

# Network

FAMILY HEALTH INTERNATIONAL, VOL. 15 NO. 4, JUNE 1995

## Progestin-only Contraception



# News Briefs

## CONTRACEPTIVE VACCINE ADVANCES

A contraceptive vaccine prototype has protected women from unwanted pregnancy in India, the first successful attempt to use the human immune system to achieve contraception.

However, injections of the prototype prompted an immune response in only 80 percent of the 148 women vaccinated under the research program carried out by the National Institute of Immunology, New Delhi, India. Also, the effect was temporary, requiring new injections every few months. The vaccine stimulates a woman's immune system to block implantation of a fertilized egg in her uterus. Experts say it will be many years before such a vaccine can be perfected for general use.

Many scientists have been searching for a vaccine for many years. "Although it's not a product yet, it's a milestone," says Dr. John Herr, University of Virginia Medical School, Charlottesville, VA, USA, who oversees a U.S. research effort to find a contraceptive vaccine. "This is clear evidence that you can inject a defined immunogen and achieve contraceptive efficacy — in humans."

The prototype vaccine causes the immune system to produce antibodies against human chorionic gonadotropin (hCG), a hormone necessary for implantation. To achieve better contraceptive effectiveness, the vaccine may be combined with another vaccine formulation

that would disrupt different mechanisms needed to achieve pregnancy.

Dr. G.P. Talwar, who is leading the Indian research team, is exploring the possibility of administering the vaccine through a biodegradable implant that would release the vaccine over time, thus avoiding the need for frequent injections. The institute's findings were reported in the Aug. 30, 1994 *Proceedings of the National Academy of Sciences*.

## TODAY SPONGE NO LONGER MADE

The only maker of a contraceptive sponge that uses the spermicide nonoxynol-9 (N-9) has stopped production of the device, but says it is considering selling the manufacturing rights to another company.

Whitehall-Robins Healthcare, based in Madison, NJ, USA, producer of the Today Vaginal Contraceptive Sponge, stopped manufacturing the sponge last year to avoid the expense of upgrading its manufacturing plant to meet government environmental standards.

At its peak in 1993, the Today sponge was used by 400,000 U.S. women, making it the most widely used over-the-counter contraceptive product for women in the United States. It has not been widely available in the developing world.

The Today sponge functions as both a barrier contraceptive and a spermicide. When inserted into the vagina, the sponge physically blocks sperm from entering the cervix while N-9 immobilizes them. One advantage of the Today sponge is its effectiveness for up to 24 hours, allowing a woman to in-

sert it hours before use. It may be used for multiple acts of intercourse during that time.

Several companies have inquired about purchasing the manufacturing rights for the sponge, says Carol Dornbush of Whitehall-Robins. "We have had inquiries about the product and we would definitely entertain them," she says. She declined to name which companies have expressed interest.

FHI conducted clinical trials that were used by the U.S. Food and Drug Administration to approve the Today sponge in 1983. Vorhauer Laboratories Inc., a California pharmaceutical firm, first introduced the Today sponge that year. Whitehall-Robins, a subsidiary of American Home Products Corporation, acquired the manufacturing rights and has been the only maker of the device. Another type of sponge, the Pharmatex sponge, is available in Western Europe. The Pharmatex sponge uses a different spermicide, Benzalkonium chloride (BZK).

## NORPLANT MORE EFFECTIVE THAN "THE PILL"

A recent U.S. study shows Norplant was much more effective at preventing pregnancy among adolescent women than the pill.

Dr. Margaret Polaneczky and colleagues at New York Hospital-Cornell Medical Center in New York studied the contraceptive use and sexual behavior of 98 young mothers (17 years old or younger) during the first year after childbirth. Pregnancy rates were substantially lower among Norplant users. At the end of one year, only one of 48 Norplant users got pregnant (she had Norplant removed) compared with 19 of the 50 users of combined oral contraceptives.

Women expressed strong satisfaction with Norplant, the study says, but those who used oral contraceptives reported that they often missed pills or failed to get refills on time. The results were published in the Nov. 3, 1994 issue of *The New England Journal of Medicine*.

## INFANT CLEARS HIV INFECTION

An infant who tested positive for HIV shortly after birth has tested negative for the infection after three months of life, the first case of a well-studied patient whose HIV infection seems to have disappeared.

Understanding the mechanism of how the child cleared the infection could have profound implications for therapy and vaccine development, and could explain why more than 70 percent of infants born to HIV-infected mothers do not become infected.

The child was born to a woman who first tested positive for HIV at four months of pregnancy, reported the March 30 issue of *The New England Journal of Medicine*. At birth, the child tested negative for HIV antibodies, but tests at 19 and 51 days did reveal the virus.

A variety of subsequent tests did not reveal any virus. Tests showed that the child had a primary infection, not merely persistent infected maternal cells. Researchers do not know if the child still has HIV infection that has eluded detection because it is hidden within the body. The child, who is five years old now, is healthy and shows no symptoms of HIV infection.

The case also raises the question of whether children born to HIV-infected mothers acquire and then clear infection more often than anyone realizes.

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*Progestin-only methods are among the most effective and safe of all contraceptives. They are suitable options for most women, yet not widely used in many countries. Front cover photo by Beryl Goldberg of women in Dabala, Ghana.*



# Progestin-only Methods Are Very Effective

Multiple modes of action make progestin-only injectables, pills and Norplant extremely reliable contraceptives.

**P**rogestins, the synthetic hormones used in Norplant, depot-medroxy-progesterone acetate (DMPA) and progestin-only pills, are modeled after a naturally-occurring hormone called progesterone. Progestin-only contraceptives work by altering the balance of such natural hormones within a woman's body.

By disrupting this balance, progestin-only contraceptives block a series of chemical signals that are essential to complete a normal reproductive cycle — either by blocking the release of an egg or by making its fertilization and implantation within the uterus unlikely.

In many women, progestin-only contraceptives stop the monthly release of an egg — ovulation. Even if an egg is released, its movement through the fallopian tubes into the uterus is more difficult because of progestin. Progestin also thickens the mucus in the cervix, which stops sperm from penetrating the mucus and reaching an egg. In the unlikely event that ovulation occurs and an egg does become fertilized, this hormonal disruption renders the endometrium (the lining of the uterus) inhospitable for implantation.

Because of their multiple mechanisms of action, progestin-only methods are among the most reliable of all contraceptives. Norplant implants and progestin-only injectables have typical failure rates of less than 1 percent, and progestin-only pills (POPs) are typically 95 percent effective.<sup>1</sup>

For POPs, the contraceptive effect wears off very quickly when pill-taking is interrupted or discontinued.

## OVULATORY SUPPRESSION

Progestins do not block ovulation every time, or in every woman. Only about 50 percent of women who use Norplant or progestin-only pills stop ovulating.<sup>2</sup> Among DMPA users, nearly all stop ovulating.

The variation in ovulatory suppression is linked to the amount of progestin in a woman's body. Women with lower levels of progestin in their bloodstream are more likely to ovulate. The more fat a woman has, the more progestin it takes to achieve the same level of contraceptive efficacy. When all women are given equal doses, progestins will typically be slightly less effective in heavier women.<sup>3</sup> The question of ovulation also rests on the type of progestin taken or, for Norplant, how long a woman has been using the implants. In the first year of Norplant use, when the progestin level is the highest, women are least likely to ovulate; only about 20 percent do. After the first year, when the flow of progestin into the bloodstream diminishes, about 50 percent of Norplant users ovulate.<sup>4</sup>

A woman's bleeding pattern is not a good indicator of whether ovulation occurs. Women who are not menstruating may ovulate. Conversely, women who are having regular periods may not be ovulating. Bleeding is not always directly tied to the release of an egg and its journey through a woman's reproductive tract. Preparation of other organs, in anticipation of the egg, may result in bleeding even if the egg does not arrive.

An egg is unlikely to become an embryo even if a woman does ovulate, since progestin makes it very unlikely that fertilization or implantation will occur. "The influence of continuous progestin exposure on the reproductive tract may be a more important contraceptive effect than the suppression of ovulation," says Dr. David K. Walmer, who studies the hormonal behavior of proteins at Duke University Medical Center in Durham, NC, USA. This continuous exposure causes the other conditions that make fertilization and implantation difficult. Those conditions return to normal quickly when exposure to progestin stops, he says.

Progestin slows down an egg's journey through the fallopian tubes from the ovaries to the uterus by reducing the number of cilia, the tiny hairs that line the tubes and sweep the egg along.<sup>5</sup> Progestin also diminishes fallopian muscle strength, making the tubal contractions weaker.<sup>6</sup>

The unusual bleeding associated with progestin methods is most likely caused by changes in the uterine lining (endometrium). Progestin blocks the build-up of the endometrium, making it less hospitable to a fertilized egg. It does this by lowering the body's response to estrogen, a key hormone needed to prepare the uterus for pregnancy. However, the endometrium continues to grow a lining that is eventually shed, a possible cause of the periodic or irregular bleeding associated with progestin contraceptives.<sup>7</sup>

Aside from interfering with fertility cycles, progestins create a physical barrier to sperm penetration. They do this by thickening the mucus that fills the cervical canal leading into the uterus. Cervical mucus normally fluctuates in thickness throughout a woman's cycle, becoming thin and watery at the peak of fertility and dense and thick following the release of an egg. Progestin keeps the mucus thick all the time, making it difficult for sperm to get through. In rare cases when sperm do penetrate, the thick mucus makes it difficult for sperm to move.

While perhaps the most immediate, the effect of progestin on mucus appears to be the shortest-lived mode of action. With progestin-only pills, the mucus only remains

in its thickened state for about 24 hours.<sup>8</sup> This aspect makes it crucial that daily progestin-only pills be taken on schedule, once every 24 hours, to achieve the most effective contraception.

With all progestin-only methods, the changes in cervical mucus appear to occur rapidly, within a few hours of administration. An FHI study under way will examine how quickly this effect takes place, in order to determine whether back-up contraceptive methods are needed.

### PHYSIOLOGICAL CHANGES

Hormones are chemical messengers in the blood. These hormones fluctuate in a predictable pattern throughout the course of a woman's normal menstrual cycle. Periodic

waves of estrogen are necessary for successful ovulation. Surges in hormones from the pituitary, a gland situated at the base of the brain, prompt the release of an egg.

A progestin contraceptive controls the flow of hormonal levels, reducing the cyclic peaks that occur in fertile women.<sup>9</sup> Contraceptive progestins "turn off" the hypothalamus and pituitary gland, preventing them from sending out the messages necessary for ovulation. Consequently, during some cycles, no single follicle — the ovary's egg producing compartments — matures sufficiently to release an egg.

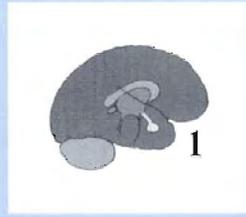
"Progestins alter the secretion patterns, centrally," says Dr. Claude Hughes, associate professor at Bowman Gray School of Medicine, Wake Forest University in

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MULTIPLE MODES OF ACTION MAKE PROGESTIN-ONLY METHODS AMONG THE MOST RELIABLE OF CONTRACEPTIVES, ALTHOUGH A COMMON SIDE EFFECT OF IRREGULAR BLEEDING MAY INTERFERE WITH DAY-TO-DAY ACTIVITIES. A WOMAN POUNDS GRAIN IN CHAD.

