

Network

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Oral Contraceptives

News Briefs

585,000 PREGNANT WOMEN DIE ANNUALLY

About 585,000 women die worldwide each year during pregnancy or childbirth, many needlessly, according to a recent report by the United Nations Children's Fund (UNICEF).

Drawn from a model developed by Johns Hopkins University in Baltimore, MD, USA, in collaboration with the World Health Organization (WHO) and UNICEF, and using data collected by WHO, the new estimate is considerably higher than a previous estimate of 500,000 maternal deaths worldwide.

The number comes from the first comprehensive worldwide survey on maternal mortality in a decade. The report also concludes that about 17.5 million women suffer injuries, infections or disabilities related to pregnancy and childbirth, many of them humiliating and painful problems, or morbidities that will continue for life.

"It is no exaggeration to say that this is one of the most neglected tragedies of our times, when 1,600 women, some in their teens, die every day during pregnancy or childbirth and many of these deaths are preventable," Carol Bellamy, UNICEF director, said in a June news conference in Paris to announce the findings.

The first and most obvious step towards reducing maternal mortality, the report says, is making high-quality family

planning services available to all who need them. Better health care during and after pregnancy is also needed. "Proper medical training of more midwives who could assist traditional birth attendants before, during and after childbirth, and access to emergency obstetric care are important ways to improve care," says Dr. Judith Fortney, FHI director of scientific affairs, who specializes in maternal health.

The most common immediate causes of pregnancy-related death include hemorrhage and sepsis, responsible for approximately half of all deaths each year. Other women die from self-attempted abortions or from other pregnancy-related conditions, including eclampsia.

Maternal deaths are most common in regions of Africa and Asia: One in 13 women dies during pregnancy in sub-Saharan Africa and one in 35 in south central Asia dies, compared with one death among 3,300 women in the United States, says the report, entitled *The Progress of Nations 1996*.

ORAL SEX MAY POSE HIV RISK

Oral sex may pose a small risk of spreading HIV, the virus that causes AIDS, according to a study among monkeys conducted by scientists in the United States.

The study shows that six of the seven monkeys in the experiment acquired simian immunodeficiency virus (SIV), a virus that acts like HIV among monkeys, when exposed to the infec-

tion through their mouths. Three of the macaque monkeys died from the disease within a year.

Casual contact through eating utensils, toothbrushes, or kissing is not considered a risk among people. To infect the animals orally, the SIV exposure was 830 times greater than the minimal amount needed to infect an animal through blood contact.

However, many people assume that HIV cannot be transmitted through oral-genital contact. The new study casts doubts on this belief, says Dr. Ruth M. Ruprecht, director of the laboratory of viral pathologies at Harvard University's Dana-Farber Cancer Institute in Boston, where the research was conducted.

The study suggests the virus can be transmitted through the mucus lining of the throat, stomach or mouth, which are rich in Langerhans and lymphoid cells, the immune system cells that both HIV and SIV target.

"Our findings, combined with case reports of oral transmission in humans, indicate that oral sex is not totally safe and there is a certain risk of infection through oral sex," Dr. Ruprecht says. About a dozen cases of oral transmission among humans have been documented worldwide. The study was published in the June 7, 1996 issue of the journal *Science*.

HIV TEST USES ORAL FLUIDS

A test using oral fluids to detect HIV infection has been approved by the U.S. Food and Drug Administration and is expected to be available this fall in the United States, western Europe and in the Latin American countries of Colombia, Costa Rica, Ecuador and Panama.

Produced by Epitope Inc., a U.S.-based pharmaceutical manufacturer, the test has been shown to be as effective as the Western blot blood test in identifying people who are infected with HIV-1.

The test, called OraSure, uses a pad held between a person's lower cheek and gum to absorb oral fluids, which are then tested for the presence of HIV antibodies, according to SmithKline Beecham, the U.S.-based pharmaceutical company that will market OraSure. Because of cost, the test is not expected to be widely available in developing countries.

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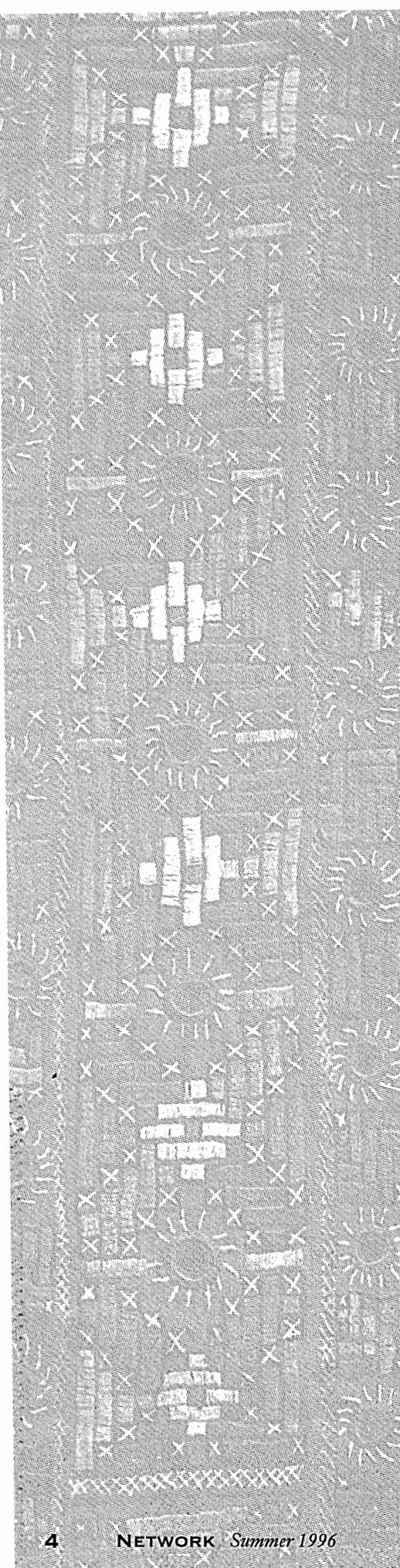
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Cover photo by Pam Hasegawa, Impact Visuals, of a mother and her adult daughter in Kenya. When used consistently and correctly, oral contraceptives offer very effective contraception that is safe to use by nearly all women, including women of any reproductive age group.





Oral Contraceptives Are Safe, Very Effective

However, pills are often used incorrectly or discontinued because of side effects or health concerns.

Oral contraceptives (OCs) are more than 99 percent effective in preventing pregnancy when used consistently and correctly, and they are safe for nearly all women. More than 70 million women use the pill worldwide, but incorrect use is common, thus lowering its annual typical effectiveness to about 92 percent.¹

OCs are among the most widely studied of all drugs. The benefits of using them far outweigh the potential risks for almost all women. However, oral contraceptives are not recommended for women at high risk of cardiovascular disease or women over 35 years old who are heavy smokers. Also, certain health problems may become worse with pill use.

"The pill is a very safe, highly effective product," says Dr. Laneta Dorflinger, FHI director of clinical trials. "But we need to find ways to make sure it is used more effectively and continuously. Since failure during typical use is quite high and discontinuation rates are 50 percent or even higher in the first year of use, we have to determine how to help women do better."

Side effects or health concerns are frequently mentioned as reasons for discontinuation, she says. For example, surveys in some countries where discontinuation rates are greater than 50 percent show about half of the discontinuations are due to side effects or health concerns: 24 percent of all pill users in the Dominican Republic stopped using them within the first year for these reasons, and 29 percent in Peru.² Changes in

menstrual patterns are a frequent complaint, as are headaches, nausea and, less frequently, vomiting associated with pill use.

Allowing women to choose a contraceptive method from among a variety of good options is one way to encourage women to continue using any method, Dr. Dorflinger says. Counseling about potential side effects and providing good management of medical concerns can also improve use. For example, the quality of counseling affects how well-prepared women will be to take the pill correctly, in addition to preparing them to handle side effects. In Zimbabwe, a survey among OC users who had missed their daily pill found only one woman in three had taken the correct action after missing the pill, illustrating one area where more thorough counseling may be able to improve effectiveness.³

SIDE EFFECTS AND HEALTH

Because the hormones in the pill mimic pregnancy, the pill has some side effects that are similar to those associated with pregnancy. Nausea or vomiting may occur in the first few cycles of pill use, but are less common in subsequent cycles (taking the pill with food can minimize nausea). Women may also experience headaches, decreased libido, and depression or mood change. Other possible side effects include breast tenderness, acne, and dizziness.

The pill regulates a woman's menstrual cycle, decreasing the amount of bleeding on the average by about 60 percent because of the reduced thickness of the endometrium. This effect may be beneficial for many women. For example, pill use can eliminate mid-cycle pain, which some women experience, and decreases menstrual cramps. Because of the decrease in bleeding, anemia may decrease.

A few women may experience amenorrhea, while others may have breakthrough bleeding between periods. Breakthrough bleeding, which can range from spotting to bleeding episodes, is generally not harmful to a woman's health but may have some cultural or religious significance. Typically, side effects diminish within a few months after a woman begins OC use.

Since the pill was first introduced more than 30 years ago, there have been hundreds of major studies on risks and benefits. Long-term medical risks include the relationship of the pill to cancers and to cardiovascular disease (see related article, page 6). Most women can use the pill without safety concerns, according to medical eligibility criteria established by the World Health Organization (WHO).⁴ It is safe for non-pregnant women past menarche and up to 40 years old (and usually safe after age 40), with or without children, of any weight including obese women. Postpartum women who are not breastfeeding may begin using the pill three weeks after giving birth, and breastfeeding women may do so after six months, although it is better to delay pill use until breastfeeding ends. Women can use the pill immediately postabortion. Women can use the pill if they have mild headaches, varicose veins, anemia, a history of diabetes during pregnancy, painful or irregular menstrual periods, malaria, benign breast disease, or thyroid disease, or if they carry viral hepatitis.

