Four decades after introduction of the pill, more women than ever are using it. Today's low-dose oral contraceptives are safer and just as effective as earlier pills. Taken regularly, the pill prevents pregnancy almost without fail. Pill users benefit in other ways, too, such as less anemia and protection from certain cancers. Lower doses have reduced the circulatory disease risks of the pill.

Currently more than 100 million women rely on the pill. It is the top modern family planning method among married women in half of countries surveyed. The pill is most popular in Western Europe, where half of married women use it. It is least used in China, India, and Japan. A great many women use the pill at some point in their lives. Outside India and China, half of married women who have ever used family planning have relied on the pill at some time. In the US, 80% of all women born since 1945 have used the pill. A method so widely used deserves continuing attention from health care programs, providers, and researchers.

Substantial Benefits and Safer Doses
Research continues to assess the benefits and risks of pill use. The greatest benefit, of course, is effective contraception, which gives women more control over their lives and avoids the risks of pregnancy and childbearing. Among women who miss no pills, only 1 in every 1,000 becomes pregnant in the first year of using even the lowest-dose pills. Because few women use the pill so consistently, however, typical first-year pregnancy rates are about 6 to 8 per 100 women. During breastfeeding, progestin-only pills are highly effec-
tive, complementing the natural protection that breastfeeding offers. They do not decrease milk production.

Oral contraceptives (OCs) offer a variety of other health benefits. For example, by reducing menstrual bleeding, OCs help prevent iron deficiency anemia, which is common and often serious in developing countries. OC use halves the risk of cancers of the uterine lining and of the ovary. Some protection persists for many years after OC use stops. Because estrogen-progestin OCs stop ovulation (release of an egg), they prevent pregnancy outside the womb, which can be life-threatening. Some evidence suggests that OCs reduce risk of colorectal cancer, too.

Compared with earlier, higher-dose pills, current low-dose formulations have considerably lowered the risk of heart attack, stroke, and blood clots in the deep leg veins attributed to OC use. Research has better defined which women would face appreciable risk of heart attack or stroke if they used OCs—women over age 35 who smoke or who have high blood pressure. For all other women, using OCs is clearly safer than childbearing in both developing and developed countries.

Resolving Uncertainties

Even some of the most persistent uncertainties concerning OCs are now coming into perspective. Research suggests that OCs may somewhat speed up the diagnosis of already existing breast cancers—perhaps because tumors are more readily detected, tumor growth is accelerated, or both. OC use does not increase lifetime risk of developing breast cancer. Among women who use OCs when young and breast cancer is rare, few additional diagnoses of breast cancer would be due to OCs.

Cervical cancer is even harder to study than breast cancer. It may never be clear whether methodological problems in research or an actual cause-and-effect relationship explain recent observations of a slight increase in risk for long-term OC users. Condoms and careful choice of a sex partner offer the sexually active woman the best protection from human papillomavirus, the primary cause of cervical cancer.

OCs for Emergencies

Combined and progestin-only OCs containing the hormone levonorgestrel can be used for emergency contraception: if the correct dosage is started within 72 hours after unprotected intercourse, it reduces the chances of pregnancy. This has long been known, but only recently has the word spread. Now OC tablets are being packaged as emergency contraceptive pills, and levonorgestrel-only tablets, which are more effective and cause less nausea and vomiting, are being introduced especially for this purpose. While not as effective as regular use of OCs or most other modern methods, emergency contraceptive pills meet a crucial need—another important benefit of one of the world's most widely used family planning methods.
Some pill users experienced such side effects as headaches, nausea, cramps, irregular menstrual bleeding, breast tenderness, or weight gain. These side effects usually are temporary and are not signs of more serious problems. They can be troubling, however, and have led many women to stop using the pill. Also, research in the 1960s and 1970s suggested that estrogen, in the doses used in early OCs, increased the risk of blood clots, stroke, and heart attack (106, 399, 406). Press reports about these findings created repeated "pill scares" and gave OCs an unwarranted aura of danger (120).