# HOW PROGESTIN-ONLY METHODS WORK



## PRIMARY MECHANISMS

### 1. Ovulation

Progestins disrupt the balance of natural hormones, blocking hormonal signals from the hypothalamus and pituitary gland near the brain that are necessary for ovulation. However, progestins do not block ovulation every time, or in every woman.

### 2. Cervical Mucus

Cervical mucus normally fluctuates in thickness throughout a woman's cycle, becoming thin and watery at the peak of fertility. Progestin keeps the mucus thick all the time, making it difficult for sperm to get through.

## SECONDARY MECHANISMS

### 3. Endometrium

Progestins block the build-up of the uterine wall, or endometrium, making it less hospitable to a fertilized egg. The endometrium continues to grow a lining that is periodically shed, a possible cause of the periodic or irregular bleeding associated with progestin contraceptives.

### 4. Fallopian Tubes

Progestins are believed to slow down an egg's journey through the fallopian tubes from the ovaries to the uterus by reducing the number of cilia, the tiny hairs that line the tubes and sweep the egg along, and by diminishing fallopian muscle strength.

Winston-Salem, NC, USA. "The signals for ovulation don't arrive at the right time. And women, therefore, don't ovulate normally. All we do is scramble the clocks in the brain by giving progestin externally."

Most women experience some sort of menstrual disruption while using progestin-based methods. Monthly periods may be replaced by amenorrhea, the absence of bleeding, or spotting. Occasionally, women experience prolonged bleeding which changes in frequency and duration.

Menstrual disruption is the most common reason women stop using progestin methods. Prolonged or excessive bleeding is generally found to be more distasteful to women than the absence of bleeding. More women stop using DMPA due to too much bleeding rather than not enough.<sup>10</sup>

Normal menstrual bleeding is caused by the shedding of a mature uterine lining. If the lining is not mature, good separation between layers and efficient shedding of the whole lining is less likely. Since the natural hormones progesterone and estrogen are

jointly responsible for the proper development of the uterine lining, progestin-induced changes in hormonal levels will affect this.

Irregular bleeding is not harmful to a woman's health. Studies show progestins have no negative effect on hemoglobin or iron levels.<sup>11</sup> When progestins cause women to miss their periods, women in some cultures worry the blood will build up inside

their bodies, says Randy Dunson, a senior research associate at FHI. But amenorrhea does not lead to a build-up of blood, nor does prolonged bleeding or spotting generally diminish blood volume or iron levels. In a World Health Organization (WHO) study of 1,214 women using progestins, only six (0.5 percent) required treatment for heavy or prolonged bleeding.<sup>12</sup> "There is a very small percentage of women who will suffer bleeding on a grand scale," says Dunson, "and the degree of bleeding may be cause for alarm. Obviously, progestin methods would be contraindicated for these women. This bleeding stops as soon as the method is discontinued."

Clients who use any progestin-only method should always receive good counseling and reassurance about bleeding problems. When women do experience prolonged or erratic bleeding, they should know that it is generally temporary. For DMPA users, spotting and break-through bleeding disappear almost entirely over time. As the duration of DMPA use increases, so does the likelihood of amenorrhea. With Norplant and progestin pills, menstrual disturbances tend to decrease over time.<sup>13</sup> A Population Council study of 816 women in Mexico City shows that the number of Norplant users who experienced eight or more days of continuous bleeding dropped from 44 percent in the first year to 27 percent and 24 percent in the second and third years.<sup>14</sup> Progestin pill-takers generally experience irregular bleeding during the first six months. The incidence of short cycles decreases as POP use continues.

When a client is worried about heavy bleeding, her fears should never be ignored. While good counseling is the first approach, short-term estrogen treatments or doses of combined oral contraceptives (which contain estrogen) can be given (see article on page 8).

#### WEIGHT GAIN AND HEADACHES

Weight gain is a common side effect of the three-month injectable DMPA, affecting more than 80 percent of women after several years of use. Weight gain also occurs among women who use Norplant or progestin-only pills but is relatively rare.<sup>15</sup> It is not known what causes weight gain among progestin users. It may stem from an increase in male hormones, called androgens, that cause masculine features, including weight gain through muscle growth. By suppressing estrogen, progestins may tip the balance

towards a higher ratio of androgenic hormones. Suppression of estrogen may also increase appetite. Women who suffer this side effect should reduce the amount of fat they eat or, if they lead inactive lives, should exercise.

The relationship between headaches or depression and progestins is disputed. Some women's rights advocates say the tendency of progestins to cause emotional distress is widespread, while many medical experts say such a side effect has not been proven. "I do not think the effects of progestin on women have been fully and adequately looked at," says Judith Norsigian of the U.S.-based Boston Women's Health Book Collective. "One side effect given the least attention is depression. There is a substantial proportion of women for whom progestin is a very problematic drug. I have heard this too many times to think it is a coincidence."

Dr. Judith Weisz, professor of obstetrics and gynecology at the Milton S. Hershey Medical Center at Pennsylvania State University, says progestin constricts blood vessels and therefore may contribute to severe headaches and chest pains in certain women. Other experts say surveys to determine whether depression or headaches are linked with hormonal contraceptive use are inconclusive.

#### HEALTH CONCERNS

Progestin methods do not cause infertility, despite a widespread belief that they do, says FHI research associate John Stanback, who conducted a study on DMPA use in Ghana. "There is a delay [in return to fertility] with Depo, but to many women, it seems like forever," he says. This misconception was one reason cited by three-quarters of 46 family planning providers in Ghana to explain why they restrict DMPA use to women over 30. In addition to fears about promoting promiscuity, providers said they wanted to ensure women already had children before giving them this method, since they incorrectly believed fertility could be lost permanently.<sup>16</sup>

Progestin pills and Norplant tend to induce ovarian cysts, which are actually persistent follicles — immature follicles that remain inactive inside the ovary. One study

found the cysts in half of POP users, compared with about one-fifth of a control group. These cysts, some of which are seven to 10 cm long, generally disappear after a couple of weeks if left alone. They are not dangerous. Invasive methods should not be used to remove them. If the cysts persist and are accompanied by abdominal pain, the patient may want to consider switching to another method.

The risk of cancers in reproductive-age women is small. It is likely that POPs, Norplant and DMPA have a modest protective effect against some cancers and may increase the risk for others by promoting cancers that have been untreated, but the long-term effects of progestin use have not been adequately studied.

Progestins have, in some studies, been shown to offer a protective effect against endometrial cancer. Combined oral contraceptives are used as a therapy against endometrial cancer, but it remains unknown whether estrogen or progestin plays the more active role. Estrogen, during the normal menstrual cycle, causes endometrial proliferation, or cellular growth. Since natural progesterone tends to stop this proliferation, some scientists conclude progestin is the more helpful agent in protecting against endometrial cancer.<sup>17</sup> Progestins have been studied for their relationship to breast cancer and no conclusive evidence has supported a significant risk.

The possibility that progestin-only contraceptives will cause heart problems in the long run does not seem to be substantiated.<sup>18</sup> Clinicians say they are confident progestins are not linked to hypertension or blood clotting — conditions that can lead to heart disease. However, women with ischemic heart disease or currently suffering from a stroke should consider other methods, according to WHO draft recommendations.<sup>19</sup> Some experts recommend that women with diabetes or cardiovascular disease may use progestin-only contraceptives.

## MANAGING MENSTRUAL DISTURBANCES

Disturbances in menstrual bleeding are one of the most common side effects of progestin-only contraceptives. While not dangerous, these disturbances can be very unsettling for women and are one of the main reasons for discontinuing this group of contraceptives.

Prior to use of any progestin-only contraceptive, a woman should be told that she is likely to experience changes in menstrual bleeding, including bleeding between menstrual periods, heavier menstrual bleeding and amenorrhea. Women should be counseled to help them compare the benefits of contraception against these possible side effects.

"Counseling is a critical and essential component to user satisfaction and continuation," according to a statement issued by medical experts who met in 1993 at Family Health International. "The goal of counseling should not be to convince women to accept a method but to help women decide what they are willing and able to do."

For many women, disruption in bleeding patterns may mean a loss of quality of life, and changes also may have cultural implications in some countries. For example, some religions restrict women's activities during the days they are bleeding. In some cultures, women incorrectly view amenorrhea as the build-up of "bad" or harmful blood in their bodies.

### CONSIDER POSSIBLE CAUSES

In managing bleeding irregularities, providers should first determine whether these irregularities are actually a progestin-only side effect or indicate another condition. For example, prolonged amenorrhea can be a sign of pregnancy, and intermenstrual bleeding can be a symptom of a more serious genital tract problem, such as cancer.

Once other conditions are ruled out, providers should counsel clients that menstrual disturbance is common among progestin-only contraceptive users. Irregular or prolonged bleeding may occur during the first three to six months a woman is using progestin-only con-

traceptives but usually subsides. Good counseling and reassurance should always be the first approach.

For women who suffer prolonged or heavy bleeding and are not reassured by counseling, some experts suggest medical treatments. Hormonal treatments and nonsteroidal, anti-inflammatory drugs are options.

However, there is some disagreement as to whether estrogen or ibuprofen treatments are advisable, since giving them on top of progestin constitutes a double treatment that may cause undesirable side effects. Also, estrogens may not be advisable for women who are using progestin-only methods in order to avoid problems from using combined oral contraceptives, which contain estrogen.

Iron supplements may be given if the client is susceptible to anemia. Providers should counsel women that irregular bleeding patterns may return once these treatments are stopped.

Amenorrhea may occur during the first few months a woman uses progestin-only contraceptives. For women who choose injectables, amenorrhea becomes more common the longer the method is used. There is no medical reason to discontinue progestin-only contraceptives if amenorrhea occurs. However, if the client finds amenorrhea unacceptable for personal reasons, the method should be discontinued. The absence of menstrual periods is normal with use of progestin-only methods, and amenorrhea is not known to be harmful or dangerous. The possible relationship of osteoporosis and prolonged amenorrhea due to progestin-only contraceptive use is under study.

—Barbara Barnett

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### BLEEDING MANAGEMENT

**Counsel:** Prior to use, every woman should be informed that she is likely to experience changes in menstrual bleeding.

**Evaluate:** Determine if bleeding irregularity is actually a side effect or indicates another condition.

**Treat:** For women who suffer prolonged or heavy bleeding and are not reassured by counseling, the following approaches may be used:

- short-term (7 to 21 days) low-dose combined oral contraceptives or estrogen
- ibuprofen or similar non-steroidal anti-inflammatories other than aspirin

**Discontinue:** If client asks for discontinuation, honor her request and offer another contraceptive method.

One recommendation is to give one low-dose combined oral contraceptive pill or estrogen once a day for seven to 21 days; or if bleeding is more severe, the pill can be given every 12 hours. Another option is to give 200 mg of ibuprofen, or any nonsteroidal anti-inflammatory drug other than aspirin, three to four times a day.

## COUNSELING BEFORE USE

Counseling women about side effects and health concerns should be given before a progestin-only method begins. Given the temporary nature of most side effects, providers should focus on helping women get through the transition period.

"Lots of women have menstrual disruption and live with it just fine," says Dr. Margaret McCann, a U.S.-based consultant who specializes in POPs. "It depends primarily on whether they were told to expect these irregularities."