Some women should not use the pill under any circumstances, according to WHO. These include women who are pregnant, have a greatly increased risk of cardiovascular disease, are both over age 35 and smoke heavily (more than 20 cigarettes a day), or have certain preexisting conditions that could be worsened by OCs. These preexisting conditions include current breast cancer, benign liver tumors, liver cancer and active viral hepatitis. High risks for cardiovascular disease include blood pressure greater than 180/110 mm Hg, diabetes with vascular complications, complicated valvular heart disease, and a history of any of these conditions — deep vein thrombosis, blood clotting in the lung, heart attack, stroke, or severe recurrent headaches with vision problems.

Under some medical conditions, the pill is not the best choice but is still acceptable if another method is not readily available or acceptable, or if a provider can monitor the woman. For example, healthy women over age 40 may generally use the pill, as can those younger than 35 who smoke. Those with sickle cell disease can use the pill but should be monitored due to an increased risk of thrombosis. Those with unexplained vaginal bleeding should usually not initiate pill use until the nature of the bleeding can be evaluated. If taking drugs that induce liver enzymes, women should usually not use the pill because the drugs are likely to reduce the effectiveness of OCs. These drugs include rifampicin and griseofulvin, which are antibiotics, and the following anticonvulsants: phenytoin, carbamazepine, barbiturates and primidone.

Without good counseling, a woman may not be able to distinguish between an expected side effect and a medical problem. A simple way to remember the danger signs of a medical problem is the English acronym ACHES: A for "abdominal" pain that is severe; C for severe "chest" pain, cough, shortness of breath; H for severe "headache," dizziness, weakness or numbness; E for "eye" problems (vision loss or blurring) or speech problems; or S for "severe" leg pain (calf or thigh). The acronym can be modified to fit other languages.⁵ These signs help identify a possible cardiovascular-related problem that may occur in the short term. The long-term risk of using the pill is very small for all women in developing countries compared to the risk of pregnancy.

There are medical benefits from pill use. Because of the pill's excellent effectiveness in preventing pregnancy, women taking OCs have less chance of an ectopic pregnancy, where the fertilized egg develops outside the uterus, a life-threatening condition. Pill use also lowers the overall risk of symptomatic pelvic inflammatory disease (PID) by about 50 percent, because the thickened cervical mucus helps keep bacteria out, possibly the thinner endometrium provides less fertile ground for bacterial growth, and the decreased menstrual flow reduces the chance of pathogenic growth or movement of bacteria up the fallopian tubes.

False rumors about health problems can lead to discontinuation or incorrect use. "Some women think the pill is unnatural and may cause blocked tubes," says Dr. Olivia McDonald, medical director of the National Family Planning Board in Jamaica, who is

SEAN SPRAGUE/IMPACT VISUALS



WOMEN AND THEIR CHILDREN GATHER IN SENEGAL. ORAL CONTRACEPTIVES ARE APPROPRIATE FOR NEARLY ALL WOMEN, REGARDLESS OF THEIR WEIGHT OR WHETHER THEY HAVE CHILDREN.

OC RELATIONSHIP TO CANCER, CARDIOVASCULAR DISEASE

The following summary of the relationship of the pill to cancers and cardiovascular diseases is based on findings from World Health Organization studies in 11 countries and other major studies.¹

Ovarian and endometrial cancer — Combined oral contraceptives (COCs) protect against ovarian cancer and endometrial cancer. The protective effect is related to the duration of use for both. For ovarian cancer, the protection after one or two years of COC use continues for at least 15 years after discontinuing COC use. For endometrial cancer, the evidence for duration of protection has not been established.

Breast cancer — A recent analysis of 54 epidemiological studies found a small increased risk of breast cancer while women are taking OCs and in the 10 years after stopping. However, researchers said it was not possible to determine if the slight risk was due to an earlier diagnosis of cancer among pill users, or the effects of the pill, or a combination of reasons.²

There is no evidence of increased risk of breast cancer diagnosed after menopause, when breast cancer most commonly occurs. Some concern remains about the increased risk among women who begin using the pill before age 20. However, because the incidence of breast cancer is so low in this age group, the absolute number of cases that may occur would be quite small. It is also important to keep in mind that the incidence of breast cancer varies among countries. The incidence is much higher in western Europe and the United States than in Latin American or Asian countries, so the small increased risk has much less impact in those countries where the incidence is low.

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Cervical cancer — Data are not sufficient to provide conclusions about the relationship of cervical cancer to pill use. Recent studies have shown that genital human papillomavirus (HPV), a sexually transmitted disease, is responsible for most of the world's 500,000 new cervical cancers each year.

Using the pill for longer than five years may increase a woman's risk of cervical cancer, although the pill does not cause the cancer. Women who use the pill for a long period should have regular cytology screening (Pap smears).

Cardiovascular disease — Initial concerns about the relationship between the pill and heart problems or stroke stemmed from early studies involving women who took the high-dose formulations. The higher doses had a greater impact on such factors as blood pressure, cholesterol levels and the coagulation system, compared to the lower doses now used in most pills. The risk of cardiovascular disease among pill users is largely limited to women over age 35 who smoke.³

In 1995, preliminary research was released from a WHO study and other research that indicated that venous thromboembolism might be slightly higher for women using pills with the new progestins. The studies involved the progestins desogestrel and gestodene. (The study did not examine norgestimate, another new progestin in use.) Fortunately, the additional risk of mortality from venous thromboembolism is very low, estimated to be no higher than two to three deaths per million users. This compares favorably with all causes of mortality in pregnancy and with the risks that many people accept in daily life.⁴

—William R. Finger

OCs dissolve in the stomach and are rapidly absorbed into the bloodstream, just like other medicines. They do not build up in a woman's body. Nor does a woman need a "rest period" from taking the pill. Taking a rest will only increase a woman's chance of an unplanned pregnancy. Also, pills do not cause birth defects when a woman goes off the pill and gets pregnant.

MECHANISM OF ACTION

OCs work primarily by suppressing ovulation, while also affecting the cervical mucus and endometrium. OCs alter the natural production of estrogen and progesterin in the body, suppressing the follicle stimulating hormone (FSH) and luteinizing hormone (LH). In a woman taking the pill, the brain does not trigger the normal surge of FSH and LH needed for the follicle to mature and release an egg. The pill keeps the cervical mucus thick to prevent sperm penetration. It also causes the endometrium not to thicken as much as normal, thus making implantation unlikely in the rare event that fertilization takes place.

The cervical mucus action is particularly important for the progestin-only pill (POP), which does not cause the extent of ovulation suppression seen with combined pills (those containing both estrogen and progestin). The mucus thickens two to three hours after a POP is taken, but remains thick for only about 24 hours unless another pill is taken. That is why the POP must be taken at about the same time, every 24 hours. If a POP is missed even by just three hours, a woman should use a back-up method if she has sexual intercourse.

The pill used today has changed substantially from the product that first went on the market in 1960. The original, "high-dose" pill had up to 150 micrograms (mcg) of estrogen, compared to today's "low-dose" pill of 35 mcgs or less. The amount of progestin has also declined substantially. More recently, new progestins have been developed for low-dose OCs, which some call the "third generation" pills.

The new formulations were designed to reduce safety risks and side effects. The low-dose pill, with much less estrogen, for

working with FHI and the Medical Association of Jamaica to provide contraceptive update seminars for Jamaican physicians, nurses and other health professionals. "So as

not to keep this unnatural thing in their body, they don't use the pill regularly," thus lowering effectiveness.

example, has less impact on blood pressure, blood clots, carbohydrate metabolism and other factors for cardiovascular-related diseases. Lower doses of estrogen have been associated with less nausea, vomiting and headaches. Some researchers think the third-generation pills with the new progestins also reduce side effects, for example, reducing rates of amenorrhea. Others feel the literature is not clear.⁶

Studies have not found clear connections between different pill formulations, changes in side effects and resulting discontinuation rates. A multicenter clinical trial involving almost 1,700 women assessed the relationship between side effects and discontinuation rates, comparing women using a 50 mcg and 35 mcg pill. The low-dose users reported significantly more intermenstrual bleeding, while those taking high doses reported more breast discomfort. "There were no significant differences between the groups for gross cumulative life table discontinuation rates," reported Vivian McLaurin and Randy Dunson of FHI, who coordinated the study.⁷

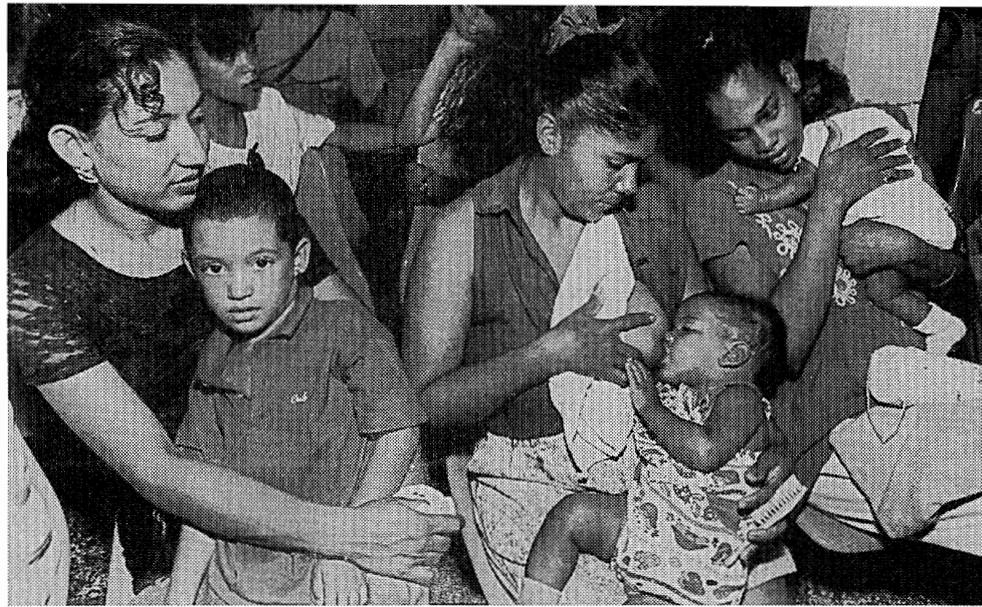
The most common pill form is monophasic, where the hormone levels are constant throughout the 21 days of active pills. Combined OCs also exist in biphasic and triphasic forms, where the ratio of estrogen and progestin varies among the active pills, twice during the cycle for the biphasic and three times for the triphasic. This variation allows the pill to mimic a woman's natural hormonal cycle more closely in the hopes of reducing side effects, although research has not generally shown this to be true. Most pills used in developing countries are monophasic.