Meanwhile, studies found striking evidence of important noncontraceptive benefits of OC use. Most notably, epidemiological studies in the 1980s demonstrated that OCs provide strong protection against endometrial and epithelial ovarian cancer (see p. 111).

The public remains largely unaware of such benefits. In the US, for example, 65% of women surveyed in 1993 could not name one noncontraceptive benefit of the pill. At the same time, 44% of respondents believed that OCs pose serious health risks. Moreover, almost two-thirds thought that pill use was at least as dangerous as childbirth (172, 352), which is not the case for most women (182, 295, 306, 413, 454).

Since their introduction, OCs have offered safe contraception for the great majority of women. Still, to reduce common side effects and to minimize the risk of any serious complications, pharmaceutical companies and health care providers have used three approaches:

- To lower the doses of both estrogen and progesterin without compromising effectiveness.
- To develop different new progestins.
- To screen women more specifically and to inform them about side effects that they may experience with OCs.

Today's low-dose combined OCs contain less than 50 μg estrogen, down from 150 μg in the first OC and up to 100 μg

The Evolution of Oral Contraception
The idea of oral contraception with hormones dates back to the 1920s (170). Not until the 1960s and 1970s, however, did inexpensive, orally effective synthetic hormones become available (170-172) in 1960, after more than a decade of research, the US Food and Drug Administration (FDA) approved the first OC. This pill, Ciba's Staffider and Company's Enovid-10, contained 9.85 milligrams (mg) of the progestational hormone medroxyprogesterone and 150 micrograms (μg) of the estrogenic hormone mestranol—about 10 times the progesterin and 4 times the estrogen contained in today's pills.

When the pill was introduced, it satisfied women's need for convenient, safe, and reliable contraception. There were some problems, however.

A Moroccan health worker hands packets of pills to a client. In Morocco pill use has risen substantially, from 14% of married women in 1980 to 32% in 1995. With more than 100 million users worldwide, oral contraceptives remain one of the most popular family planning methods.
in the OCs of the late 1960s and 1970s. Estrogen doses of 30
or 35 μg ethinyl estradiol are the most common. Progestin
doses also have dropped substantially. For example, doses
of norethindrone (norethisterone) have dropped from
almost 10 mg to 1.0 or 0.5 mg.

The reduction of estrogen doses followed early research that
related the likelihood of thromboembolic disorders to the
size of the estrogen dose (121). US clinical trials found
that estrogen doses as low as 20 μg, com-
bined with a progestin, usually limit pregnancy rates to less than 1 per 100
women per year (27, 28, 39, 141, 209,
248, 400, 404, 499, 543). Also, side
effects such as nausea, vomiting,
abdominal cramps, breast discomfort, and head-
ache occurred less often with less es-
trogen. Initial menstrual bleeding
irregularities are more frequent, how-
ever (116, 119, 262, 369).

The progestin doses in OCs vary widely,
because progestins differ greatly in poten-
tiency by weight (121). Currently, doses of
progestins in the norethindone family
—norethindrone, norethindrone ace-
tate, ethynodiol diacetate, and nore-
thenoral—range from 0.4 to 2 mg. Pills
containing the more potent progestins
levonorgestrel, desogestrel, and gestodene use doses of 0.05 to 0.15 mg.

The different progestins have somewhat
different physiological effects and in-
teract differently with estrogens, possi-
ibly modifying the effects of both
hormones (46, 467).

Research suggests that lower doses do
lower risks for some conditions. For
example, as lower-dose pills have come
into wider use, findings from epidemi-
ologic studies suggest that risks of
OC-related venous thromboembolism, heart
attack, and stroke have declined. Sig-
ificantly increased is the risk that OCs
may increase the risk of pregnancy more
than with combined OCs.