Some providers hesitate to tell patients about menstrual side effects, says Dr. Joseph deGraft-Johnson of FHI, a physician from Ghana. "There seems to be a common belief among service providers in developing countries that when clients are told about the possibility of their developing menstrual irregularities, they may opt not to use progestin-only contraceptives," he says.

"Studies have shown, however, this not to be the case. It has been found that, when counseled about the potential for menstrual irregularities, women who use progestin-only methods tend to have a higher continuation rate."

— Sarah Keller

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RELIGIOUS OR CULTURAL BELIEFS MAY DISCOURAGE SOME WOMEN FROM USING PROGESTIN-ONLY METHODS, SINCE THEY CAN CAUSE IRREGULAR BLEEDING. GOOD COUNSELING AND REASSURANCE HELP TO PREPARE WOMEN FOR THESE SIDE EFFECTS. A YOUNG WOMAN READS IN ISLAMABAD, PAKISTAN.

# POPs Are Very Safe, Have Few Side Effects

While particularly well-suited for certain women, taking the pills on time is crucial for effective contraception.

**P**rogestin-only pills (POPs) are not as well-known or widely used as combined oral contraceptives, but they are especially suitable for certain women: those who are breastfeeding and those who cannot tolerate estrogen.

Progestin-only pills, also called minipills or progestin-only oral contraceptives (POCs), contain no estrogen. They also have a smaller amount of progestin than combined pills, which contain both estrogen and progestin.

"The safety level of the POP is high, and it causes a smaller range of side effects than combined pills," says Dr. Linda Potter, an FHI public health scientist who studies oral contraceptives. "It is an excellent method for breastfeeding women who want to use a hormonal method, because it contains no estrogen and the progestin dose is so low." POPs also have the advantage of being fully controlled by users, which is not the case for other progestin-only methods.

Timing, however, is crucial — POPs must be taken within three hours of the same time every day to be most effective. "If the pills are taken at about the same time each and every day, they are extremely effective," Dr. Potter says.

Combined pills are not recommended for breastfeeding women because the estrogen in them affects lactation. Despite these and other differences, both combined pills and POPs currently bear the same product

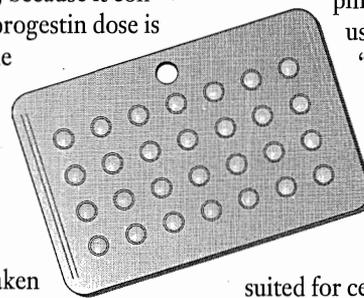
labeling in the United States, leading to the misconception that POPs carry the same contraindications and side effects as combined pills.

Because POPs are somewhat less effective, less forgiving of user mistakes and frequently cause irregular menstrual bleeding, providers and users generally have preferred combined pills. Consequently, many providers have little experience offering progestin-only pills or counseling on their correct use.

## EFFECTIVENESS AND TIMING

When used consistently and correctly ("perfect" use), POPs are estimated to be 99.5 percent effective in preventing pregnancy, compared with the 99.9 percent effectiveness rate estimated for combined pills.<sup>1</sup> The effectiveness of POP use among average people (called "typical" use), which includes inconsistent or incorrect use, is thought to be about 95 percent, while combined pills are estimated to be 97 percent effective.

POPs are particularly well suited for certain groups of users, experts say. These include lactating women, older women who smoke, and women who suffer from migraine headaches, hypertension, diabetes or cardiovascular problems, all of whom are discouraged from using combined pills because of their estrogen content. POPs do not significantly change the metabolism of carbohydrates, important for diabetic



women, and they do not significantly alter lipid metabolism, blood coagulation factors or blood pressure, all of which can be associated with cardiovascular risks.

The two groups that often use POPs — breastfeeding women and older women — typically are less fertile than other groups. Consequently, the effectiveness of these pills may be lower for women who are more fertile. Also, minipills may be less effective for heavier women than for those who are lighter.<sup>2</sup>

POPs contain one of several synthetic progestins, which are capable of producing biological effects similar to those that would be stimulated by progesterone, a natural female hormone. Levonorgestrel (LNG), norethindrone (NET) and lynestrenol are among synthetic progestins widely used. POPs are marketed under brand names such as Ovrette, Micro-Novum and Micronor. Like other progestin-only methods, POPs are thought to prevent pregnancy in several ways: by thickening cervical mucus so sperm cannot penetrate it, preventing ovulation, slowing transport of the ovum through the fallopian tubes and changing the endometrium.<sup>3</sup>

The small amount of progestin in the pills is metabolized quickly by the body. Twenty-four hours after taking a pill, little or no progestin remains, so it must be promptly replenished by taking another pill. Some women could conceive if they take a pill as little as three hours late, so those who cannot follow a rigid schedule should use a different method, experts say.

This timing requirement is the most difficult issue for minipill users, says Dr. Emily Bernardo, who has conducted clinical trials with POPs at Jose Fabella Memorial Hospital in Manila. "We ask women about their regular schedule, what time they are least busy and whether their husband is on night duty or day duty," she says. "We ask what time they can easily remember to take their pill. It should be at the same time every day."

Taking the pill in the afternoon can theoretically make it more effective, because the body's progestin level will be highest in the evening, a typical time for intercourse. Waiting until bedtime each day to take a POP, however, may increase the risk of pregnancy since a forgotten pill will be many hours overdue if delayed until after sleeping.

Unlike combined pills, which have a hormone-free interval, the synthetic hormone used in POPs must be taken without interruption every day in order to be effective. "We also emphasize that [clients] have to take the (progestin-only) pills as scheduled, even if they do not have sex, or if they have some spotting or bleeding," Dr. Bernardo says. "Women who are used to combined pills tend to miss minipills if they have spotting."

#### SAFE FOR BREASTFEEDING

In some countries — such as Jordan and Kenya — more than half of the women are breastfeeding an infant under six months old when they first visit a family planning clinic, according to an International Planned Parenthood (IPPF) study.<sup>4</sup> "If we are going to provide good services to those women, we need to have available methods of contracep-

USAID



THERE IS NO NEED TO SWITCH FROM POPs TO ANOTHER METHOD AFTER BREASTFEEDING. A WOMAN WITH HER CHILD IN MALI.

tion suitable for use during breastfeeding," says Dr. Carlos Huezo of IPPF. "The POP has that very important role."

Breastfeeding women who want to prevent pregnancy should consider nonhormonal contraception first, according to FHI, IPPF and other organizations.<sup>5</sup> But for women who want oral contraception or who cannot use other methods, POPs are preferred over combined pills, which reduce the quantity of breastmilk.<sup>6</sup>

Progestin-only pills do not reduce production of breastmilk, studies show.<sup>7</sup> Only a small amount of progestin is passed to the infant during breastfeeding. What little progestin is taken in through breastmilk does not seem to have a negative effect on infant growth or development, according to two new prospective studies of 2,466 infants by the World Health Organization (WHO).<sup>8</sup> These studies compared infants breastfed by women using nonhormonal contraception to

those breastfed by women using various types of progestin-only contraceptives in Egypt, Kenya, Chile, Thailand and Hungary. The infants' growth, including weight and arm circumference, and their development, including hearing, motor and language skills, were examined. The researchers concluded that POPs and other progestin-only contraceptives, when started at least six weeks postpartum, did not harm infants whose mothers used them during breastfeeding.

Although no adverse effects have been reported in children exposed to small amounts of synthetic hormones early in life, most experts recommend delaying the use of any hormonal method, including POPs, until six weeks postpartum. The natural contraceptive effect of fully or nearly fully breastfeeding during amenorrhea, called the

Lactational Amenorrhea Method (LAM), can provide temporary protection until another method is initiated.

Both providers and users should be aware that women can use POPs even when they stop breastfeeding, says Dr. Bernardo of Fabella Memorial Hospital. There is no need to switch to combined pills or other contraceptives unless the woman wants a change or has trouble taking POPs on schedule.

"One of the major reasons for discontinuation is that the women are no longer breastfeeding" or only breastfeed occasionally, Dr. Bernardo says. Some women, she says, may have the mistaken impression that the minipill should be used only during breastfeeding and stop using the minipill without beginning another method.

Many breastfeeding women have been prevented from using POPs because oral contraceptive labels caution against their use during lactation. However, these labels were written for combined pills, not for progestin-only pills. Dr. Potter of FHI and Dr. Margaret F. McCann, an epidemiologic consultant in reproductive health based in Chapel Hill, NC, USA are collaborating with the U.S. Food and Drug Administration (FDA) to draft new insert labels for POPs, which will make this distinction clear.

The new labeling will also eliminate the other precautions related to the estrogenic component of combined pills. "The current label is old, inaccurate and hard to read," says Dr. Philip Corfman, the U.S. FDA's supervisory medical officer for fertility and maternal health drugs. The new label may be ready by the end of the year, Dr. Corfman says.

## HEALTH ISSUES

Fewer studies of POPs have been completed than of combined pills and some other contraceptive methods. However, evidence from examinations of the progestin component in combined pills and from other progestin-only contraceptives points to the conclusion that POPs have few negative health consequences.



RICHARD LORD

WHILE POPs ARE IDEAL FOR BREASTFEEDING MOTHERS AND CERTAIN OLDER WOMEN, THEY ARE A SUITABLE CHOICE FOR MOST WOMEN. A WOMAN IN KENYA.

## HOW TO USE PROGESTIN-ONLY PILLS

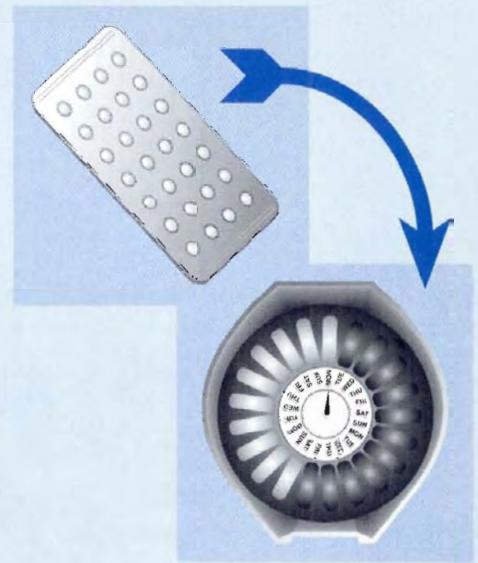


### Starting

- ❑ A woman may begin using progestin-only pills (POPs) any time. A woman who begins during the first five days of her menstrual period does not need a backup contraceptive. If she starts at other times, a backup contraceptive should be used for 48 hours.
- ❑ Pills should be taken within three hours of the same time every day, even if a woman is not having sex frequently.
- ❑ Mothers who are breastfeeding should wait six weeks after giving birth before using POPs. Women who do not breastfeed their infants, or have had abortions or miscarriages, may begin POPs immediately postpartum.
- ❑ Users should have a backup contraceptive method available in case of late or missed pills.

### Switching and stopping

- ❑ There is no need to switch from POPs to combined pills during or after breastfeeding, but a breastfeeding woman may do so after six months postpartum. Ideally, a breastfeeding woman should not begin using combined pills until at least six months postpartum because the estrogen in combined pills may affect breastmilk quantity.
- ❑ A woman who is not breastfeeding may switch from POPs to combined pills at any time, beginning the combined pills on the first day of her menstrual period, even if she has not finished the POP pack.
- ❑ If switching from combined pills to POPs, begin POP use after the last active combined pill.
- ❑ Switching POP brands may be done any time. To conserve pills, a woman may begin the new brand the day after taking the last pill of the previous pill pack.
- ❑ POPs can be discontinued at any time, without finishing a pill pack. Fertility returns rapidly.



