched were more likely to have risk factors for STDs, including multiple sexual partners and first sexual intercourse at an early age. However, others say it is difficult to determine whether douching increases a woman's risk of infection or whether douching is simply a common practice among women at risk of STDs for other reasons.¹⁰

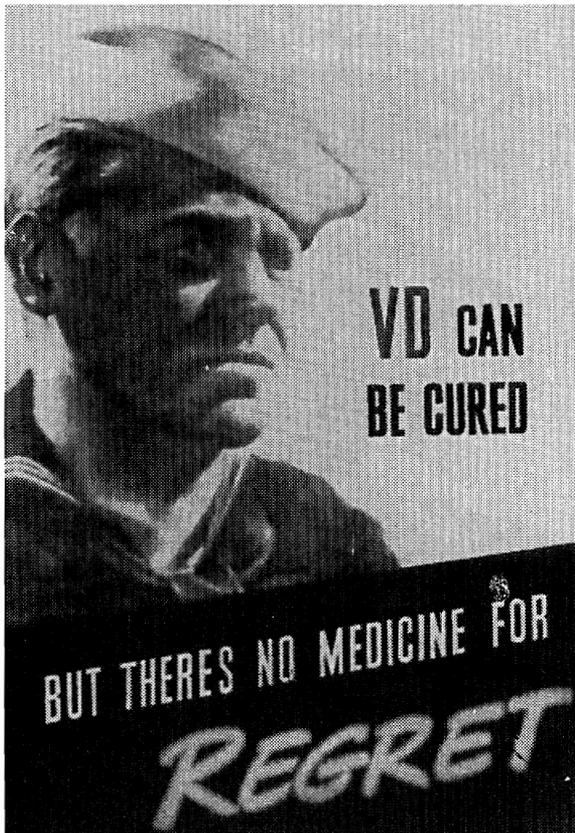
Normally, the pH in the vagina is low (acidic), but the pH levels change during intercourse with ejaculation, menses, estrogen deficiency, menopause and bacterial vaginosis. Researchers believe that pH levels in the vagina may play an important role in STD transmission.

Several small studies have examined the changes in normal vaginal microorganisms after douching. One study of 20 women in the United States found that small amounts of a douche preparation containing the antiseptic, chlorhexidine gluconate, did not significantly alter the vaginal flora after 30 days of use.¹¹ A small study at the Università di Sassari in Italy evaluated seven vaginal douche preparations to determine their *in vitro* effects on lactobacilli, a bacteria commonly found in the vagina. Lactobacilli produce hydrogen peroxide, which in-

hibits the growth of some pathogens, possibly STD pathogens.¹² Researchers concluded that frequent use of these douches could change the composition of the normal vaginal flora.¹³ A study of 10 women in the United States, which compared two types of douche preparations, found that those containing acetic acid (the acid in vinegar) caused short-term minor changes in the vaginal flora, while solutions containing povidone-iodine (Betadine) caused significant changes in the vaginal flora, which could increase the risks of infections and possibly the risks of pelvic inflammatory disease.¹⁴

The use of soft drinks as a postcoital douche is frequently suggested as a folk remedy to prevent pregnancy after unprotected sex, but is not effective since sperm enter the cervix within seconds after ejaculation. A study of seven men in Nigeria examined the effects of four different types of soft drinks on *in vitro* motility of sperm. The study found that one brand of drink, Krest bitter lemon, immobilized all sperm within one minute. The study did not, however, explore microbicidal effects.¹⁵ A study conducted in the United States investigated the spermicidal effects of Coca-Cola and found that different formulations of the soft drink did reduce sperm motility.¹⁶ A separate study of cola drinks found little effect on sperm motility. Researchers suggested the introduction of these liquids into the vagina might cause infection.¹⁷

Some researchers suggest that a microbicidal postcoital douche might be more culturally acceptable than condoms, which require negotiation between partners. A postcoital douche of tea or beer, which has a low pH, or sour milk, which contains lactobacilli that result in low pH levels, might offer protection against STDs, including AIDS, researchers suggest.



A U.S. NAVY POSTER FROM WORLD WAR II DISCOURAGES RISKY SEXUAL BEHAVIOR, USING THE TERM "VENEREAL DISEASE," OR VD, IN REFERRING TO SEXUALLY TRANSMITTED DISEASES.



UNITED NATIONS/B. WOLFF

WOMEN GATHER AT A MARKET IN LOMÉ, TOGO.

SOAP AND WATER

Genital washing has been suggested as a means to prevent STD transmission to men. Studies of military personnel in World War I and World War II found that washing with soap and water soon after exposure to STDs helped prevent chancroid.