WHO CAN TAKE THE PILL?

The pill is ideally suited for women who want to delay pregnancy and space children. Fertility almost always returns soon after a woman quits taking the pill. The pill is a good choice for those who want to control their own contraception. A woman can use the pill without a partner's knowledge, if desired. Women must arrange for resupply on a regular basis and be conscientious about taking the pill throughout the cycle.

According to WHO, breastfeeding women who want to take the pill should use the progestin-only pill, beginning no sooner than six weeks after delivery if fully breastfeeding. In general, combined oral contraceptives are not recommended for

BERYL GOLDBERG



FOR BREASTFEEDING MOTHERS, COMBINED ORAL CONTRACEPTIVES SHOULD BE DELAYED SIX MONTHS AFTER GIVING BIRTH. THE PROGESTIN-ONLY PILL, HOWEVER, MAY BE USED AFTER SIX WEEKS. THESE WOMEN WAIT WITH THEIR YOUNG CHILDREN AT A FAMILY PLANNING CLINIC IN SANTO DOMINGO, DOMINICAN REPUBLIC.

breastfeeding mothers because estrogen diminishes the amount of breastmilk. Although combined OCs may be used six weeks postpartum if lactation is well-established and other options are not available or acceptable, ideally breastfeeding women should not use combined pills until at least six months postpartum.

A U.S. Agency for International Development panel of experts from several collaborating organizations, including FHI, has identified procedures health providers need to follow in order to distribute the pill safely.⁸ The only essential procedure is good counseling on efficacy, side effects, changes in menstrual patterns, correct use, problems that require seeing a health-care provider, and STD protection. Distribution does not need to be confined to clinics. Community-based distribution systems can follow these procedures, making the pill more easily accessible.

Sometimes unnecessary procedures are required before prescribing the pill. Providers in many countries require that a woman be having her menstrual period in order to get a prescription for the pill, to ensure that she is not pregnant. This step is medically unnecessary since screening at any time can reasonably assure that a woman is not pregnant. An unplanned pregnancy may result if

a woman must wait several weeks before beginning the pill. Providers can be reasonably sure that a woman is not pregnant if she has not had pregnancy symptoms, such as absent or altered menses, and she is within the first seven days of onset of normal menses, or has not had recent sexual activity, or has been correctly and consistently using a reliable method.

Some procedures, such as breast exams and blood pressure tests, may be indicated for some women before beginning OCs. However, pelvic exams and screening for cervical cancer and STDs should not be routinely required for OC use, but may be appropriate for good preventive health care. Routine lab tests for cholesterol and other functions have no relationship to safe pill use and should not be required before pill use.

In Senegal, the expense of lab tests was compared with possible safety risks. Before 1990, full laboratory tests were routinely given to women before they could receive the pill. A prospective study of 410 women found that the cost to the woman of the required laboratory tests ranged from U.S. \$55 to \$216, as much as five times the monthly per capita income in Senegal. Of

the 410 women, 20 were found to have possible health problems upon initial testing. Nine of the 20 returned for retesting. Of those, only one was confirmed as having a problem that meant she should not take the pill. The study and a subsequent meeting led to a change in policy in Senegal, with the government no longer requiring laboratory testing before pills can be prescribed. "However, many doctors and midwives have resisted the recommendation, and laboratory testing prior to prescriptions of the pill is still widespread in urban Senegal," reported John Stanback of FHI, the study coordinator, and his colleagues.⁹

STD/HIV CONSIDERATIONS

Oral contraceptives do not protect against sexually transmitted diseases (STDs), including HIV. If a woman is at risk of becoming infected with an STD, she should use condoms consistently regardless of her OC use.

"Pills are designed to prevent pregnancy, and they do it well," says Dr. David Grimes, chief of obstetrics and gynecology at San Francisco General Hospital, University of California at San Francisco, who has published reviews on pill safety issues. "Pills are not designed to protect against STDs. I have a coffee pot that works very well, but it can't answer the phone. For the phone, I had to buy an answering machine. The coffee pot was never intended to answer the phone. Nor was the pill designed to protect against STDs."

Research is not clear on the possible relationship of OC use to the transmission of STDs. Women using the pill are more likely to have chlamydial cervicitis, an STD. Transmission of HIV can be more likely if a person has an STD, including chlamydial infection. However, research has not shown whether there is an association between pill use and risk of HIV transmission.

A recent animal study has raised concerns about a possible increased risk. In the study, rhesus monkeys were given doses of the hormone progesterone, the body's natural form of progestin. The monkeys were found to be more likely to become infected after exposure to simian immune deficiency virus (SIV), a virus similar to HIV in humans. However, data from human studies are inconsistent. More research is needed to assess the implications of this study among humans (see related article on page 18).

— William R. Finger

FOOTNOTES

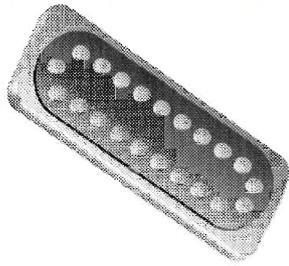
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BERYL GOLDBERG



ORAL CONTRACEPTIVES SHOULD NOT BE USED BY WOMEN AT HIGH RISK OF CARDIOVASCULAR DISEASE OR WOMEN OVER 35 WHO ARE HEAVY SMOKERS. A WOMAN HAS HER BLOOD PRESSURE MEASURED AT A CLINIC IN SANTIAGO.

HOW TO USE ORAL CONTRACEPTIVES



Starting

- ❑ A woman who has not recently given birth can start taking oral contraceptive (OC) pills any time, as long as she is reasonably sure she is not pregnant.
- ❑ If the woman begins taking combined pills (COCs) during the first seven days after her menstrual period begins, or progestin-only pills (POPs) during the first five days, she does not need a back-up contraceptive method since the risk of conception is virtually nil.
- ❑ If a woman starts COCs after the seventh day of onset of menses or POPs after the fifth day, she should use a back-up contraceptive during the first month.

Postpartum Women

- ❑ If a woman is breastfeeding, she may begin COCs at six months postpartum or when she quits breastfeeding. COCs contain estrogen and may decrease breastmilk production. Breastfeeding women can safely start taking POPs six weeks after delivery, since they do not contain estrogen.
- ❑ Postpartum women who are not breastfeeding may begin taking COCs three weeks after delivery. POPs can be taken immediately after delivery.
- ❑ After abortion, women may begin oral contraceptives immediately. No back-up contraceptive is needed for COCs if the woman begins within the first seven days following abortion, or for POPs if she begins within five days.



Missed Pills

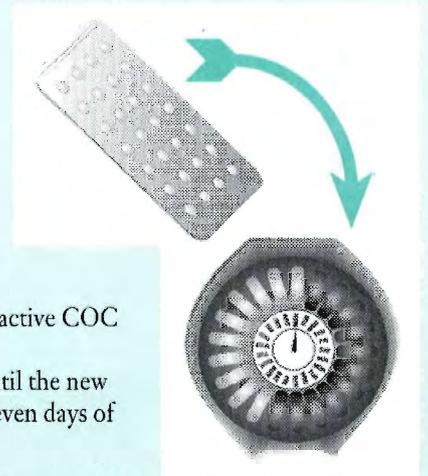
- ❑ Pills should be taken every day, even if the woman is not having sex daily. Pill users should have available a back-up contraceptive method, such as condoms, in case of missed pills.
- ❑ If a woman misses one active (hormone-containing) COC, she is not likely to become pregnant. When this happens, she should take the missed pill as soon as she remembers, then take the next pill at the regular time even if this means she takes two pills in one day. No back-up contraceptive method is necessary when one pill is missed.
- ❑ If a woman misses two or more active COC pills in a row, she should take an active pill daily for at least seven consecutive days. During this time, she should abstain from sex or use a back-up contraceptive.
- ❑ If her pill pack has fewer than seven active pills remaining, she should finish the remaining active pills and start a new pack immediately (without using inactive pills of the old pack or taking a seven-day break

from pill-taking). In this case, the woman will not have her menstrual bleeding at her regular time. If her pack has at least seven pills remaining, she should complete the pack and take her standard hormone-free break.

- ❑ With POPs, a woman who misses one or more pills should take the most recently missed pill as soon as she remembers and the next pill at the regular time, even if that means taking two pills in one day. She should use a back-up contraceptive or abstain from sex for 48 hours.
- ❑ Clients who often forget pills should discuss their pill-taking habits with providers, who can advise on how to take pills more effectively or suggest alternative contraceptive methods.

Switching and Discontinuing Pills

- ❑ A woman can stop taking pills or switch to another method any time. She may do so without finishing a pill pack.
- ❑ Fertility returns rapidly after pills are discontinued.
- ❑ Women who discontinue OCs are likely to experience temporary spotting or bleeding.
- ❑ Women who want to prevent pregnancy but want to stop taking pills should consider starting another contraceptive method before they discontinue OCs.
- ❑ A woman who switches from COCs to POPs should begin POP use immediately after the last active COC pill.
- ❑ A woman who switches to certain contraceptive methods may need a back-up contraceptive until the new method becomes effective. However, if the woman begins another hormonal method within seven days of taking her last active pill, she does not need a back-up method.



Better Communication Improves OC Use

Simply telling a woman to take pills daily may not motivate correct or continued use.

Careful communication between clients and providers is important for the provision of all contraceptive methods, but it is especially relevant to oral contraceptive (OC) use because of the need for daily pill-taking and for following other instructions.

Research shows that the quality of interpersonal communication between clients and health-care providers — how the provider and client interact on a personal level — influences both the attendance at family planning clinics and the initiation and continuation of all reversible contraceptive methods.¹

“Taking a pill every day can be difficult. That is why Norplant and Depo-Provera were invented, because it is so hard for people to remember to take pills,” says Dr. Deborah Oakley, a professor at the University of Michigan School of Nursing who has studied provider behavior as it relates to pill compliance.