### Missed and late pills

- ❑ If a woman misses a pill, she should take one as soon as she remembers and use another contraceptive method or abstain from sex for 48 hours. The next pill must be taken at the regular time, even if that means taking two pills in one day.
- ❑ A backup contraceptive should be used for 48 hours after an episode of heavy vomiting or diarrhea, which may purge the progestin from a woman's system.
- ❑ A woman who has unprotected sex because of a late or missed POP can consider emergency contraception within 72 hours. She should continue taking the POPs but consult her provider as soon as possible.
- ❑ If a woman accidentally becomes pregnant while using POPs, the fetus will not be harmed by the small amount of progestin in the pills. However, she should discontinue use as soon as she knows she is pregnant.

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— Carol Lynn Blaney

There are relatively few absolute contraindications for POPs. A recent draft of WHO guidelines specify pregnancy and post-molar trophoblastic tumors as absolute contraindications. Breast cancer and unexplained abnormal vaginal bleeding are among several conditions in which the method is not usually recommended unless other more appropriate methods are not acceptable, the draft guidelines say.<sup>9</sup>

Women who are taking drugs that reduce the effectiveness of POPs, including most anticonvulsants or rifampicin, a medication used primarily for tuberculosis, also should choose another contraceptive. Some women develop persistent ovarian follicles when using POPs; these are not contraindications unless they are painful or require surgery.

The incidence of ectopic pregnancies in POP users is similar to the rate for women who use no contraceptives but higher than for other contraceptive users.<sup>10</sup> "Because POPs prevent pregnancy, they prevent ectopic pregnancy," Dr. Potter says. "But once pregnancies occur, a somewhat larger proportion of them are ectopic among POP users than among other contraceptive users."

Women with a history of ectopic pregnancy can use POPs but all users should be aware of the danger signs for ectopic pregnancy, Dr. Potter says. These include abdominal or pelvic pain usually occurring on one side of the body, vaginal bleeding with pain when a period is late or especially light, and fainting or dizziness that lasts more than a few seconds.

Progestin-only pills cannot prevent lower-reproductive tract infections, and their interaction with HIV is unknown.

Therefore, women at risk of sexually transmitted diseases, including HIV, should receive counseling about practicing safer sex and the use of barrier contraceptives in addition to minipills.<sup>11</sup>

POPs do not increase breast cancer risk, according to results of limited studies.<sup>12</sup> Very few studies have included the relationships between minipills and other cancers, but studies on contraceptives containing similar progestins suggest that minipills are not likely to increase cancer risk.

POPs may protect against certain cancers, says Dr. McCann. Lack of ovulation, which is linked with prevention of ovarian cancer for women using combined pills, occurs in about half of POP users. POPs may have other beneficial health effects, such as protecting against benign breast disease and reducing the severity of sickle cell crises.<sup>13</sup>

A FAMILY PLANNING WORKER CONDUCTS A HOME VISIT IN THE GAMBIA.

WELL-TRAINED COMMUNITY-BASED WORKERS ARE CAPABLE OF DISTRIBUTING POPs.

CAROLINE PENI



## REACHING WOMEN

Women who decide to use progestin-only pills as their contraceptive method often experience changes in the duration of their menstrual cycles, irregular bleeding or amenorrhea. Some POP users also experience headaches, breast tenderness, nausea and other symptoms sometimes associated with hormone use.<sup>14</sup>

The menstrual disturbances, however, have led more than one-fifth of women in some studies to stop using POPs.<sup>15</sup> Thus, providers need training on how to inform and counsel women about side effects that they might experience when using POPs.

"Most of the side effects do not seriously affect the health of the client," says Dr. Joseph Ruminjo, an obstetrician-gynecologist at Kenyatta National Hospital in Nairobi, Kenya, and 1994-96 Mellon fellow at FHI. "The client can tolerate them if she has adequate information and counseling. Once the client has started the method, you need to continue giving some form of support, and she may require reassessment" of whether POPs are the best contraceptive choice for her.

Experts point out that older women and breastfeeding women may be more likely to have irregular bleeding for other reasons and so may be more likely to tolerate this side effect of POPs.

One way to increase women's choices is to make POPs more available through outlets other than clinics. Community-based distribution would be an excellent way to market minipills, as long as providers were thoroughly trained on the differences between them and combined pills, says Dr. Huezo of IPPF. Many health workers do not know how pills work and are not aware of the distinctions between pill types, he says.

— Carol Lynn Blaney

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## POPS LESS WIDELY USED

Progestin-only pills (POPs) are less widely used and available than combined pills. For example, the U.S. Agency for International Development (USAID) shipped only 3 million packets of POPs worldwide in 1994, compared with 62 million packets of combined pills, according to Mark Rilling, program analyst with USAID's Office of Population.

While USAID considers POPs to be an acceptable contraceptive option for some women and intends to continue providing them, the worldwide market for them is small, Rilling says. The London-based International Planned Parenthood Federation (IPPF) reports a similar trend. IPPF shipped

16 times more combined pills than POPs during 1994, says Dr. Carlos Huezo, the organization's medical director.

New efforts to clarify the role of progestin-only pills may make them more acceptable. For example, new studies have provided additional evidence that POPs do not harm breastfed infants whose mothers use them. A new label that reflects these findings, and clarifies other distinctions from combined pills, is being developed for POPs by the U.S. Food and Drug Administration, based on a draft developed by FHI. The pills also are being more actively promoted among some family planning organizations, and may prove useful for community-based distribution.

— Carol Lynn Blaney

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# Progestin-only Injectables Offer Many Advantages

Once available, progestin-only injectables become popular because of convenience, safety and effectiveness.

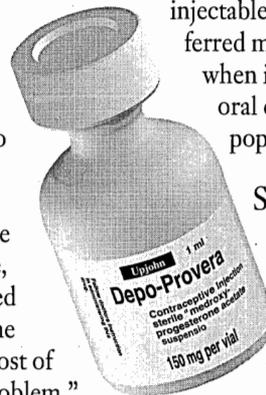
**P**rogestin-only injectables are among the most effective and safe of all contraceptives, yet they are not widely used in many countries. Contributing to this limited use are a lack of accurate information about health concerns and not enough counseling for users about managing side effects.

"Injectables are very effective, very convenient for most users, very easy for providers to deliver and can be distributed easily in nonclinical settings by nonphysicians," says Dr. Roberto Rivera, FHI's international medical director. "The main disadvantage of this method is the disruption of the menstrual cycle, and this aspect is usually perceived differently from one culture to the next. It is a perceived risk, and most of the time not a serious medical problem."

There are two progestin-only injectables in use worldwide, depot-medroxyprogesterone acetate (DMPA), usually sold under the brand name Depo-Provera; and norethindrone enanthate (NET-EN), sold under the name Noristerat. DMPA is delivered in a water-based, crystalline suspension and absorbed gradually by the body. The normal injection of 150 mg is intended to be administered every three months, but contraceptive protection continues for an additional two weeks, which provides a "grace period" for women who are late receiving their next injection. NET-EN is in an oily solution and requires a big-

ger needle than DMPA for injection. A 200 mg injection of NET-EN is usually administered every two months. Both DMPA and NET-EN are injected in either the upper arm or buttocks. This article focuses primarily on DMPA, the three-month injectable.

"Injectables have many advantages, but they face a major barrier — not being widely available," says Dr. Rivera. "Once available, injectables rapidly become one of the preferred methods. There may be a time when injectables will be equal in use to oral contraceptives, now the most popular reversible method."



## SAFE AND EFFECTIVE

Injectable contraceptives have very low failure rates. If a woman receives her injections on time, this method is more than 99 percent effective, as good as surgical sterilization.<sup>1</sup>

Upon discontinuing the use of DMPA, there is a delay in the return to fertility that is longer than for other methods — about 50 percent of women conceive within 10 months of their final injection. By 24 months following the last injection, more than 90 percent of women have returned to fertility, virtually the same proportion as among women who used oral contraceptives or intrauterine devices.<sup>2</sup> Because of this delay, women who wish to get pregnant relatively soon after discontinuation are probably not good candidates for this method.

Progestin-only injections may be given any time a woman is not pregnant. Ideally, a woman should receive the first injection dur-

ing the first seven days after the onset of a normal menstrual period. Generally, DMPA takes effect within the first five days, so in most women, DMPA prevents ovulation in that menstrual cycle. It is safe to get the first injection at other times, but a backup contraceptive method should be used in those cases. Like other progestin-only methods, DMPA acts by preventing ovulation and by thickening cervical mucus, which becomes a barrier for sperm.

Progestin-only injectables are safe for breastfeeding mothers and will not harm the infant or decrease the quantity of breast-milk.<sup>3</sup> However, even though no adverse effects have been reported, experts recommend that breastfeeding mothers delay using any progestin-only method until six weeks postpartum as a precaution against theoretical concerns. Postabortion women and postpartum mothers who are not breastfeeding may begin DMPA and other progestin methods immediately, without a six-week delay.

As with other progestin-only methods, almost any woman in good health who is not pregnant can use progestin-only injectables. They are safe for women who have hypertension, superficial thrombophlebitis, valvular heart disease, biliary tract disease, benign breast disease, thyroid disease, epilepsy or irregular menstrual periods. For women with ovarian, endometrial or cervical cancer, the advantages of using injectables generally outweigh the risks, according to draft guidelines developed by the World Health Organization (WHO).<sup>4</sup>

Injectables do not protect a woman against transmission of sexually transmitted disease (STD), including HIV; studies have not yet determined whether they have a relationship to HIV transmission. Research has shown that DMPA is beneficial to a woman who has sickle cell disease, which is common in Africa and the Caribbean.<sup>5</sup> Thus, DMPA is the method of choice for women with this disease.

A woman can use injectables without her partner knowing it, which may be helpful to women whose partners refuse to use contraception. Also, a woman who is unable or unwilling to use another method consistently or who cannot tolerate estrogen-related side effects is a good candidate for DMPA.

## MENSTRUAL IRREGULARITY

The major side effect of progestin-only injectables is menstrual irregularity. Nearly all women experience some changes in their menstrual pattern, usually more frequent or prolonged bleeding initially and infrequent bleeding or amenorrhea after about a year of use. Two of every three women experience amenorrhea after two years of use.<sup>6</sup> Other possible side effects include weight gain, headaches, nervousness and mood changes.