Progestin-only OCs are a good option for breastfeeding
women who want oral contraception because, unlike com-
bined OCs, they clearly do not reduce milk production (see
box, p. 5). The progestin-only pill was developed in the early
1970s in response to the reports on estrogen and thrombo-
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0.6 mg of the norethindrone progestins or else 0.03 to
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gestin-only pills are taken continuously, with no hormone-
free intervals between cycles. Progestin-only pills have
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feeding, they are somewhat less effective than combined
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In the 1970s and 1980s, multiphasic OCs were developed.
These pills have become popular in the developed coun-
tries but are not widely available in developing countries.
The doses in multiphasic OCs change during each pill cycle
to keep hormone doses low (170). Like other low-dose OCs,
multiphasics appear to provide highly
effective contraception when taken
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minimal breakthrough bleeding, spot-
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OCs (437).

Making OC Use Easier
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Also, as many as half of all new users
stop using the pill within a year, and
many women who take OCs for a
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rate suggests that many women are having difficulties
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For breastfeeding women who have resumed menstruation, progestin-only pills, or "mini-pills," are a good option if they want to use a hormonal method. In contrast to combined pills, there is no research that progestin-only pills will reduce milk production.

Why Progestin-Only Pills?
Postpartum women often want to delay another pregnancy, and, indeed, birth intervals of at least two years are healthiest for both siblings (31). Intrauterine and barrier methods offer good postpartum contraception with no effect on lactation. Many women, however, prefer to use OCs. Because combined pills may inhibit milk production, some providers are reluctant to give them to breastfeeding women. If providers will not give OCs to breastfeeding women, however, some women may stop breastfeeding in order to obtain them (21).

Progestin-only pills are a good alternative. They have no adverse effects on lactation. Most research has found either that they have positive effects—increasing milk quantity or improving its nutritional quality—or that they have no effect (72, 145, 211, 296, 530, 531). Women who choose progestin-only pills can use them and continue to breastfeed until lactation naturally stops.

The main comparative disadvantage of progestin-only pills—higher pregnancy rates than combined pills—is offset by the protection against pregnancy that breastfeeding itself provides; during breastfeeding ovulation is uncommon before menstruation resumes and may be irregular even after menstruation has resumed (70). Also, the bleeding irregularities associated with progestin-only pills may not bother postpartum women because they may be amenorrheic or expect irregular bleeding postpartum (207). Progestin-only OCs may not be the best method, however, for women with a history of gestational diabetes (temporary diabetes that develops only during pregnancy). A recent study of women with a history of gestational diabetes found that those who used progestin-only OCs during breastfeeding were almost three times more likely to develop chronic non-insulin-dependent diabetes than women who used nonhormonal methods. Use of combined OCs did not increase the risk of diabetes for women with a history of gestational diabetes (266).

Although combined OCs do affect breast milk, these effects do not seem to harm infants. With combined OCs milk volume usually decreases slightly, even with low estrogen doses (21, 116, 211, 297, 452). Breast milk composition may change, too, although findings vary. Most studies report decreases in mineral content (211, 296). A number of studies have found, however, that reduced milk volume in OC users did not affect their infants' weight gain (57, 208, 452, 529). Studies in Chile reported slower infant weight gain but no other adverse effects on infant health (98, 116, 351). The longest follow-up study found no effects on the health or the physical, intellectual, or psychological development through age eight of Swedish children whose mothers used combined OCs while nursing (329).

Progestin-only pills do not adversely affect a mother's milk supply, and women using progestin-only pills breastfeed as long as women using no contraception or a method other than OCs (111, 297, 529, 551). In one study 83% of progestin-only pill users breastfed for four months or longer compared with 49% of combined OC users (90).

When to Begin?
When can breastfeeding women begin to use progestin-only pills? As a general rule, as soon as six weeks after childbirth—birth, according to the World Health Organization—medical eligibility criteria for contraceptive methods (338). If a woman is partially breastfeeding and her child receives much other food or drink, six weeks after childbirth is the best time to start progestin-only pills. If she waits longer, density may return (190, 255). In contrast, if a woman plans to breastfeed exclusively or fully for a lengthy period, some providers may advise her to wait and offer her progestin-only pills later. Of course, a program can provide any woman with pills immediately postpartum with instructions about when to start them, if contacting her later might be difficult. In all cases it is important that the woman has access to the pills before she needs them.