“If providers think their job is only to give the method to women who are medically eligible, we’re not going to get anywhere,” she says. “Providers need to come to see it as their responsibility to ask about the environment for use, how women will use the pill, and help women figure out strategies for correct use.”

Based on a review of research on family planning counseling, Oakley has identified several techniques for improving client-provider communication: She suggests providers greet their clients by name; assure an

atmosphere of privacy; and sit at the same eye level as their client, instead of at a higher level. Counselors can improve communication by asking clients about their family planning goals, listening carefully to answers, and by being aware of such “nonverbal” cues as the client’s attitude.² Listening to a client’s particular doubts and concerns, including her difficulties with using contraception, is necessary to determine what each woman needs, and what type of counseling will be most effective.

Good communication is important because each user enters a clinic with her own needs and concerns, says Dr. Linda Potter, an FHI principal scientist who is currently a visiting researcher at Princeton University. And each woman has a unique set of economic or family constraints that may limit her ability to follow an oral contraceptive routine, says Dr. Potter, whose research has focused on oral contraceptive compliance. For example, some women may live in remote rural areas, making it difficult to travel to clinics or pharmacies for refills and counseling; others may be too poor to spend scarce resources on refills; and still others may come from families that do not allow women to travel outside the village, and do not support the use of contraceptives.

A recent review of literature on oral contraceptives by Dr. Potter shows that nearly one-third of all pill-users worldwide

do not take OCs correctly and up to 60 percent take pills irregularly.³ Pregnancy rates are substantially higher for some types of pill users than others. For example, married women in the United States who have moderate incomes and are over age 30 have low pregnancy rates — only 3 percent a year while taking OCs. However, about 27 percent of low-income U.S. adolescents get pregnant each year while using the pill.⁴

A WOMAN'S SITUATION

Sometimes, a woman arrives at a clinic with doubts about not having another child. She may feel ambivalent about the goal of preventing pregnancy and may need guidance to resolve her feelings. Other women will feel more certain that they want to use contraceptives, but have trouble taking pills correctly and may need help figuring out what they are doing wrong. Common pill-taking errors include missing pills and transition errors between stopping one pill pack and beginning another.

"We probably need to do more questioning and listening about what a woman's situation is," says Dr. Oakley. "Instead, we try to determine which contraceptive method a woman is medically eligible for, without examining her personal situation. Providers don't assess a woman's particular ability to take pills every day."

Providers may need to make a distinction between telling a woman to take pills every day, and motivating her or enabling her to do so, says Dr. Potter. Some women may frequently miss pills but do not realize they are doing so. Others may lack the ability to get home in time to take a pill on schedule, or to make up a missed pill.

In the clinic, women may talk about their pill-taking behaviors inaccurately. An analysis compared a record kept by an electronic device inside the pill pack, which registered each time a pill was dispensed, with women's self-reported diary cards. The study showed that the women's own reports were only accurate 45 percent of the time.⁵

Diary data reported an average of one missed pill per cycle. By contrast, electronic data showed that participants actually missed an average of two pills per cycle, increasing to three missed pills by the third cycle. Providers can help women develop good pill-taking strategies by asking questions about how a woman leads her life, and how she deals with various situations that may interfere with her contraceptive routine.

A review of contraceptive provision in the United Kingdom shows providers rarely attempted to discover the cause of noncompliance and frequently became angry with clients for missing pills. Such anger threatens to break clients' trust or confidence in the provider and may discourage clients from returning. Anger also fails to get at the root causes for contraceptive errors and misses an opportunity for improving a woman's pill-taking habits.⁶

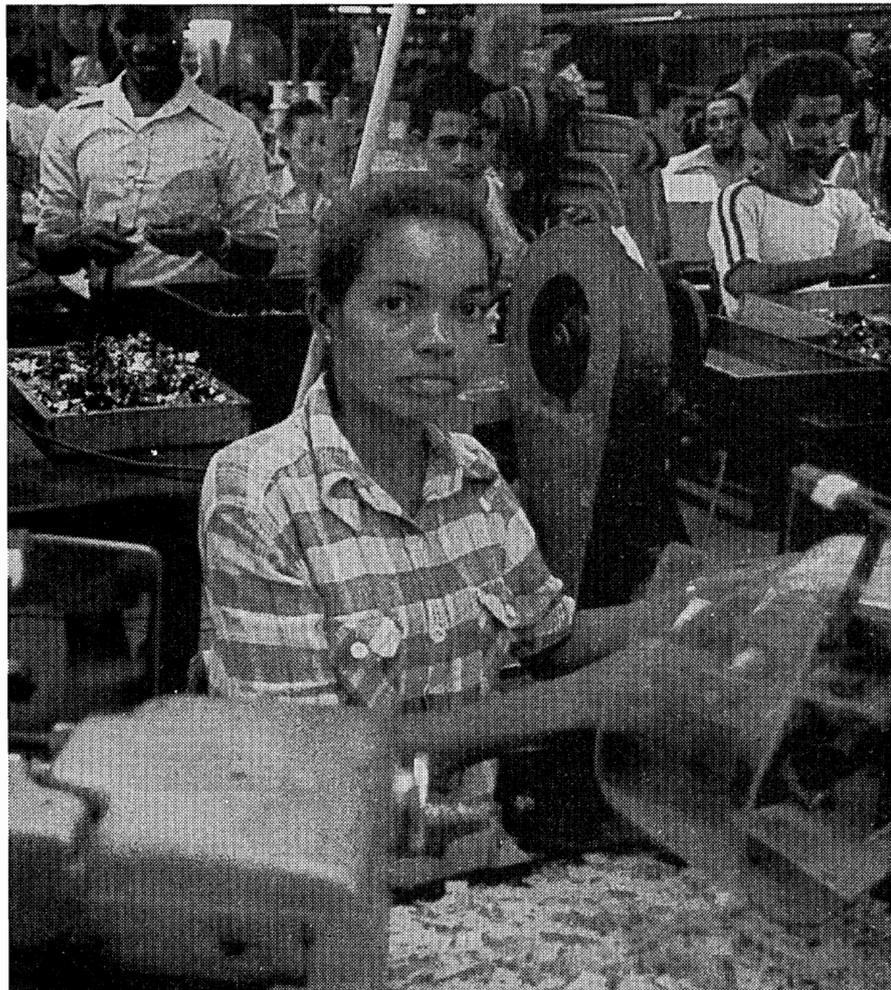
A recent study by McFarlane Consultants, a Jamaican-based research firm, and Dr. Karen Hardee, FHI senior research scientist, examined the quality of care at 346

health facilities in Jamaica through interviews and surveys of 1,074 health workers and 135 supervisors. Researchers also used 20 women posing as clients to visit clinics and report how they were treated by providers.

According to these "simulated clients," no providers explained all of the advantages, disadvantages, and side effects of the combined pill. Only half of the providers explained that the pill must be taken every day, and that pills must be taken in a sequence indicated by arrows on some pill packages. Providers rarely gave information on what to do about missed pills.

Although experience shows it is important to let clients voluntarily choose their family planning method, the simulated clients said they felt pressured to accept a method, especially the pill, during nine of their 50 clinic visits. One nurse offered a client a choice between the pill and the injectable, but refused to give information about either method until the client had made a decision.

PHILIP WOLMUTH/IMPACT VISUALS



A WOMAN WORKS IN A DOMINICAN REPUBLIC FACTORY. BECAUSE OF CHANGING WORK HOURS OR COMMUTING SCHEDULES, SOME WOMEN MAY FIND IT DIFFICULT TO GET HOME IN TIME TO TAKE A PILL ON SCHEDULE.



SEAN SPRAGUE/IMPACT VISUALS

SITTING AT EYE LEVEL WITH A CLIENT, USING HER NAME, AND LISTENING CAREFULLY TO HER COMMENTS ARE AMONG WAYS TO IMPROVE COUNSELING. A COMMUNITY HEALTH WORKER VISITS A WOMAN AT HER HOME IN BANDUNG, JAVA.

Frequently, providers' own perceptions of their services do not match clients' reports. One objective of the Jamaican study was to find out how providers rated their own services. While providers reported spending an average of 20 minutes with each female client, more than half of the counseling sessions at simulated client visits, 29 out of 50, took 10 minutes or less.⁷

DIFFICULT WORK

Unfortunately, funding and time constraints frequently lower the quality of counseling that providers can offer. Family planning providers are often overworked and balance multiple jobs, and some are dissatisfied with their careers.

A 1995 assessment of the quality of family planning in Malawi, by the Centre for Social Research at the University of Malawi, surveyed 160 family planning providers at 42 health-care facilities throughout the country. Results showed that many providers are not in their chosen line of work, and most perform family planning services in addition to other health-care duties. Providers reported feeling divided between making services more accessible to clients and not wanting to further increase their own workload. Although most providers said

they did not want to turn clients away, they often refused to meet with clients who had missed group counseling sessions to avoid having to repeat basic information. While providers recognized that long waits are frustrating to clients, they generally gave priority to other types of patients, creating an average wait of three hours for family planning clients.

The Malawi assessment team trained six women to pose as clients desiring family planning services. They made a total of 85 health-care visits. In one-tenth of the client-provider interactions, the simulated clients either were turned away by providers or reported they would be too embarrassed to return because of how they were treated. Nearly 60 percent of providers used language that simulated clients found difficult to understand, and most providers placed a higher value on giving medical information about contraceptive methods than attending to individual clients' knowledge, abilities, motivation and intentions for use.⁸

In Nepal, research shows communication suffered when providers were disrespectful of clients from a lower economic caste. To investigate the quality of client-provider interactions at clinics in Kathmandu, the Nepal Family Planning/

Maternal-Child Health Project of the Ministry of Health sent simulated clients to 16 clinics. The study showed that traditional class hierarchies and social discrimination interfered with communication between clients and providers. Lower-class clients were less likely to receive good information and courteous treatment than their middle-class counterparts.⁹

In other research, clients report a lack of trust when they go to a clinic.¹⁰ These feelings can discourage clients from returning for follow-up visits or initiating and continuing contraception. Clients are more likely to use OCs correctly and return for refills if health workers take the time to understand clients' personal needs and circumstances, and treat them with respect.