In sub-Saharan Africa, genital washing has been theoretically proposed as a way to reduce STD and HIV incidence. Lack of circumcision in men may be a risk factor for development of chancroid, a common cause of genital ulcer disease in Africa. Genital ulcer disease appears to be a risk factor for contracting HIV. Health advocates suggest that education about postcoital and precoital washing with instructions on how to clean the area beneath the foreskin of the penis might be one way to reduce the incidence of STDs in east, central and southern Africa, where male circumcision is less common and genital ulcer disease more common than in west Africa.¹⁸

But a study in Singapore, which questioned 100 prostitutes about methods they used to prevent sexually transmitted diseases, found that postcoital washing with antiseptic solutions had no STD prevention effect for this group of women.¹⁹

— Barbara Barnett

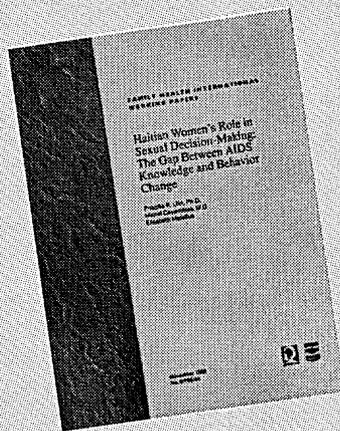
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Resources

FHI WORKING PAPER ON AIDS KNOWLEDGE IN HAITI

The discrepancy between women's knowledge about AIDS and the measures they take to protect themselves is the subject of a new FHI working paper, *Haitian Women's Role in Sexual Decision-Making: The Gap Between AIDS Knowledge and Behavior Change*.



The Gap Between AIDS Knowledge and Behavior Change. The paper reports on qualitative research among poor Haitian women and men, in which focus groups were used to explore norms of sexual behavior and communication as a means to reduce behavioral risk (see related article, page 10). The 85-page report is available at no charge from: Publications Coordinator, Family Health International, P.O. Box 13950, Research Triangle Park, NC 27709 USA. Telephone (919) 544-7040, or fax (919) 544-7261.

NEWSLETTER ON REPRODUCTIVE HEALTH

Nexus, a bimonthly newsletter, covers reproductive health, sexually transmitted diseases, sexuality and women's and children's health. A digest of articles appearing in the Indian press, *Nexus* seeks to increase the quantity and quality of print media coverage of reproductive health. The newsletter is a resource for journalists, doctors, researchers and NGOs. Within India, subscriptions for single copies are free; additional subscriptions cost Rs. 32 per issue. Outside India, one year's subscription costs U.S. \$18. Subscription requests should be sent to Ms. Sadhna Mohan, Editor, *Nexus*, Population Services International, E-18A East of Kailash, New Delhi, 110065, India. E-mail address: nv.del@psi.sprintprg.sprint.com. Payments should be made via demand draft to Population Services International, payable at New Delhi.

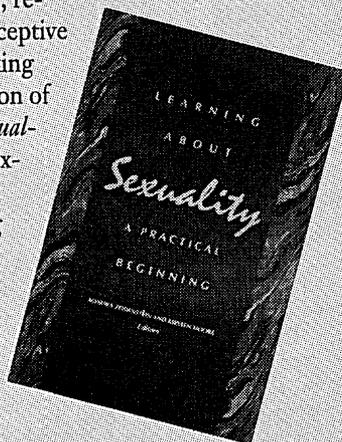
POPULATION COUNCIL PUBLICATION

Health-care providers and social and biomedical scientists discuss sexuality, reproductive health, contraceptive practices, and health-seeking behavior in a new collection of essays. *Learning about Sexuality: A Practical Beginning* explores the experience of sexuality; the links among sexuality, contraception and reproductive health; and the prospect of challenging attitudes and

behavior related to sexuality. The 404-page book is free to readers in developing countries, and costs U.S. \$20 elsewhere. To request a copy, write to: The Population Council, One Dag Hammarskjold Plaza, New York, NY 10017 USA. Telephone (212) 339-0514, or fax (212) 755-6052.

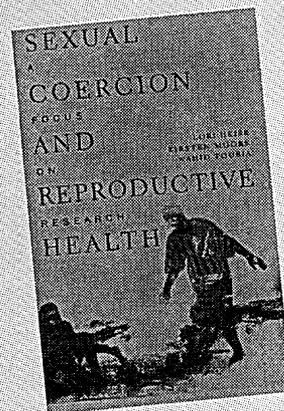
BEIJING CONFERENCE COMMITMENTS

Commitments made at the 1995 Fourth World Conference on Women held in Beijing are summarized in a publication from Family Care International. *Commitments to Sexual and Reproductive Health and Rights for All: Framework for Action* outlines the actions recommended at the conference in the areas of policy, legislation, research, services, training and health education. Available in English, French and Spanish, the book costs U.S. \$1 in developing countries, and U.S. \$2 elsewhere. To order, write Family Care International, 588 Broadway, Suite 503, New York, NY 10012, USA. Telephone (212) 941-5300, or fax (212) 941-5563.



SEXUAL COERCION EXAMINED

The causes and consequences of sexual coercion in several cultures are examined in *Sexual Coercion and Reproductive Health*. The 59-page book emphasizes the importance of addressing sexual health when considering family planning, gender issues, AIDS and STDs, and young people. Family planning and reproductive health workers often see the effects of sexual coercion and sexual violence when they encounter un-



wanted pregnancy, STDs, unsafe abortion, and psychological trauma. The book is free of charge to readers in the developing world, and costs U.S. \$10 to others. Write: The Population Council, One Dag Hammarskjold Plaza, New York, NY 10017. Telephone (212) 339-0514, or fax (212) 755-6052.