Most family planning programs prefer not to offer any hormonally induced contraception in the early postpartum months. This is because trace amounts of contraceptive hormones—usually less than one-tenth of 1% of maternal doses—can reach infants in breast milk. No health risks have been linked to such exposure, however (300, 530, 531).

In any case, as noted, fully or nearly fully breastfeeding women who are amenorrheic do not need OCs in the early postpartum period. Fully breastfeeding is more than 98% effective in protecting against pregnancy as long as a woman breastfeeds (1) in the first six months postpartum and (2) her milk is amenable (237). This rate—two pregnancies per 100 women in the first six months after childbirth—is about the same as typical OC effectiveness (see p. 10).

Program practices about when to offer progestin-only pills to fully or nearly fully breastfeeding women can be based largely on the breastfeeding patterns of the client population. To protect herself from pregnancy, the client should begin progestin-only OCs when menstruation returns or at six months postpartum, whichever comes first (84, 237, 485).

*Postpartum women have little need of contraception for up to six months after giving birth if they have not resumed menstruating and they are fully or nearly fully breastfeeding—this is, breastfeeding after, day and night, with breastfeeds accounting for at least 85% of the baby's feedings (325, 552). Recent studies have reported a high degree of pregnancy protection for at least six months postpartum and intrauterine contraception up to 12 months, if noncontraceptive

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**Progestin-Only OCs for Breastfeeding Women**

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In 44 of 68 developing countries with survey data on ever use of contraception, more married women have used the pill than any other modern family planning method. In these 68 countries about 40% of married women who have ever used family planning have used the pill at some point. This estimate does not include China, where recent data on ever use are not available. In China and India pill use historically has been limited. If India also were excluded from the estimate, the percentage of married family planning users who have ever used the pill would rise to about 50%.

In some countries pill use has been very common. In Bots- rai1945 have used the pill in various countries including Bangladesh, Botswana, Cape Verde, Colombia, the Dominican Republic, Jamaica, Nicaragua, South Africa, Thailand, and Trinidad and Tobago. Among developing regions, the pill has been most widely used in Latin America, where 55% of all married women have used the pill at some time. More than one-third of married women in the Near East and North Africa have used the pill, while not quite 15% have used it in sub-Saharan Africa (see Table 1).

Similarly, many sexually active unmarried women have used the pill. In 12 of 28 countries with surveys, most of these women have used the pill than any other modern family planning method. Overall, in these countries 52% of women who have ever used family planning have relied on the pill at some point—39% of all sexually active unmarried women. In Bolivia, Colombia, the Dominican Republic, Guatemala, Nicaragua, and Zimbabwe, between 50% and 60% of sexually active unmarried women have used the pill.

Experiences with the pill is probably even more common in developed countries than in developing countries, although data on ever use are not available for many developed countries. In Canada 86% of women surveyed in 1995 had used the pill (1). In the US 80% of all women born since 1945 have used the pill, according to a 1990 estimate (10). Perhaps the highest level of experience with the pill is among Common women: For example, 94% of western German women ages 30 to 44 have taken the pill (21).

Current Use of OCS

Worldwide, an estimated 8% of all married women currently use the pill. OCS rank third among all family planning methods currently used by married women, close to 19% rely on female sterilization, and 13% rely on the IUD. These percentages are greatly influenced by the world’s two most populous countries, China and India, where there is little pill use. OCS are the top modem method among married women in 78 of 139 countries with available data and, if China and India are omitted from the world estimate, the most widely used contraceptive method overall. Outside China and India about 12% of married women use the pill. By comparison, 9.5% rely on female sterilization, and almost as many use traditional or folk methods. About 9% use IUD (Table 2 presents OC use data with and without China and India.)