STRENGTHS AND WEAKNESSES

To improve client-provider interaction, programs must first identify their strengths and weaknesses. In the Philippines, researchers conducted in-depth interviews and clinic observations to help improve quality of care in the Philippine Family Planning Program (PFPP).

The study examined 107 family planning workers and 1,440 clients. Overall, Filipino providers received high marks from their clients. The area in need of improvement, according to 52.5 percent of the clients, was providers' tendency to be too authoritative and tell clients what to do. One-third of clients felt providers always advocated a particular contraceptive method, rather than giving them a choice.

The study compared clients in two parts of the country that were similar in size and demographics, but one area had significantly higher contraceptive prevalence than the other. Filipino clients who lived in the higher-use area generally rated their providers more favorably and had more contact with family planning providers. Clients who lived in the lower-prevalence area liked their providers less and received fewer family planning visits. About 77 percent of the client-provider interactions in the high-use area were person-to-person or individualized, compared to 54.2 percent in the low-use area.¹¹

In Peru, higher quality service also appeared to be correlated with greater contraceptive use. A recent Population Council analysis of the 1992 Demographic and Health Survey in Peru, combined with an assessment of the national service delivery system, showed that contraceptive prevalence among 7,841 women was 16 to 23 percentage points higher in areas with better quality services, compared with areas with services the researchers rated as lower quality. Quality was measured by six categories, including method choice, provider bias, privacy, and keeping clients adequately informed.¹²

A comparison of 78 U.S. adolescents aged 13 to 18, who were randomly assigned two kinds of counseling methods, showed clients had a significantly greater contraceptive continuation rate when they were encouraged to talk with counselors about sexual feelings. After one year, only 47 percent of the young women who received conventional counseling were still contracepting, compared to 98 percent of the teenagers who received counseling that encouraged personal discussion of sexuality.¹³

Supervisors play an important role in creating a good climate for counseling, according to the Pathfinder Fund, a U.S.-based reproductive health organization that has prepared a handbook for improving provider skills. The handbook describes how supervisors can promote better client-provider communication by creating an atmosphere of trust among clinic staff, and improving communication among staff members and management. Role-playing and group discussions among staff are some of the suggestions.¹⁴

— Sarah Keller

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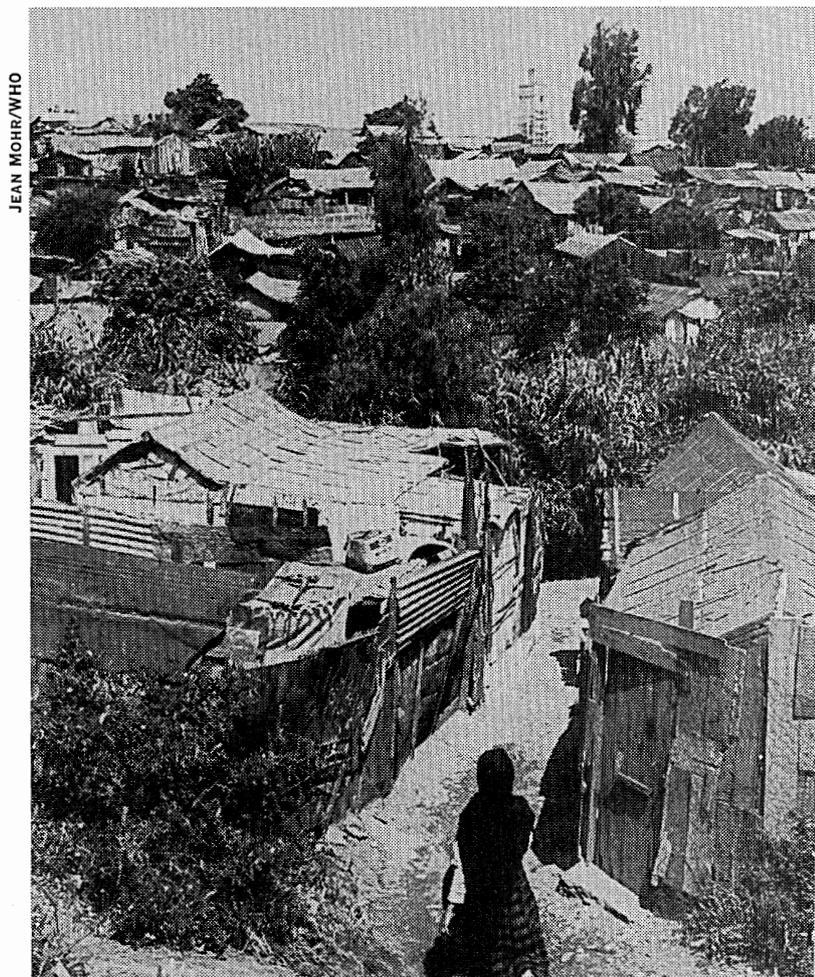
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A MOROCCAN WOMAN WALKS THROUGH A SHANTY TOWN NEAR RABAT. RESEARCH SHOWS THAT SOME PROVIDERS ARE DISCOURTEOUS TO LOWER-INCOME CLIENTS, THUS DISCOURAGING A CLEAR UNDERSTANDING OF HOW TO USE ORAL CONTRACEPTIVES.



JEAN MOHR/WHO

OCs Provide Emergency Contraception Option

Although not as effective as a regular method, OCs used after sex may prevent pregnancy.

Women can prevent pregnancy even after unprotected sex by using a readily available contraceptive method: Certain types of oral contraceptives, when used as directed in high doses after unprotected intercourse, are safe and 75 percent effective in preventing pregnancy.¹

Although not as effective as a regular method, this "emergency contraception" can prevent unwanted pregnancy among women who have been sexually assaulted, experienced a contraceptive failure, forgotten to use a regular contraceptive method or used it incorrectly. Emergency contraception can protect them from resorting to an unsafe abortion — which kills up to 70,000 women in developing countries every year² — and it may prevent life-threatening complications of pregnancy among women who are too young or too old to bear a child safely.

"Emergency contraception should be emphasized as an option in family planning services," says Dr. Roberto Rivera, FHI's corporate director for international medical affairs. "It has an important role as a back-up method, particularly for the use of barrier methods, and it should be provided simultaneously with them." FHI considers the use of barrier methods with emergency contraception as a back-up to be a form of dual method use.

Oral contraceptives used for emergency contraception do not cause abortion because they act before pregnancy begins. These emergency contraceptive pills (ECPs)

are thought to alter the uterine lining, or endometrium, thus preventing implantation.³ In some cases, they may also interfere with ovulation or fertilization or with the luteal phase. Using the pill on an emergency basis is safe, even for many women who should not use oral contraceptives routinely.

Combined oral contraceptives taken at a dose of at least 100 micrograms (mcg) ethinyl estradiol and 0.5 milligrams (mg) levonorgestrel can be used for emergency contraception if taken within 72 hours of unprotected intercourse and repeated 12 hours later, as can doses of progestin-only pills totaling 0.75 mg levonorgestrel if used within 48 hours and repeated 12 hours later.

In June, an advisory panel to the U.S. Food and Drug Administration (FDA) concluded unanimously that certain oral contraceptives approved for daily use are also safe and effective as emergency contraceptive pills. The panel said the following dosages of six brands were known to work: two tablets per dose of Wyeth's Ovral or four tablets of Wyeth's Nordette, Lo/Ovral or Triphasil (yellow pills only) brands, or four tablets of Berlex Laboratories' Levlen or Tri-Levlen (yellow pills only) brands.

Emergency contraception can be achieved in other ways: Within 72 hours by using an antiprogestin (a single dose of 600 mg mifepristone) or by inserting a copper-bearing intrauterine device (IUD) within five days.

BELLAGIO CONSENSUS

Despite the safety and effectiveness of emergency contraceptive pills, many providers are hesitant to offer them. At a 1995 international conference on emergency contraception held in Bellagio, Italy, experts from FHI, World Health Organization (WHO) and other organizations outlined three main reasons why emergency contraception is not widely available: Women and providers are uninformed about it, few products are marketed for it, and many health programs do not offer them.⁴

"Women everywhere should have access to these safe and effective ways to prevent unwanted pregnancy," the Bellagio consensus statement reads. "We must make access to emergency contraception a reality."

Many women's health advocates agree. Information on emergency contraception "is information every woman should have," says Judy Norsigian of the Boston Women's Health Book Collective, which publishes *Our Bodies, Ourselves*, a popular health manual for women.

Enthusiasm for emergency contraception is growing as international agencies, researchers and providers see its usefulness. "We already have the supplies for the method," says Dr. Charlotte Ellertson, a program associate at the Population Council in New York. "All it takes now is information. With emergency contraception, the information is the method. We just require a new mindset."

While some health-care workers eagerly offer emergency contraception, others have reasons for not providing it. A 1994 survey by the International Planned Parenthood Federation (IPPF) found that many providers are reluctant to offer emergency contraception because they are afraid it will be linked with abortion, their staffs have no training to offer it, women have not requested the service, and other reasons.⁵

Other providers have expressed concern that access to emergency contraception may make it less likely that some women could refuse unwanted sexual intercourse, or that women will substitute the method for regular contraception, thus exposing themselves to a greater risk of unwanted pregnancy and sexually transmitted diseases.

Dr. Ellertson points out that women are unlikely to use emergency contraceptive pills excessively. "The reason that women would not use emergency contraceptive pills as an ongoing method is that ECPs are less effective than other methods," she says. "ECPs also

have some unpleasant side effects that we think would dissuade women from using them over and over again." Nausea, for example, is common among users. Studies are under way to find out how women use emergency contraception, she says.

These questions need to be addressed, but they should not keep providers from offering emergency contraception to women who need it, experts agree. "It is important not to deny women this method," says Dr. Pramilla Senanayake, IPPF assistant secretary general. Provider education is of prime importance, she says. Emergency contracep-

lines developed by Pathfinder International.⁷ "Women in need of emergency contraception are facing a serious personal crisis," the guidelines read. "Make them feel confident that you are prepared to help. Avoid prolonged counseling that might make the woman uncomfortable."