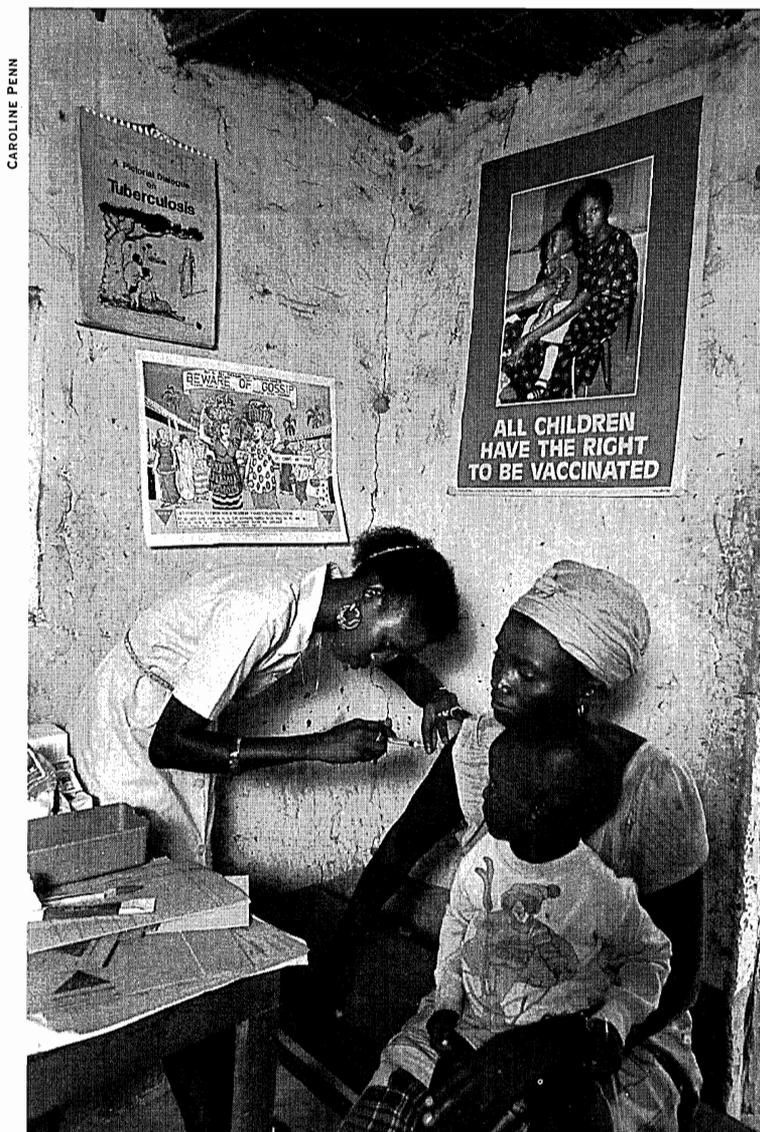
Menstrual irregularities are rarely a medical concern, and good counseling can minimize discontinuation due to menstrual changes. "Just over two-thirds of the women who discontinued use [in one survey] did so either to be sterilized or to have another child," says Dr. Sriani Basnayake, medical director of the Family Planning Association (FPA) of Sri Lanka. "Only 5 percent discontinued because of menstrual disturbances. The intensive counseling

provided at the FPA's clinics may be a reason as to why women tolerate their menstrual disturbances so well."

A recent study of 200 new DMPA users in Bangladesh found that menstrual patterns and other factors did affect continuation rates in the Asian country. Women perceived heavy bleeding and spotting as important problems, while amenorrhea was virtually never considered the most significant problem associated with use, the study found. About two of every three women received counseling about amenorrhea but only three of 10 were told about heavy bleeding or spotting. Counseling about amenorrhea may be so effective that women do not report it as a problem, the report says.<sup>7</sup>

Amenorrhea often persists after use is discontinued, which may have contributed to the incorrect belief that injectables impair fertility. "Many service providers continue to think that injectables impair fertility, even though studies as early as the 1970s show

PROGESTIN-ONLY INJECTABLES ARE MORE  
THAN 99 PERCENT EFFECTIVE, WHEN  
ADMINISTERED ON TIME. A WOMAN GETS  
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PLANNING CLINIC.





A PANEL FROM A FLIP-CHART USED IN COUNSELING DMPA CLIENTS.

this not to be the case,” says Dr. Carlos Huezo, medical director of the London-based International Planned Parenthood Federation (IPPF). A recent FHI study in Ghana found that many providers there believe DMPA causes permanent infertility.<sup>8</sup>

Because of the potential for increased bleeding in the early months, a woman who has a pattern of very heavy bleeding should be carefully counseled about the changes and monitored closely during these months. The loss of too much blood could result in anemia or other medical problems. Prolonged bleeding can usually be remedied on a short-term basis with combined oral contraceptives, which contain estrogen.

For women who like injectables but not the bleeding irregularities, monthly injectables that contain both estrogen and progestin have been developed. One brand, Cyclofem, available in Mexico, Indonesia and several other

countries, combines an estrogen with DMPA. Mesigyna, available in some countries, uses an estrogen and NET-EN.

#### CANCER STUDIES, BONE METABOLISM

In the 1980s, a series of multi-center studies coordinated by WHO found that, overall, women who have used DMPA do not have a higher risk of breast or cervical cancer compared with other women. The studies also found that DMPA users have a reduced risk of endometrial cancer. Similar results were found in a cervical cancer study conducted in Jamaica by FHI, in conjunction with the University of West Indies and the Jamaica Cancer Society.<sup>9</sup>

A recent analysis has pooled the data from the WHO study on breast cancer and a similar one in New Zealand.<sup>10</sup> The combined data set is the largest case-control analysis of the association between breast cancer and DMPA use. The analysis found no increased risk of breast cancer when looking at all women who had ever used DMPA, nor was any increased risk observed among women who have been using DMPA for five or more years. However, the authors did find that women had a slightly greater risk of breast cancer during the first five years of use and that women under age 25 had an increased risk with longer use.<sup>11</sup> While the risk of breast cancer is greater among recent DMPA users under the age of 35, breast cancer at this age is very rare and the increased risk remains relatively small, explains Dr. Pamela Schwingl of FHI, who studies cancer risks.

Theoretical concerns have been raised about how DMPA use affects long-term bone development, especially among adolescents. Currently, women under age 16 may use DMPA when the advantages of using the method outweigh theoretical risks, according to draft guidelines developed by WHO and to another set of standards from the U.S. Agency for International Development (USAID). Women older than age 16 have no such restrictions.<sup>12</sup>

Preliminary evidence suggests that long-term DMPA use may be associated with reduced bone density but that this effect may be reversible after DMPA use is stopped.<sup>13</sup> In all women, bone density declines following menopause, leading to a gradual weakening of the bones. "The degree of weakening depends on the peak level of bone mass attained prior to menopause and the subsequent rate of bone loss," says Dr. Eilene Bisgrove, who directs FHI's research in this area.

Adolescence is a time of rapid development in bone density and length. Linear bone growth may continue for up to two years after menarche. DMPA use lowers estrogen levels, and estrogen is needed for developing and maintaining strong bones.

"For these biological reasons, DMPA use could have detrimental effects on bone growth during adolescence, with possible long-term consequences on bone density," says Dr. Bisgrove. "If DMPA effects on bone are going to show up, it would most likely be during adolescence, but the two large-scale prospective studies currently under way do not include women under age 18." Dr. Bisgrove hopes to undertake a prospective study involving women ages 13 to 19.

The Upjohn Company, maker of the DMPA brand Depo-Provera, is conducting a seven-year prospective study on bone density involving 450 women, ages 25 to 35. "Until we see results from this prospective data, the relationship is an open question," says Dr. James Jacobs of Upjohn, a medical monitor for the study.

#### ONE AREA, ONE TYPE

If more than one type of injectable is available, a provider might give a woman NET-EN by mistake when the client needs DMPA, an error more likely during supply shortages. Since NET-EN is a two-month injectable, a woman might not have adequate contraception during the three months before her next DMPA injection. IPPF's International Medical Advisory Panel addressed

this issue, responding to a report from the Bangladesh Family Planning Program, where doorstep deliveries of DMPA are widely used. Because of the different sized needles and schedules used for DMPA and NET-EN, along with supply concerns, the panel recommended that only one progesterin-only injectable be used within a specific geographical area.<sup>14</sup>

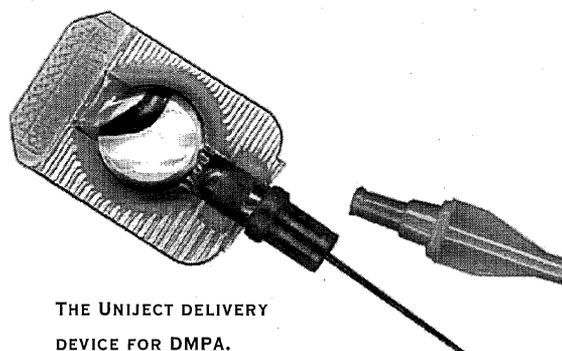
A community-based distribution program can make injectables much more widely available. A recent study of two Bangladesh districts found that "female field workers can provide injectable contraceptives safely and effectively, and that in contrast to clinic-based delivery, the doorstep delivery significantly increased the acceptance of injectables."<sup>15</sup>

Users can get confused about the time for the next injection. In the Philippines, a "Couples Choice Injectable" project uses a date card that is simple to follow. For nonliterate women, programs in Sierra Leone, Nigeria and The Gambia use three crescent moons to illustrate how long DMPA is effective.

Injectables involve the potential for reusing needles, which could increase transmission of diseases if needles are not properly sterilized between uses. A new delivery device called Uniject eliminates this danger. It combines the needle with a one-dose vial of the contraceptive solution. This device can only be used once, since it cannot be refilled. Field tests in Brazil have resolved technical questions and are focusing on cost and acceptability issues, says Dr. Peter Hall of WHO, which is conducting this research with the U.S.-based Program for Appropriate Technology in Health.

"The use of injectables is going to increase," says Dr. Hall. "We hope it can be as safe as possible. Preventing the reusability of needles would make injectables a far safer method."

— William R. Finger



THE UNIJECT DELIVERY DEVICE FOR DMPA.

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(continued)

## INJECTABLES USE INCREASING RAPIDLY

Worldwide use of progestin-only injectables appears to be increasing rapidly. From 1990 to 1994, United Nations Population Fund shipments increased almost four-fold, from 4.5 million doses annually to 16.7 million.

In October 1992, the U.S. Food and Drug Administration approved DMPA for use as a contraceptive in the United States, which allowed the U.S. Agency for International Development (USAID) to begin supplying it to other countries. Consequently, in 1994 USAID agreed to purchase at least 4.25 million one-dose vials of DMPA to be distributed over 30 months.

USAID is sending its largest initial shipments to Mozambique, Nepal, Peru, Tanzania and Uganda. "The first shipments only went out in September [1994], so it's too early to know if they will result in significantly increased use," says John Crowley, USAID coordinator of DMPA procurement. USAID has contracted with FHI to monitor the quality of DMPA sent to other countries.

Some of the first USAID shipments went for social marketing programs, which use private-sector marketing and sales techniques to achieve public health goals. In Nepal, for example, the Social Marketing for Change (SOMARC) program of the U.S.-based Futures Group is using these supplies in a pilot project at 50 privately owned pharmacies, working closely with the Ministry of Health and other partners. It is common in Nepal for people to get various injections at pharmacies.

The project includes site visits and training in how to give the injections, says Gretchen Bachman of SOMARC. SOMARC also markets DMPA in the Phil-

ippines, Jordan, Jamaica, Egypt and the Central Asian Republics. Population Services International (PSI), also supported by USAID, is considering adding DMPA to its existing social marketing projects in Nigeria, Guinea, Indonesia and Bangladesh.