### Table 1. Estimated Ever Use of Oral Contraceptives Among Married and Sexually Active Unmarried Women Ages 15—49, by Region, 2000

<table>
<thead>
<tr>
<th>Region</th>
<th>Married Women</th>
<th>Sexually Active Unmarried Women</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>% Ever Using OCS</td>
<td>Using Any OCS</td>
</tr>
<tr>
<td>Asia</td>
<td>16.9</td>
<td>56.0</td>
</tr>
<tr>
<td>East Asia (except China)</td>
<td>14.2</td>
<td>85.9</td>
</tr>
<tr>
<td>India</td>
<td>5.3</td>
<td>46.9</td>
</tr>
<tr>
<td>South Central Asia (except India)</td>
<td>21.8</td>
<td>49.1</td>
</tr>
<tr>
<td>Southeast Asia</td>
<td>38.8</td>
<td>78.5</td>
</tr>
<tr>
<td>Latin America &amp; Caribbean</td>
<td>55.1</td>
<td>84.0</td>
</tr>
<tr>
<td>Caribbean</td>
<td>42.7</td>
<td>69.8</td>
</tr>
<tr>
<td>Central America</td>
<td>41.4</td>
<td>76.8</td>
</tr>
<tr>
<td>South America</td>
<td>48.0</td>
<td>88.3</td>
</tr>
<tr>
<td>Near East &amp; North Africa</td>
<td>35.7</td>
<td>70.8</td>
</tr>
<tr>
<td>Near East</td>
<td>31.6</td>
<td>76.1</td>
</tr>
<tr>
<td>North Africa</td>
<td>43.3</td>
<td>61.6</td>
</tr>
<tr>
<td>Sub-Saharan Africa</td>
<td>35.0</td>
<td>38.6</td>
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<tr>
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<td>39.6</td>
</tr>
<tr>
<td>East Africa</td>
<td>19.5</td>
<td>41.4</td>
</tr>
<tr>
<td>Southern Africa</td>
<td>16.7</td>
<td>82.0</td>
</tr>
<tr>
<td>West Africa</td>
<td>7.4</td>
<td>21.9</td>
</tr>
<tr>
<td>All developing areas except China</td>
<td>23.4</td>
<td>57.8</td>
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<tr>
<td>All developing areas except China &amp; India</td>
<td>31.6</td>
<td>63.0</td>
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</table>

Sources: Demographic and Health Surveys, Reproductive Health Surveys, and
US Bureau of the Census International Database.

Population Reports
Considering developing countries alone, 50% of married women use the pill—far lower than use female sterilization at 21%, and IUD at 13%. When China and India are removed from the use estimate, however, OCs become the most popular method in developing countries, used by 10% of married women compared with 5% relying on female sterilization and 8% on traditional methods. IUD use falls to 7%.

In developed countries, OCs are the most widely used method. Some 16% of married women use the pill. Condoms and the IUD tie for second place at 14%, while slightly less than 14% of married women use traditional or folk methods.

Worldwide, among sexually active unmarried women, OCs are even more widely used than among married women. In countries with available data, 20% of sexually active unmarried women use the pill. Data on current contraceptive use among unmarried women are available in Africa, Eastern Europe, Latin America, the Caribbean, and most developed nations. OCs are the most popular method among unmarried women in Latin America, North America, and Northern and Western Europe.

Patterns in use of family planning methods vary considerably within and across regions and countries. Differences in availability, access, cost, promotion, program policy, as well as people's preferences, help to explain these differences. Indeed, exceptionally high rates of use for any one method can suggest that access to other methods may be limited.

Near East and North Africa. In this region nearly 10 million women use OCs—13% of the region’s 74 million married women. Three of every 10 family planning users are pill users. In Algeria, Iran, Kuwait, Morocco, Oman, Qatar, and the United Arab Emirates, OCs are the most widely used method.