The best counseling is nonjudgmental and includes information about the efficacy, advantages, disadvantages, side effects and other characteristics of emergency contraceptive pills. If appropriate, counselors should also present options for contraception following the use of emergency contraceptive pills, the guidelines say.



SPOR/IMPACT VISUALS

MANY WOMEN AND PROVIDERS ARE UNFAMILIAR WITH EMERGENCY CONTRACEPTION, LIMITING ITS USE WHEN NEEDED. YOUNG WOMEN LEARN SEWING AT A SCHOOL IN KANTANGI, KENYA.

tion "should be built into the normal educational program for physicians, nurses, midwives and health-care providers."

Communicating with providers, policy-makers and women is a crucial step in changing attitudes, according to an FHI study.⁶ Communication can increase access, the authors say, by "strengthening providers' knowledge of emergency contraception, increasing women's awareness of its availability and where to obtain it, and overcoming political obstacles."

Women who seek emergency contraception are often embarrassed and frightened: They may be adolescents who have had their first sexual contact, or women who have been sexually assaulted.

Because of these special circumstances, providers' attitudes are very important in counseling potential users, according to guide-

CLARIFYING GUIDELINES

One reason more women do not use emergency contraceptive pills is that there is confusion about what they are and how they should be used.

Because they are commonly called "morning-after pills," some women and providers mistakenly believe that the pills cannot be taken later than the next morning or must be taken within a few hours after intercourse. Others confuse emergency contraception with RU 486 (mifepristone), which can be used for emergency contraception but is better known as a way of inducing abortion.

Combined oral contraceptive pills used postcoitally are the same ones used as a regular contraceptive method, but taken in higher doses of two or four tablets. Although the hormone doses in COCs when used for emergency contraception are relatively high,

they are short-lived and can be used safely, even by women with cardiovascular problems. According to WHO, the only absolute contraindication for emergency oral contraceptive use is pregnancy.⁸ If a woman is already pregnant, she should not use emergency contraception. But if a pregnant woman mistakenly takes the pills, there is no evidence that they will harm the fetus.⁹

Emergency contraceptive pills have been used for decades, but guidelines for their use are inconsistent, says Dr. Linda Potter, an FHI public health scientist. Dr. Potter and Tara Nutley, an FHI program officer, have recently completed a comparison of ECP guidelines used by eight organizations and researchers. Suggested contraindications, drug interactions and other issues varied dramatically.

IMPROVING AVAILABILITY

Emergency contraceptive pills are safe and effective, but they are not always convenient. Up to 50 percent of women who use COCs for emergency contraception have nausea, and many of those women vomit, potentially reducing the effectiveness of the pills.¹⁰ In addition, the short time limit for initiating

ECPs may discourage women who must travel long distances to clinics or are unable to reach them soon enough to receive pills. For example, many clinics close on weekends, when emergency contraception is most often needed.

Several international studies are examining how to make emergency contraceptive methods more available and useful to a wide variety of women. For example, the South-to-South Cooperation in Reproductive Health is comparing vaginal delivery of emergency contraceptive pills with oral use, in a trial involving 600 women in six countries.

So far, the two delivery methods seem to be equally effective at preventing pregnancy, says Dr. Josue Garza-Flores, director of the Mexico City-based Center for Assistance in Human Reproduction and a researcher on the study.

But vaginal delivery doesn't seem to reduce nausea and vomiting, he says. Still, because vaginal delivery prevents vomiting of the pills themselves, it may prevent having to repeat a dose after vomiting.

WHO is also looking for a way to reduce side effects in a trial involving 2,200 women in 15 countries, says Dr. Paul Van Look, associate director of WHO's Special Programme of Research, Development and Research Training in Human Reproduction.

Dr. Fabienne Grou of the University of Montreal is examining whether combined oral contraceptives are effective as emergency contraception if initiated later than 72 hours after unprotected sex.

"If it works for only 40 or 50 percent of women, that would be good" for those who have no other choice, Dr. Grou says. She has found one difficulty in recruiting for the study: Women in Quebec receive education about emergency contraception in school, and few request it beyond 72 hours.

Dr. Ellertson of the Population Council is planning a similar study, which will test the effectiveness of different regimens, such as using other progestins, extending the 72-hour time limit or giving one dose of hormones instead of two.

LIMITED APPROVAL

So far, few products have been marketed or labeled for emergency contraception. In many countries, women or providers obtain the needed pills by simply using a portion of pills from a monthly packet of combined oral contraceptives.

In the United States, the June action by the FDA's Reproductive Health Drugs Advisory Committee paves the way for possible labeling of combined oral contraceptives for emergency use. However, no pharmaceutical company has formally requested FDA approval for marketing pills specifically for emergency contraception.

"There is probably enough information in the published literature to approve that use, if we should get an application [from a drug company]," says Dr. Philip Corfman, an FDA medical officer. The FDA cannot approve relabeling of drugs for new uses without an application.

In other countries, emergency contraceptive pills have been approved, and they have been packaged and labeled differently from monthly cycles of oral contraceptives to make their use clear. Berlin-based Schering sells two products — PC4 and Tetragynon — for emergency contraception, primarily in western Europe. Each packet includes a user information leaflet and four pills containing levonorgestrel and ethinyl estradiol.

Schering believes ECPs should be offered by prescription only, says Lutz Schaffran, Schering's head of international family planning. For that reason, the pharmaceutical company does not sell ECPs in Asia and Latin America, where oral contraceptives are typically bought in pharmacies without prescription.

In spite of these restrictions, emergency contraceptive pills are becoming more widely available. For example, Schering is selling the pills to African governments that request them because in Africa, unlike Latin America and Asia, clinics and medical professionals are more likely to provide the pills, Schaffran says. Zaire requested the first shipment, which will primarily be used in refugee camps, he says.

BERYL GOLDBERG



EMERGENCY CONTRACEPTION IS AN OPTION FOR WOMEN WHO HAVE EXPERIENCED A METHOD FAILURE, FORGOTTEN TO USE CONTRACEPTION OR WERE SEXUALLY ASSAULTED. STUDENTS TALK AT A UNIVERSITY IN MONTEVIDEO, URUGUAY.

The Consortium for Emergency Contraception, a group of seven organizations, plans to work with industry to produce an inexpensive emergency contraceptive product. It will help introduce the product in up to 15 developing countries over the next five years.

The first model introduction will begin in Kenya soon. Model service delivery guidelines and other materials will be field-tested in Kenya and three other countries. "The thing that has surprised us the most is the extraordinary level of interest in these methods and the relative lack of controversy," says Dr. Sharon L. Camp, the consortium's acting coordinator.

"Many health-care providers see this as an important addition to the range of choices they have to give women who want control over childbearing," she says. "It is a method that could reduce the need for abortion, and in Kenya, illegal abortion is a very serious health problem."

VIETNAM AND LATIN AMERICA

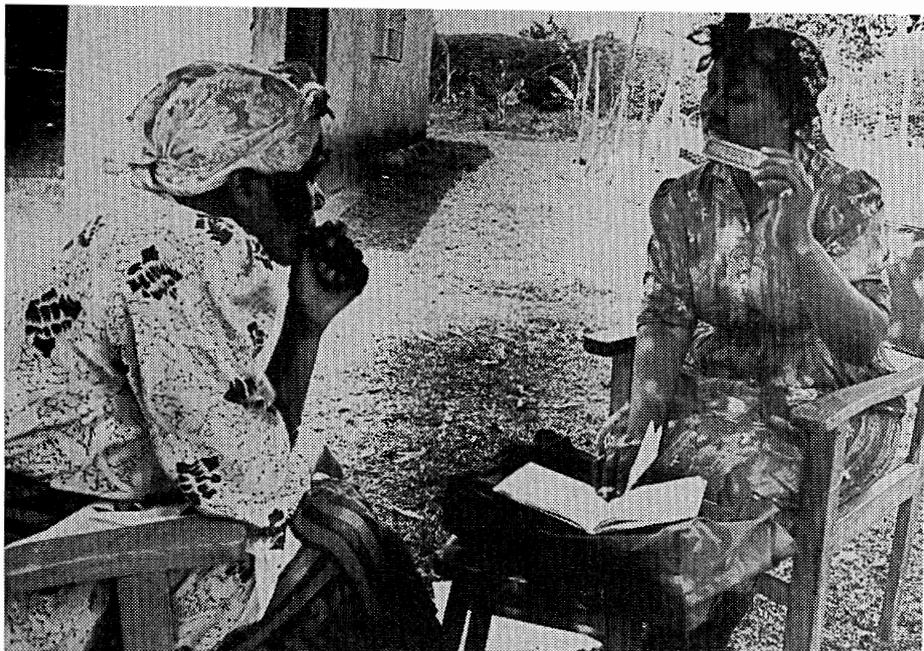
In Vietnam, health-care providers rarely offer emergency contraception. A 1995 Population Council survey in Ho Chi Minh City found that providers knew little about emergency contraceptive pills, says Dr. Nguyen thi Nhu Ngoc, vice-director of Hungvuong Hospital and a principal investigator on the study.

But Vietnam has been moving to broaden its contraceptive choices — once limited primarily to IUDs and tubal ligation — to include oral contraceptive pills. At a recent meeting of 300 Vietnamese providers, Dr. Nguyen says, many showed an interest in bringing emergency contraception to their practices. Before doing so, they must learn how to provide the method correctly, she says.

Pathfinder International is beginning this type of education in Hanoi. This year, Pathfinder will provide training on emergency contraceptive pills to 300 pharmacists, the health-care workers who provide the bulk of oral contraceptives in Vietnam. The organization will also produce client instructions, says Cathy Solter, a Pathfinder medical services associate.

In most of Latin America, emergency contraception is virtually unavailable, primarily because it is confused with abortion, says Dr. Garza-Flores of Mexico City. Abortion is restricted and stigmatized in Latin America.