### INFORMATION ENCOURAGES USE

Even though DMPA has been available in some 90 countries for many years, only a few countries report substantial use of injectables among married women of reproductive age: Indonesia (15 percent), South Africa (14 percent), Thailand (9 percent) and Jamaica (8 percent). An estimated 12 million women worldwide currently use injectables, compared with 70 million women who use oral contraceptives.<sup>1</sup>

Lack of up-to-date scientific information about injectables may have discouraged use of the method. In a 1993 survey among family planning providers in Ghana, for example, 82 percent reported using a minimum parity requirement before allowing a woman to use injectables. Many of these providers believed incorrectly that injectables can cause permanent infertility.<sup>2</sup>

To help ensure that providers throughout the world have the most up-to-date information, FHI has prepared a lecture module on injectables, which includes slides, a suggested text for the lecture, audience handouts, a wall poster and scientific journal references. FHI has received comments from about 50 trainers who have used the injectables lecture module in 28 countries, making more than 200 presentations to an estimated 10,000 health-care professionals.

In recent years, the World Health Organization, International Planned Parenthood Federation, USAID and others have published new guidelines on using injectables. USAID's guidelines are part of its effort to maximize access to and quality of family planning services. New standards are gradually leading to changes in many countries, which may affect the number of women using DMPA.

"Until recently, no woman under age 30 or with fewer than three children could use injectables in Kenya," explains Dr. Joseph Ruminjo of Kenyatta Hospital in Kenya, currently a Mellon Foundation fellow at FHI's U.S. headquarters. "Now the government has relaxed these guidelines, and the pool of potential users is much larger."

In the last four years, the proportion of married women of reproductive age using injectables in Kenya has more than doubled, from 3 percent to 7 percent, according to Demographic Health Surveys. The change in guidelines and attention to counseling appear to be the major reasons, says Dr. Ruminjo.

—William R. Finger

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# Norplant Removals Vital to Quality Care

Removing implants, after five years of use or upon request, is an important feature of Norplant service.

**F**or many women, Norplant is an ideal contraceptive. The device, implanted by a family planning provider under the skin of a woman's arm, offers a highly effective long-term means of preventing pregnancy, with no compliance required by the user.

However, at the end of its five-year effectiveness period — or sooner if the woman desires — Norplant must be removed. Ensuring access to safe, easy and affordable removal is an element of good quality care that begins before the device is inserted, experts say. Adequate staff training is essential, since removals are more difficult when insertions have been poorly performed. Counseling clients about when and how to obtain removals is crucial.

"There are two concerns with removal," says Dr. Juan Díaz, the Population Council's medical advisor for Latin America and the Caribbean. "One is technique — providers learning how to perform the procedure. The other is counseling for clients. All the information about removal should be given to clients in the very beginning," before insertion.

Because Norplant has been available less than a decade in most countries, more insertions have been performed than removals. As clinicians gain more experience with the method, they should refine strategies for tracking and accommodating large numbers of clients who seek removals at the end of the

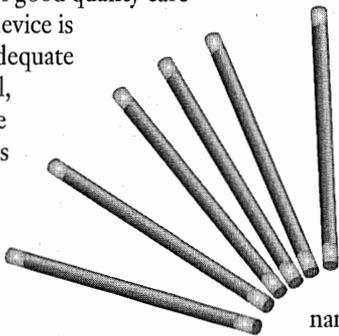
five-year effectiveness period and improve access for women who want early removals. Removal techniques are also being improved over time.

## LONG DURATION, FEW SIDE EFFECTS

Norplant is inserted through a small incision in a woman's upper arm. Six thin flexible capsules containing the progestin levonorgestrel are placed under the surface of the skin and slowly release the progestin into the woman's bloodstream. Studies by the Population Council, which developed Norplant, show the pregnancy rate during the first year of use is very low, only 0.2 percent. The cumulative pregnancy rate at the end of five years is 3.7 percent.<sup>1</sup>

Like other progestin-only methods, Norplant prevents pregnancy through several different means. The levonorgestrel (LNG) released from the capsules thickens cervical mucus, making it difficult for sperm to pass through the cervix and reach the uterus. Also, progestin can suppress ovulation and can cause a thinning of the endometrial lining, making implantation of a fertilized ovum difficult.

While Norplant can produce unpleasant side effects, such as menstrual disturbances, numerous studies have shown it to be a highly acceptable contraceptive method for many women. A study conducted by the



Egyptian Fertility Care Society (EFCS), with assistance from FHI, found that during the first six months of use, 93 percent of the 1,351 acceptors were satisfied with Norplant.<sup>2</sup> Women said they liked the method because of its long duration and high effectiveness, because it produced fewer side effects for them than the pill or intrauterine device, and because it was inserted in the arm and did not require a gynecologic exam.

An FHI study of Norplant acceptors in five Asian countries — Bangladesh, the Philippines, Nepal, Sri Lanka and Singapore — reported that among 882 women who used Norplant for five years, 70 percent found the method “very favorable.”<sup>3</sup> Women cited the five-year duration of Norplant, ease of use, and high effectiveness as advantages.

Norplant contains no estrogen, which means it can be used by women who are breastfeeding or have health conditions that might preclude use of combined oral contraceptives, which contain estrogen. The

World Health Organization (WHO), the Population Council and FHI are currently conducting a study of more than 8,000 Norplant users to determine benefits and side effects of the method.

#### FIVE-YEAR REMOVALS

When Norplant’s approved five years of effectiveness ends, a woman’s risk of pregnancy begins to increase. Researchers speculate that the risks of ectopic pregnancy, a potentially life-threatening condition in which the fetus develops outside the uterus, may increase as well.<sup>4</sup> Therefore, timely removal of Norplant is important.

Program managers should plan carefully for Norplant removals at the same time they train providers and plan the logistics of supply and distribution. For example, in Haiti, Senegal and Mali, where FHI is working with other organizations to introduce Norplant, information about removals is included in the introduction strategy for the method.

In Mali, where FHI also is conducting a study of Norplant acceptability and client satisfaction, a system is being developed to track Norplant clients, says FHI researcher Karen Katz. FHI is establishing a simple database containing information about acceptors: name, address, date of insertion, any complications during Norplant use, a date to remind the client of removal, and the planned date of removal. Clinic staff will collect the data at the time of insertion and during counseling. Reminders of the importance of Norplant removal will be disseminated throughout the community, and community health workers plan to locate clients who do not return before the removal date.<sup>5</sup>

Similar reminder systems have been established in other countries. In Egypt, EFCS keeps a registry of Norplant users, with expected date of removal; detailed address information; husband’s name, occupation and work address; names and addresses of two relatives, friends or neighbors; and

NORPLANT IS INSERTED AT A CLINIC IN IBADAN, NIGERIA.



JOHN STANBACK

telephone numbers if available. A study of 1,536 women showed that 80 percent returned on time for removals. Those who did not were contacted by social workers, who explained that the contraceptive effects of the capsules would soon expire. At the end of study, EFCS was able to contact all but 1.5 percent of participants.

In Indonesia, where about half of the world's 3 million Norplant users live, implant removal presents unique problems, says Dr. Firman Lubis, executive director of Yayasan Kusuma Buana (YKB), a family planning organization in Djakarta. First, there is the sheer volume of Norplant removals — 200,000 are anticipated in 1995. Many women received Norplant during "sa-faris" — insertions by mobile health teams. Also, the Indonesian government is conducting a relocation project to move citizens from crowded urban centers to less populated parts of the country, making it difficult to track some clients.

To reach Norplant users, Indonesian family planning organizations rely on mass media campaigns, including announcements on the radio and in newspapers. Family planning field workers, who live in rural villages and keep lists of clients and their contraceptive methods, remind Norplant users about removal. Special reminders are given to people in relocation programs.

To help improve systems to track Norplant clients, the Population Council asked clients in Brazil to suggest reminders for removal. Among their recommendations were that clinic staff repeatedly tell Norplant users to come back for removal, that cards with removal dates be provided by the clinic, that providers offer thorough counseling about the importance of removal, and that women write themselves reminders.

In Kenya, providers try to link removal with an important personal event in the client's life, such as the date their child starts school or the woman's birthday. In 1995, women are being asked to return for removal when the 21st century begins. Clients also receive reminder cards, as well as verbal reminders from clinic staff. Community nurses visit the homes of women who do not return.

In planning for removals, program managers should anticipate the number of clients who will seek removal and plan for staffing and needed medical supplies. Clinics

should consider offering removal services on evenings and weekends as well as during typical clinic hours. Providers should be prepared to answer clients' questions about reinsertion or the use of other contraceptives.

Most experts agree that both providers and clients should share responsibility in ensuring Norplant is removed on time, and that women be able to get a replacement or have another method available.

"Can the family planning program reasonably be expected to track down every Norplant user, given that women might move within the five years?" asks Dr. Karen Hardee of FHI. "Providers need to make sure clients understand the importance of Norplant removals and that Norplant is no longer effective after five years. Clients need to understand they will need additional contraceptive protection."

#### EARLY REMOVALS

While family planning programs must develop strategies to remove Norplant at the end of five years, they must also accommodate women who want Norplant removed earlier. Family planning providers must honor requests from women who want early removal for reasons such as intolerance of side effects or desire to become pregnant.

"If there are specific side effects, they should be talked through with the client. There should be discussion between the client and the provider," says Dr. Peter Hall, chief of the WHO Unit on Research on Introduction and Transfer of Fertility Regulation. "But if the client says she wants Norplant removed, that's that. In the end, the client's decision should be final."

"Before insertion, the client should receive information and counseling about side effects," says Dr. Lubis of Indonesia. "If side effects occur, there should be more counseling. If the client is agreeable, there can be a waiting period to see if the problems lessen; but if she insists, removal should be immediate."

Some women's health advocates have expressed concern that it is the provider, not the client, who decides when — or whether — Norplant is removed. Women's groups

also have warned that some women could be unduly pressured into using Norplant or that Norplant could be inserted without women fully understanding its contraceptive effects.

Norplant users in the Dominican Republic, Egypt, Indonesia and Thailand reported some dissatisfaction with removals, according to focus group discussions held by the U.S.-based Program for Appropriate Technology in Health (PATH). Women who asked to discontinue Norplant because of menstrual bleeding disturbances experienced the greatest resistance from providers, who typically encouraged clients to wait and see whether menstrual cycles would return to normal. Some women in Thailand were told Norplant was expensive and would not be removed because of minor side effects.<sup>6</sup> In Indonesia, nearly 30 percent of 394 early removals were among women who had made at least three requests before the device was removed.<sup>7</sup>

An FHI study of Norplant users in Bangladesh found that only half of the women seeking early removal had their implants removed upon first request, while 15 percent made more than three requests before removal. Although clients were often given advice and treatment to manage side effects, some clients were discouraged from early removals by being told that Norplant was expensive and could not be removed at will; that Norplant must remain in place a minimum of two years; or that the client was disrespectful for making the request.<sup>8</sup>

"Providers walk a fine line between encouraging women experiencing minor side effects to continue using the method and refusing outright to remove the implants upon a woman's request," wrote Dr. Ahmed Kashmiri and Fayza Gamil of the EFCS. "Providers may view reassurance as 'counseling' while clients perceive it as pressure to continue using the method."<sup>9</sup>

Nasreen Huq of Naripokkho, a Bangladesh women's advocacy group that has raised concerns about Norplant use, says: "A client should receive explanations about how her body works, about the menstrual cycle, and about conception and contraception. If she understands how the different contraceptive methods function to prevent pregnancy, then she will understand how Norplant works and why side effects occur. She will be able to make a judgment about whether she can cope with the side effects."