For the past 18 months, Dr. Garza-Flores has been offering emergency contraception at his clinic, and about 80 women, mostly young, have requested it. In order to



RICHARD LORD

THE OPTION OF USING OCS AS EMERGENCY CONTRACEPTIVE PILLS (ECPs) SIMPLY REQUIRES INFORMATION ON HOW THEY SHOULD BE USED. A COMMUNITY-BASED WORKER EXPLAINS ORAL CONTRACEPTIVE USE TO A WOMAN IN AWENDO, KENYA.

reach more women, Dr. Garza-Flores is working with Mexico's national human rights commission, which helps victims of sexual assault. He is hoping to convince the commission to make information on emergency contraception available to women, he says.

Brazil is also moving toward making emergency contraception accessible. In March, the Ministry of Health and the Population Council organized a nationwide meeting to follow up on last year's Bellagio conference. Out of the meeting came policy recommendations that will be distributed throughout the country, says Dr. Juan Díaz, a Population Council senior associate in Brazil.

The group recommended that emergency contraception be included in the Ministry's technical norms; that combined oral contraceptives be the emergency method of choice in Brazil; and that access to emergency contraception be promoted.¹¹ According to the group, "All women of reproductive age at risk of developing an unwanted pregnancy should have access to emergency contraception."

— Carol Lynn Blaney

Carol Lynn Blaney, a former Network staff writer, is a free-lance science writer who lives in San Jose, CA, USA.

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Does Progesterone Increase HIV Risk?

A recent animal study has raised questions about the connection between hormonal contraceptives and the risk of HIV infection. The study found that rhesus monkeys given the hormone progesterone were more likely to become infected after vaginal exposure to simian immunodeficiency virus (SIV) than monkeys that had not been given the hormone.

The finding raises the possibility that contraceptives containing progestins, which are synthetic versions of the natural hormone progesterone, may increase the risk of acquiring HIV infection among humans. Oral contraceptives, injectables, Norplant and the LNG-IUD contain progestins.

When preliminary findings from this study were first reported, Family Health International distributed an information packet to more than 3,000 family planning providers. It included a "question and answer" sheet offering scientific information on contraceptive methods as they relate to this study and a concise list of related studies, with a brief description of their key findings.

"First and foremost, all couples at risk of any sexually transmitted disease (STD), including AIDS, should be advised to use latex condoms," said a cover letter from Dr. Theodore M. King, FHI's president, and Dr. Willard Cates Jr., FHI's corporate director of medical affairs.

"This long-accepted recommendation remains unchanged by the new study," their letter said. "While other barrier methods of contraception may provide a degree of protection from bacterial STDs, using latex condoms consistently and correctly during intercourse continues to be the most effective prevention strategy. Other options to reduce sexual transmission of HIV are possible. Abstinence from sexual activity is the safest one. Also, no sexual

transmission is possible within a mutually-faithful relationship where both partners are uninfected."

While hormonal methods do not protect against STDs, they are excellent for preventing unintended pregnancy. They are safe, convenient to use and effective. Women should continue using them, but those women who are uncertain of their partners' STD or HIV infection status should also encourage their partners to use condoms. This "dual use" approach combines excellent contraception with the best practice for STD prevention.

Regarding the new study, findings from animal models do not necessarily translate into evidence of disease transmission in humans. More research is needed to examine whether any relationship exists between the progestins typically used in contraceptives and HIV transmission. Progesterone occurs naturally in every woman's body, with higher levels during the second half of the menstrual cycle and during pregnancy.

A National Institutes of Health (NIH) meeting of experts from NIH and other organizations reviewed the new findings. FHI's Dr. Cates, who chaired the meeting, says participants strongly encouraged no change in the long-standing advice to clients that progestin-only contraceptives are safe and effective choices, but offer no STD protection.

Women should consider the health risks they face from not using adequate contraception. Each year, an estimated 585,000 women die worldwide from complications due to pregnancy and childbirth.

FHI believes this new study should encourage physicians and other health care providers to advise women regarding their risks of STDs, including HIV. Clients at risk should be strongly encouraged to use latex condoms. The "question and answer" sheet and summary of studies follows.

HORMONAL CONTRACEPTIVES AND THE RISK OF STDs

A recent animal study has found that rhesus monkeys given doses of the hormone progesterone, a hormone produced naturally by the human body, are more likely to become infected after exposure to simian immunodeficiency virus (SIV), a virus similar to HIV in humans. More research is needed to assess the implications of this study for humans. The following questions and answers discuss current scientific knowledge about the relationship between hormonal methods and STDs.

Question: *What did the new study find?*

Answer: The study found that rhesus monkeys implanted with long-acting pellets of progesterone are more likely to become infected after vaginal exposure to SIV, compared with monkeys that have not been given the hormone. Of 18 monkeys treated with progesterone for six months, 14 became infected with the virus, compared to only one in 10 monkeys not implanted with progesterone.

Researchers theorize that the reason progesterone-treated animals became infected more easily was that the vaginal epithelium — the protective lining of the vagina — was significantly thinner compared with the other monkeys. A thinner lining may provide an easier pathway for the virus.

The National Institutes of Health, which financed the study, has said that the possible increased risk of SIV infection in monkeys does not necessarily have any implications for HIV transmission among humans. Further research is needed to examine any relationship between progestins and HIV transmission. Existing epidemiological studies among humans do not demonstrate consistent findings to support the postulated hormonal-STD risk.

The new study was conducted at the Aaron Diamond AIDS Research Center in New York City, and the AIDS Animal Models Laboratory at the Laboratory for Experimental Medicine and Surgery in Primates in Tuxedo, NY. Study results are preliminary and have not yet been published in a scientific journal.

Question: *Are women who use hormonal methods at greater risk of acquiring HIV?*

Answer: Hormonal contraceptives provide effective protection against pregnancy, but offer virtually no protection against STDs, including HIV. Progestins, which are synthetic versions of the natural hormone progesterone, are used in all hormonal methods. While several studies have attempted to explore the relationship between HIV infection and progestin-containing contraceptives, the relationship remains unclear.

Some researchers suggest the possibility that certain physiological changes that may be caused by progestin use may increase susceptibility to HIV. These include, for example, the thinning of the vaginal lining.

Question: *Should women using hormonal contraceptives continue using them?*

Answer: The results of this initial animal study are not expected to change the current consensus among public health and family planning organizations about the recommended uses for hormonal contraceptives. These methods are safe, effective and convenient to use, and many women benefit from using them. FHI joins NIH and the World Health Organization in saying the current data are not sufficient to change current family planning recommendations. However, the findings underscore the importance of barrier method use to prevent STD/HIV.

Each woman should choose the contraceptive option that best suits her needs, in consultation with her physician or family planning provider. A mutually faithful monogamous couple, free of HIV infection, faces no risk of sexually infecting each other with HIV. Anyone at risk of any sexually transmitted disease should use latex condoms with every act of intercourse. Condoms can be used simultaneously with hormonal methods to provide excellent contraception with the best practice for STD prevention.

Question: *Should a woman at risk of STDs consider initiating hormonal methods if she is not currently using them?*

Answer: Anyone engaging in high-risk sexual behaviors — whether using progestin methods or not — should use latex condoms

consistently and correctly. Hormonal methods can provide excellent contraception for couples using latex condoms for STD protection, and should be considered by people who wish to increase their protection against unintended pregnancies.

The health risks from an unintended pregnancy are sizeable. Approximately 585,000 women worldwide die each year due to pregnancy-related complications, and millions more suffer major health problems related to unintended pregnancy or childbirth.

Question: *Do hormonal methods protect women against STDs?*

Answer: Hormonal contraceptives do not protect against STDs of the lower genital tract, the site where HIV is thought to be acquired. Oral contraceptives have been associated with increased detection of cervical STDs, but also are correlated with lower risks of symptomatic pelvic inflammatory disease (PID).

Barrier methods of contraception (such as condoms, diaphragms and spermicides) offer better protection against STDs than other contraceptive methods but are somewhat less effective at preventing pregnancy.

Question: *What should a couple use to protect against both unintended pregnancy and STDs?*

Answer: Couples who want effective protection against pregnancy and STDs should consider using two contraceptive methods — one to prevent pregnancy and latex condoms to prevent STDs. Condoms must be used correctly, and with every act of intercourse, to provide the best protection against STDs, including HIV.

Other barrier methods, such as spermicides and the female condom, offer some protection against STDs, but further study is needed to document the degree of protection. When a man will not use a condom, these barrier methods may offer a degree of protection.

PROGESTERONE AND STDs: SELECTED STUDIES

Daly CC, Helling-Giese GE, Mati JK, et al. Contraceptive methods and the transmission of HIV: Implications for family planning. *Genitourin Med* 1994; 70(2):110-17.

Choice of contraceptives may influence a woman's risk of contracting HIV, depending on her exposure to HIV. The relationship between oral contraceptives and HIV is unclear, although researchers suggest that some physiological changes caused by OC use may increase susceptibility to HIV. These include ectropion of the cervix; a higher incidence of chlamydia among OC users; and irregular menstrual bleeding. Injectable contraceptives containing progestins might also increase susceptibility to HIV by causing irregular menstrual bleeding and thinning of the vaginal lining. The relationship between IUD use and HIV risks also is inconclusive. Spermicides containing nonoxynol-9 inactivate HIV in the laboratory, but studies in humans (Kenya and Zambia) show conflicting results. No studies have been conducted to determine the effectiveness of the female condom in protecting against HIV.

Cates W Jr., Stone KM. Family planning, sexually transmitted diseases and contraceptive choice: A literature update—part I. *Fam Plann Perspect* 1992; 24(2):75-84.

Numerous studies have been conducted on the effects of contraceptive use on STD risks. Condoms alone, spermicides alone, or a combination of physical and chemical barriers appear to offer protection against some STDs. Male latex condoms provide an effective barrier against most bacterial and viral STD organisms, including HIV, the virus that causes AIDS. Vaginal pouches, including the female polyurethane condom, have been shown to be effective *in vitro* in protecting against HIV. Spermicides can kill or inactivate HIV *in vitro*, but few studies have been done *in vivo*. Spermicides also appear to be effective *in vitro* in protecting against other STDs, including gonorrhea and herpes. Barrier methods, used in combination with spermicides, also protect against infection.