The most common side effect of Norplant use — and one of the most common reasons for early discontinuation — is changes in menstrual bleeding patterns, including amenorrhea. An FHI-supported study of 400 Sri Lankan women who used Norplant during clinical trials found that 9.7 percent requested early removal because of menstrual problems.<sup>10</sup> In Nigeria, when women were asked what they liked least about Norplant, nearly 60 percent reported no problems but 36.4 percent said they disliked changes in menstrual patterns.<sup>11</sup>

Four out of five Norplant users report menstrual changes. The first approach for managing this problem is good counseling and reassurance. If counseling is not sufficient, temporary use of estrogens, combined oral contraceptives or ibuprofen may help minimize bleeding problems (see related article, page 8).

Other side effects may include headaches, dizziness, enlargement of the ovaries, breast tenderness, nervousness, nausea, acne and weight gain. Typically, side effects occur during the first few months of Norplant use, then subside.

## REMOVAL TECHNIQUES

Since Norplant was introduced in the 1980s, a variety of removal techniques have been developed, with the aim of making the process easier for providers and more comfortable for clients.

When inserted correctly, Norplant capsules form the shape of an arc or fan under the surface of the skin. In the "standard" method, developed by the Population Council, capsules are extracted by making an incision at the base of the arc and using a clamp to guide the capsules through the incision. In the "pop out" method, used when implants are easily located, the provider guides the capsules through the incision with his fingers.

The "U" technique, developed by an Indonesian physician, involves a vertical incision between the third and fourth capsules and uses modified no-scalpel vasectomy forceps to grasp each capsule and extract it. In another procedure called the Emory method, recently developed at Grady Family Planning Clinic in the United States, a larger amount of anesthetic is given and a slightly larger incision is made at the base of the arc. The larger incision allows for easier removal of deeply placed capsules, its developers say, and reduces the time it takes for removal to about eight minutes. Several studies report the average removal time for Norplant using other approaches is about 20 minutes, and that the side effects may include pain, bruising or infection at the removal site. Most Norplant clients report that removal is more uncomfortable than insertion.

Difficult or complicated Norplant removals are unusual, according to an FHI retrospective study of the 4,546 women from 11 countries. Fewer than 5 percent of Norplant users reported problems. However, there were certain factors associated with difficult removals.<sup>12</sup>

"Proper insertion technique under aseptic conditions is very important in predicting whether implant removal will be difficult," says FHI researcher Randy Dunson. "Acquiring an infection at the time of insertion or experiencing a complication at inser-

tion are associated with complicated removal. Difficult removals can be attributed to deep initial placement of the capsules. Removals can be difficult if the provider has not been trained or has limited experience with removals."

Providers are usually trained in insertion and removal techniques at the same time, but because the time between insertion and removal can be several years, family planning programs should offer refresher training. Another option is for clinicians more experienced in Norplant removals to supervise those with less experience.

## NORPLANT COSTS

The cost of Norplant is a consideration for family planning program managers as they decide whether to add the contraceptive to their current mix of methods. The cost of purchasing Norplant should be weighed against the potential increase in contraceptive use. Program managers must also consider the costs of training staff, plus the labor and supply costs involved in providing services for client acceptance, follow-up and discontinuation. Whether the method is affordable to clients is a factor. An FHI study in Thailand found the implant's costs (including the costs of acceptance, follow-up and discontinuation) to be higher than the costs of IUDs and injectables.<sup>13</sup>

Because some family planning programs receive initial supplies of Norplant from donors, the device has been inserted at low or no cost to clients. Yet some women have found the cost of removal a problem. For example, an Indonesian woman requested Norplant removal due to menstrual bleeding problems and was referred to a midwife some distance away from her home. When she arrived, she was told she must pay twice her family's monthly income for removal.<sup>14</sup>

To address this problem, programs in Kenya and Egypt have incorporated the cost of removal in the initial cost of insertion. The client pays only once, so money does not become a barrier to removal. In Brazil, the cost of removal is approximately the same as insertion. At YKB clinics in Indonesia, women can pay for Norplant in monthly installments. If Norplant is removed early, the woman is not obligated to complete payments.

"This (contraceptive) method is provider-controlled," wrote Dr. Kashmiri and Gamil of EFCS. "That is why each Norplant service provider has to be aware of the fact that removal should be made upon the user's request, even if no reason is given. If removal is denied, the client might seek removal somewhere else, where training and infection control are lacking."

— Barbara Barnett

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NASH HERNDON/FHI



BEFORE NORPLANT IS INSERTED, COUNSELING SHOULD EMPHASIZE THE IMPORTANCE OF REMOVAL AT FIVE YEARS, AS THIS WOMAN IS LEARNING AT A CLINIC IN EGYPT.

# New Approaches Seek Greater Safety, Appeal

New injectables, vaginal delivery systems and implants are among products being developed.

**N**ew progestin-only contraceptives under development may make progestin methods more appealing and more widely used. The new approaches may increase safety for certain users and may fit the needs of new groups.

New delivery systems and new formulations of progestins are being studied. These approaches would be added to the currently available progestin-only methods, which include injectables, such as DMPA; the implant system Norplant; and progestin-only oral contraceptive pills, often called POPs.

"The more methods you can provide, the better," says Dr. Rosemarie Thau, director of contraceptive development at the U.S.-based Population Council, which is developing several new progestin methods. "It is important to have optimal methods for each particular stage in reproductive life."

Progestin-only vaginal methods, including rings and suppositories, will give users control over when to begin and end contraceptive use. New implant systems should increase the ease of insertion and removal compared with Norplant, or even eliminate the need for removal. New injectable contraceptives are being designed to reduce the amount of hormone necessary to have high contraceptive effectiveness. Although currently available progestin-only

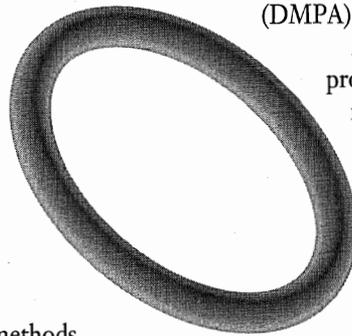
methods are considered safe for breastfeeding women to begin using six weeks after delivery, new progestins under study may offer even safer options.

Besides developing new methods, more research is needed on long-term effects of progestins, including cardiovascular effects, cancer and other health issues. Dr. Catherine d'Arcangues, manager of the World Health Organization (WHO) task force on long-acting systemic agents for fertility regulation, points to other gaps in knowledge, such as whether progestins affect HIV transmission and whether prolonged use of depot-medroxyprogesterone acetate (DMPA) has any effect on bone.

Another issue with progestin-only methods also remains to be resolved — how to reduce menstrual irregularities. According to Dr. Nancy Alexander, chief of contraceptive development for the U.S. National Institute of Child Health and Human Development (NICHD), some of

the questions to be answered include: Why do some women, but not all, have irregular bleeding? Do differences in women's own natural hormone levels lead to differences in bleeding patterns? What are effective treatments for bleeding irregularities?

Five new studies commissioned by NICHD will try to answer such questions. One involves giving women estrogen at the



time Norplant or DMPA use is initiated to determine whether this reduces the frequency of irregular bleeding and why. "With better understanding of what causes the bleeding, we could solve the problem that is so vexing with progestin-only approaches," Dr. Alexander says.

Following are some new progestin-only approaches or applications being developed. In general, the methods share the same side effects as those already available, primarily menstrual disturbances. Some of the methods, in addition to being highly effective at preventing pregnancy, also have other benefits, such as reduced menstrual bleeding and increased hemoglobin levels.

**New progestin applications** — Many of the progestin-only systems under development use progestins that have been used in oral contraceptives. One new progestin that may prove more suitable for breastfeeding women is Nestorone, being used by the Population Council for several different approaches including implants, vaginal rings and other non-oral methods. Nestorone is transported rapidly through skin, so it is being developed into a topical (transdermal) contraceptive cream.

Nestorone is inactive when taken orally, because it is metabolized rapidly by the liver. Thus, it should be a good choice

for breastfeeding mothers because it would not be readily absorbed into an infant's system if taken in with breastmilk.

Nestorone, also known as ST-1435, has been studied as a potential contraceptive for many years. Nestorone suppresses ovulation effectively at the doses being used for systems under development and appears not to disrupt carbohydrate and lipid metabolism.<sup>1</sup>

Another new progestin known as etonogestrel, or 3-keto-desogestrel, is being used in a contraceptive implant. Desogestrel, the parent compound, is used in currently available combined oral contraceptives. It is metabolized to its active form, 3-keto-desogestrel, after ingestion.

**Vaginal methods** — Vaginal rings, unlike available long-acting methods, allow user control over the method. The user inserts and removes them. Unlike diaphragms, they are manufactured in one size and do not require fitting.

The rings currently under development slowly release a progestin through the vagina into the bloodstream over the course of three to six months, depending on the device. One ring under study may be effective for up to a year. Progestin-only vaginal rings must be worn continuously but can be taken out for a couple of hours at a time without diminishing their effectiveness. After re-

moval of the ring, the progestin level in the body drops within a day, and fertility returns rapidly.

Potential concerns include unintentional expulsion, interference with intercourse, cervical changes, vaginal irritation and infection.<sup>2</sup> In addition, vaginal rings are more costly to produce than some other contraceptive methods.

Several types of progestin-only rings are being developed, including those releasing progesterone, Nestorone or megestrol. A levonorgestrel ring also has been tested by WHO, which found that the device's annual failure rate was as low as 3.7 percent.<sup>3</sup> However, some women in one trial were found to have vaginal lesions. WHO is doing further studies to determine whether the lesions were produced by the ring. A Nestorone ring and other vaginal rings undergoing phase II clinical trials testing by the Population Council have not been found to cause vaginal lesions.

Another vaginal progestin-only method is a suppository being developed by the U.S.-based Contraceptive Research and Development Program (CONRAD). Inserted daily, whether or not intercourse occurs, the suppository dissolves in the vagina to release

RICHARD LORD



A VAGINAL RING THAT RELEASES PROGESTIN GRADUALLY IS AMONG NEW PROGESTIN-ONLY METHODS UNDER DEVELOPMENT. A DOCTOR IN SANTO DOMINGO, DOMINICAN REPUBLIC, SHOWS A VAGINAL RING TO A CLIENT.

progesterone, a naturally occurring female hormone. It may be an excellent alternative for women during the postpartum period.

**Transdermal contraceptives** — Experimental concepts for progestin contraceptives include those that would be placed on the skin as creams, gels, patches or “bracelets.” With such transdermal application, progestin passes through the skin into the bloodstream to prevent pregnancy.

A contraceptive cream with Nestorone as the active ingredient is being tested by the Population Council. Users spread about 0.5 ml of cream on their abdomen area every day. The skin acts as a reservoir, enabling the body to maintain a steady level of the synthetic hormone.

**Non-biodegradable implants** — A new generation of implants is being designed to make insertion simpler and removal easier than the currently available Norplant. Systems being developed use one or two implants, compared with the six-rod system used by Norplant. These new implants have different lengths of effectiveness.

An improved version of Norplant called Norplant II consists of two levonorgestrel-releasing rods. This should simplify insertion and removal, since only two rods would be inserted instead of six. Studies have found that Norplant II is comparable to Norplant in effectiveness and side effects. Ongoing studies show that it is effective for at least three years.