Cates W Jr., Stone KM. Family planning, sexually transmitted diseases and contraceptive choice: A literature update—part II. *Fam Plann Perspect* 1992; 24(3):122-28.

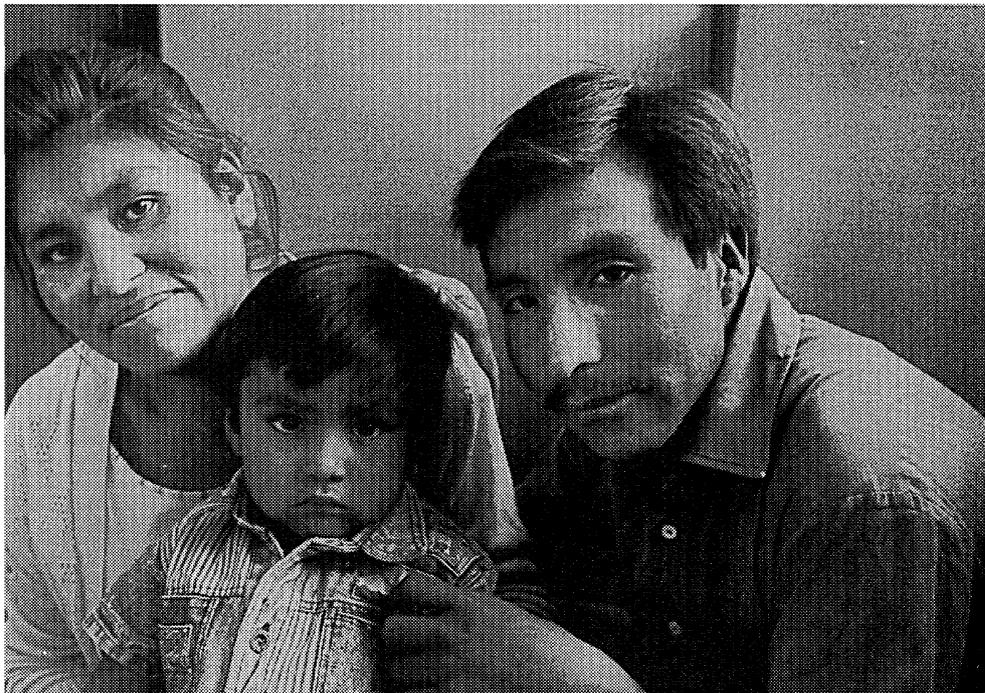
Oral contraceptives, intrauterine devices (IUDs) and sterilization provide effective protection against pregnancy but offer

no protection against STDs, including AIDS. Oral contraceptives appear to protect against symptomatic pelvic inflammatory disease (PID), yet the effect of OCs on HIV risks is unclear. IUD use may increase the risks of PID, but this risk usually occurs around the time of insertion. Tubal sterilization appears to reduce the risk of PID, but research is not conclusive. Sterilization protects against upper genital tract infections but not lower tract infections. Women who have cervical gonorrhea and chlamydia are at increased risk of endometritis following abortion, even when aseptic practices are followed. Couples who want effective protection against pregnancy and STDs may need to use two contraceptive methods—one to prevent pregnancy, another to prevent STDs. Couples who want to use only one method are faced with trade-offs; they must risk increased likelihood of either pregnancy or STDs. Also, couples must assess the risks of childbirth. A more effective woman-controlled contraceptive method that also protects against STDs is needed.

Kapign SH, Shao JF, Lwihula GK, et al. Risk factors for HIV infection among women in Dar-es-Salaam, Tanzania. *J Acq Immune Defic Syndr* 1994; 7(3): 301-09.

A study of 2,285 women at high risk for HIV was conducted at three family planning clinics in Dar-es-Salaam. After controlling for known and potential risk factors, women who had used an IUD had a significantly increased risk for HIV infection. Women who used other contraceptives, including oral contraceptives, did not have an increased HIV risk. Other study findings were that women with two or more partners in the five years prior to the study had twice the HIV risk as women with only one partner. Also, women who experienced abnormal vaginal discharge (often an STD symptom) had an increased risk of HIV, and unmarried women, particularly women in cohabiting

BERYL GOLDBERG



A PERUVIAN FAMILY VISITS A CLINIC IN AREQUIPA.

A WOMAN USING NORPLANT, WHICH CONTAINS PROGESTIN, IS EXAMINED AT THE INPPARES CLINIC IN LIMA, PERU.



BERYL GOLDBERG

relationships, had the highest HIV-positive prevalence. HIV risks increased as women's and men's education levels increased.

Mati JKG, Hunter DJ, Maggwa BN, et al. Contraceptive use and the risk of HIV infection in Nairobi, Kenya. *Int J Gynecol Obstet* 1995; 48: 61-67.

A study of 4,404 women attending family planning clinics in Nairobi, Kenya examined the relationship between contraceptive use and HIV-1 infection. The study examined previous and current use of various methods, including oral contraceptives, injectable contraceptives, IUDs and condoms. There was no significant trend in risk of HIV infection with duration of use of oral contraceptives, injectables or IUDs. Prevalence of HIV was slightly elevated among women who had used OCs more than two years; however, researchers did not find this significant.

Saracco A, Musicco M, Nicolosi A, et al. Man-to-woman sexual transmission of HIV: Longitudinal study of 343 steady partners of infected men. *J Acq Immune Defic Syndr* 1993; 6(5): 497-502.

A study of 343 seronegative women (women who are not infected with HIV) found that condoms do offer protection against contracting HIV. The women were in stable monogamous heterosexual relationships. Their only risk for acquiring HIV

was having sex with their HIV-infected partner. The annual seroconversion rate (the rate of women who became infected with HIV) was 5.7 percent to 9.7 percent among couples never or not always using condoms. The seroconversion rate fell to 1.1 percent among couples who always used condoms. Among the 22 women who used oral contraceptives, none became HIV-positive. One of two women using an IUD became HIV-positive.

Rehle T, Brinkmann UK, Siraprasiri T, et al. Risk factors of HIV-1 infection among female prostitutes in Khon Kaen, Northeast Thailand. *Infection* 1992; 20(6): 328-31.

A study of sex workers in Khon Kaen in northeast Thailand was conducted to determine what factors increase HIV risks. More than 350 prostitutes were interviewed about sexual practices, including women who worked in brothels ("direct prostitutes") and women who worked in massage parlors ("indirect prostitutes"). Researchers found that direct prostitutes were 7.4 times more likely to be HIV-positive than indirect prostitutes. Users of injectable contraceptives had a 2.4 times higher risk of having HIV infection than did users of other contraceptives, including pills, condoms or IUDs. Researchers did not determine whether HIV-contaminated needles were the reason for higher HIV infection risks. Higher risks may have been associated with atrophy or weakening of the vaginal lining, making it more susceptible to tears during intercourse and creating a route for HIV infection.

Other risk factors for HIV were duration of work in Khon Kaen (women who had worked in the town less than a month were 5.5 times more likely to be infected than those who had been there more than two years) and work in provinces with greater than 40 percent HIV prevalence.

Allen S, Lindan C, Serufilira A, et al. Human immunodeficiency virus infection in urban Rwanda. *JAMA* 1991; 266(12): 1657-63.

A study of 1,458 women in Rwanda examined risk factors for HIV infection. Thirty-two percent of the women were HIV-positive. Twenty-two percent of women had used oral contraceptives, and 20 percent had used injectables in the five years prior to the study. Both groups had a significantly higher prevalence of HIV infection than nonusers. However, higher-risk women — those living alone or in nonmonogamous unions — were more likely to have used oral or injectable contraceptives. When type of sexual relationship was taken into account, hormonal contraceptive use was not associated with increased prevalence of HIV infection. Factors increasing women's risk of HIV infection included being unmarried and having more than one lifetime sexual partner.

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Resources

FHI HOME PAGE

DEBUTS

Family Health International's new home page on the Internet provides a variety of scientific and educational materials on reproductive health, family planning, sexually transmitted diseases and women's studies. The FHI page is located on the World Wide Web at <http://www.fhi.org>. The World Wide Web allows the use of photographs and other visual aids, as well as easy links from one document to another or to other World Wide Web home pages that have related materials. A "text only" version

is being developed for users who prefer downloading materials more quickly. Examples of materials available include most articles from recent issues of FHI's *Network*, *AIDScriptions* and *The Women's Studies Project Newsletter*; selected FHI working papers, manuals and

related documents; the text from FHI's current corporate report; and recent FHI news releases.



FHI CASE STUDY ON ADOLESCENTS

Family Health International's Women's Studies Project has published a case study on the Program for Adolescent Mothers in Jamaica. Administered by the Women's Center of Jamaica Foundation, the island-wide program helps pregnant teenage girls continue their education during pregnancy and teaches teens about family planning.

Case Study of the Women's Center of Jamaica Foundation Program for Adolescent Mothers includes interviews with program participants, as well as community members and the women's center staff. Single copies can be obtained free by contacting: Publications Assistant, Family Health International, P.O. Box 13950, Research Triangle Park, NC 27709, USA. Telephone: (919) 544-7040. Fax: (919) 544-7261.

ception can prevent pregnancy after unexpected, unprotected intercourse. The booklet contains guidelines for using oral contraceptives or the copper IUD for emergency contraception. Single copies are free by writing: PATH, 4 Nickerson St., Seattle, WA 98109-1699, USA. Telephone: (206) 285-3500. Fax: (206) 285-6619.

are explored and appropriate research methodologies are discussed. Single copies are available at no cost by contacting: Publications Assistant, Family

QUALITY OF CARE WORKING PAPER

Family planning programmatic research is discussed in *Measuring Service Delivery Practices: What Have We Learned?* This FHI working paper presents the results of three years of research on service delivery practices and describes advances in measurement and definition. Areas of consensus and debate in service practices

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EMERGENCY CONTRACEPTION

An illustrated booklet on emergency contraception for adolescents tells the story of two teenage African girls who have unprotected sex. Afterwards, one girl takes no action, hoping she will not get pregnant; the other seeks help and obtains emergency contraception so she can delay childbearing and finish school. The text and illustrations depict a situation in which emergency contra-