Implanon is a single-rod, three-year implant containing the progestin etonogestrel (3-keto-desogestrel). The implant is inserted under the skin of the arm using a non-surgical procedure, which is likely to be easier for providers to master than surgical approaches. Implanon has been shown to inhibit ovulation effectively, unlike some other progestin-only methods that rely primarily on other contraceptive mechanisms, such as producing changes in cervical mucus.<sup>4</sup> Women have used the method for a total of more than 40,000 cycles with no pregnancies, according to N.V. Organon, the Netherlands-based corporation that is developing the device.

A single-rod implant using Nestorone is being developed by the Population Council. In one clinical trial with the implant, no

pregnancies were reported among 70 women, 54 of whom used the device for two years.<sup>5</sup>

South-to-South Cooperation in Reproductive Health in Brazil is studying another single-rod implant system containing norgestrol acetate. In a preliminary trial of this device, called Uniplant, only one pregnancy occurred in 100 women, 80 of whom had completed one year of use. Menstrual disturbances were more common in the first six months of use than in the final six months.<sup>6</sup>

**Biodegradable implants** — The Annuelle implant system consists of four or five rice-grain-sized capsules of norethindrone (NET) and cholesterol. Inserted in a row under the skin of the arm, the pellets are designed to release progestin gradually and prevent pregnancy over the course of a year or longer. They are eventually absorbed into the body so they do not have to be removed.

If a woman desires, the implants can be removed during use, and the level of NET in the body drops within a day. However, the pellets may be difficult to remove after substantial degradation has occurred.

Phase I and II trials have been conducted with different formulations of one to five Annuelle pellets. FHI and CONRAD have conducted the most recent clinical trials of Annuelle.

Capronor, another biodegradable implant, releases levonorgestrel from one or more tubes inserted into the arm or hip. Studies of the first version of the device indicated good acceptability but also showed problems with rash and capsule migration. The implants were modified, and have recently been tested in animals with favorable results. Capronor is designed to be effective for one to two years. Capronor was developed by the U.S.-based Research Triangle Institute and NICHD.

**Injectables** — New injectable contraceptives are being formulated to vary their duration of use, reduce the overall amount and lower the initial peak of progestin in the body while maintaining effectiveness. Some formulations consist of a progestin enclosed in microscopic capsules of a polymer in order to maintain a slow, steady release rate. Others use crystalline forms of a progestin or a progestin ester to achieve the same goal.

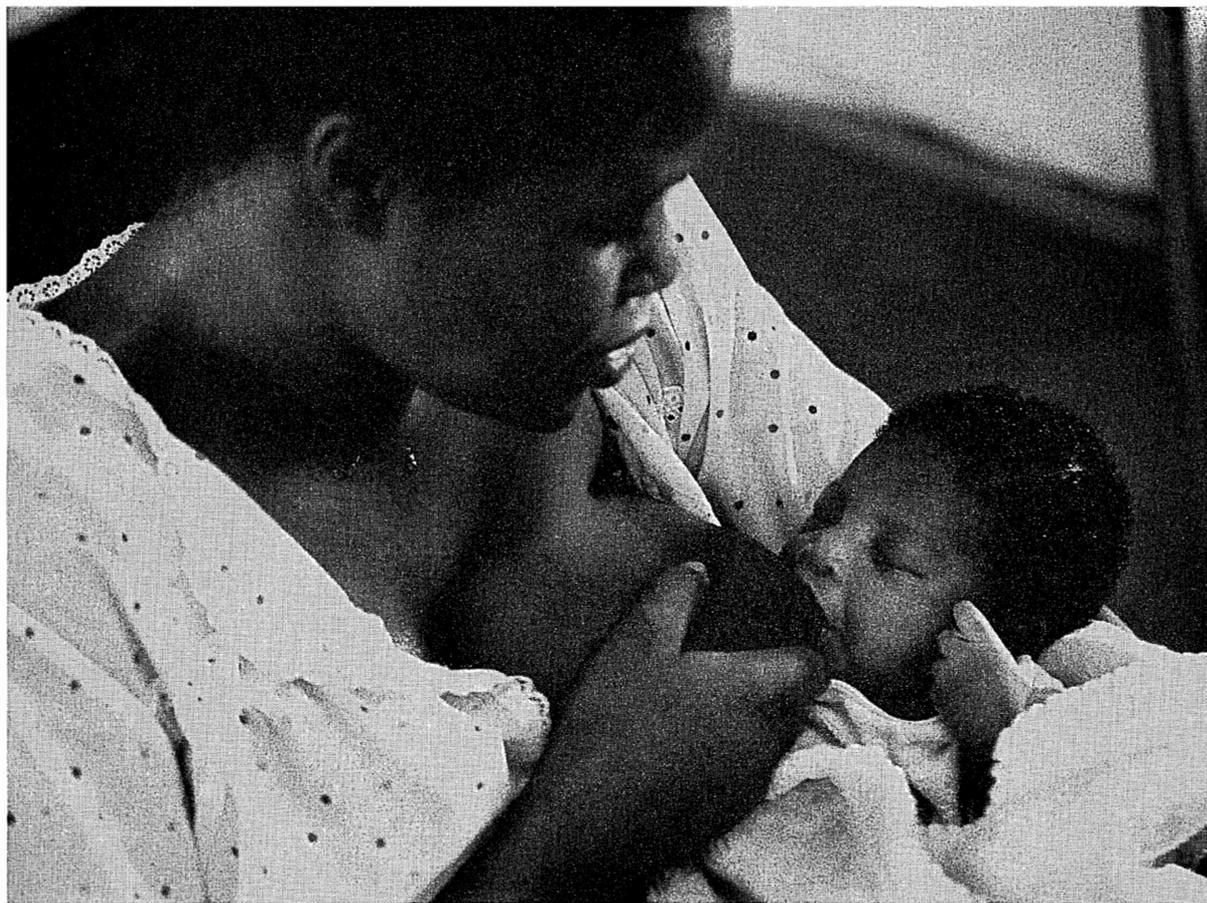
These injectables can be effective for one to three months or longer, depending on the formulation. A disadvantage of injectable contraceptives in general is that they cannot be removed or counteracted once in the body.

Among progestins being considered for new injectables are progesterone, Nestorone and levonorgestrel butanoate. Levonorgestrel butanoate, also known as HRP 002 or CDB 1830, is a three-month injectable contraceptive being studied by NICHD and WHO. It may allow for a more rapid return to fertility than DMPA.

**Progestin-releasing IUD** — For women who cannot tolerate a copper IUD but who want its effectiveness and convenience, an IUD that releases levonorgestrel may provide an option. Known as the LNG-20 or Levonova, the IUD was shown in clinical trials to be as effective as the copper T 380Ag. The LNG-20 decreases bleeding and lowers the risk of myoma (benign muscle tumor).<sup>7</sup> However, the progestin-releasing IUD causes more amenorrhea, ovarian follicular cysts and some other hormonal side effects than the copper model.

Already approved in some European countries, the LNG-20 is effective in preventing pregnancy for at least five years. The device, a Nova-T IUD with a silastic collar containing levonorgestrel, may have a limited market because it is more expensive than the copper IUD. Its benefits, however, may make it an appealing option for some women.

— Carol Lynn Blaney



SOME PROGESTIN-ONLY METHODS UNDER DEVELOPMENT MAY OFFER EVEN SAFER OPTIONS FOR BREASTFEEDING WOMEN. A NIGERIAN MOTHER BREASTFEEDS HER INFANT.

## FOOTNOTES

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# Resources

## POPS SUPPLEMENT AVAILABLE FROM FHI

A supplement to the December 1994 issue of *Contraception*, vol. 50, no. 6 (suppl. 1), on progestin-only oral contraception, is available from FHI. Written on behalf of FHI by Dr. Margaret F. McCann and Dr. Linda S. Potter, the 195-page supplement provides a comprehensive review of progestin-only



pills (POPs), including mode of action, pharmacology, efficacy, pregnancy outcomes, and effective POP use. The issue also covers metabolic effects, cardiovascular disease, cancer and other medical considerations, interaction of POPs with drugs, common side effects, and breast-feeding.

A copy is free to developing country health professionals by writing: Publications Coordinator, Family Health International, P.O. Box 13950, Research Triangle Park, NC 27709, USA.

## DMPA POSTER ON QUALITY OF CARE

An FHI wall poster on the injectable contraceptive DMPA is available in English, Spanish or French. DMPA — Three-Month Injectable Contraceptive covers basic information about the contraceptive, with an emphasis on quality of care considerations. The poster is intended for use in clinics. A free copy is available to developing country organizations by writing: Publications Coordinator, Family Health International, P.O. Box 13950, Research Triangle Park, NC 27709, USA.

## TALC BOOK ON FISTULAS

Vesicovaginal fistulas, caused primarily by obstetric complications, constitute a major health problem in many developing countries. They can be surgically treated, and a new book, *Step-by-step Surgery of Vesicovaginal Fistulas*, describes classes of fistulas, their prognosis, and postoperative care and follow-up. The 100-page book, illustrated with color photographs, is available from TALC, P.O. Box 49, St. Albans, Herts, AL1 5TX, United Kingdom, or call 44 1727 853869. The price is G.B.£ 1, plus G.B.£ 2.50 for shipping. Those without foreign exchange can apply for a free copy from SIMAVI, Spruitenbosstrat 6, Haarlem, The Netherlands.

## AVSC WORKING PAPER SUMMARIZES STRATEGIES

*Quality Management for Family Planning Services: Practical Experience from Africa*, a working paper from AVSC International, summarizes strategies for improving quality of care in sub-Saharan African family planning programs. Developed from a decade of experience, the strategies described in the paper include AVSC's COPE self-assessment methodology and advice on how to improve training and supervision. Single copies are available free by contacting: Material Resources Department, AVSC International, 79 Madison Ave., New York, NY 10016, USA, or call (212) 561-8000, or fax (212) 779-9439.

## FUTURES GROUP BOOKS FOR IMPROVING COMMUNICATION SKILLS

Recognizing that effective public relations is critical to the success of contraceptive social marketing projects, The Futures Group has published four books to help program managers improve their communication skills. The books, comprising The Futures Group's Practical Guide series, cover public relations, crisis communication, how to handle an interview and answer media

questions, and public speaking with confidence and style. All books can be obtained free by contacting: PR Department, The Futures Group, 1050 17th St., NW, Suite 1000, Washington, DC 20036, USA, or call (202) 775-9680.

## BOOKLETS AVAILABLE ON PAP TESTS

Two booklets on screening for reproductive cancer are available from Education Programs Associates. One booklet, called *What you should know if your Pap test is abnormal*, describes the purpose of the Pap test, the meaning of an abnormal Pap test, and follow-up care for women who have abnormal test results. The other booklet, *You can make a difference*, explains



how a woman can check her breasts for lumps that might be cancerous.

Cost of *What you should know if your Pap test is abnormal* is U.S. 60 cents each and U.S. 45 cents for *You can make a difference*. The cost is discounted for orders of more than 500 copies. To order, contact: Distribution Department, Education Programs Associates, 1 West Campbell Ave., Building D, Campbell, CA 95008, USA, or call (408) 374-3720, or fax (408) 374-7385.