### Table 2. Estimated Current Oral Contraceptives Use Among Married and Sexually Active Unmarried Women Ages 15–49, by Region, 2000

<table>
<thead>
<tr>
<th>Region</th>
<th>Married Women % Using OCs</th>
<th>Married Women Using OCs (in Millions)</th>
<th>Sexually Active Unmarried Women % Using OCs</th>
<th>Sexually Active Unmarried Women Using OCs (in Millions)</th>
</tr>
</thead>
<tbody>
<tr>
<td>DEVELOPING AREAS</td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>ASIA</td>
<td>4.5</td>
<td>20.3</td>
<td>2.7</td>
<td></td>
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<tr>
<td>China</td>
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<td>7.6</td>
<td>1.7</td>
<td></td>
</tr>
<tr>
<td>East Asia (except China)</td>
<td>1.9</td>
<td>0.3</td>
<td>0.7</td>
<td></td>
</tr>
<tr>
<td>South Central Asia (except India)</td>
<td>1.2</td>
<td>2.5</td>
<td>2.9</td>
<td></td>
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<tr>
<td>Southeast Asia</td>
<td>13.5</td>
<td>12.4</td>
<td>23.4</td>
<td></td>
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<tr>
<td>LATIN AMERICA &amp; CARIBBEAN</td>
<td>13.8</td>
<td>11.4</td>
<td>20.3</td>
<td>23.5</td>
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<tr>
<td>Caribbean</td>
<td>10.4</td>
<td>0.6</td>
<td>12.3</td>
<td>12.3</td>
</tr>
<tr>
<td>Central America</td>
<td>6.4</td>
<td>1.9</td>
<td>13.2</td>
<td>26.0</td>
</tr>
<tr>
<td>South America</td>
<td>16.4</td>
<td>9.0</td>
<td>23.1</td>
<td>25.6</td>
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<tr>
<td>NEAR EAST &amp; NORTH AMERICA*</td>
<td>13.3</td>
<td>9.0</td>
<td>29.7</td>
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<tr>
<td>Near East</td>
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<td>5.1</td>
<td>23.2</td>
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<tr>
<td>North Africa</td>
<td>18.3</td>
<td>4.7</td>
<td>42.5</td>
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<td>0.1</td>
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<tr>
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<td>3.6</td>
<td>23.4</td>
<td>10.4</td>
</tr>
<tr>
<td>Central Africa</td>
<td>0.9</td>
<td>0.1</td>
<td>2.6</td>
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<td>East Africa</td>
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<tr>
<td>Southern Africa</td>
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<td>0.7</td>
<td>19.8</td>
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<td>0.8</td>
<td>20.8</td>
<td>6.1</td>
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<tr>
<td>All developing areas</td>
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<td>54.3</td>
<td>11.2</td>
<td></td>
</tr>
<tr>
<td>All developing areas except China &amp; India</td>
<td>9.8</td>
<td>44.2</td>
<td>23.1</td>
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<tr>
<td>DEVELOPED AREAS</td>
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<td></td>
</tr>
<tr>
<td>AUSTRALIA &amp; NEW ZEALAND</td>
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<td>4.8</td>
<td>39.8</td>
<td>36.1</td>
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<tr>
<td>EASTERN EUROPE &amp; CENTRAL ASIA</td>
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<td>3.8</td>
<td>9.0</td>
<td>6.5</td>
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<tr>
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<td>18.4</td>
<td>40.7</td>
<td>44.6</td>
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<tr>
<td>North</td>
<td>24.7</td>
<td>2.6</td>
<td>20.6</td>
<td>40.6</td>
</tr>
<tr>
<td>South</td>
<td>14.1</td>
<td>3.3</td>
<td>19.4</td>
<td>26.4</td>
</tr>
<tr>
<td>West</td>
<td>9.0</td>
<td>12.5</td>
<td>61.6</td>
<td>55.0</td>
</tr>
<tr>
<td>NORTH AMERICA</td>
<td>16.1</td>
<td>6.5</td>
<td>21.1</td>
<td>35.8</td>
</tr>
<tr>
<td>All developed areas</td>
<td>15.9</td>
<td>29.7</td>
<td>22.5</td>
<td>31.1</td>
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<tr>
<td>WORLD</td>
<td>7.7</td>
<td>94.0</td>
<td>13.6</td>
<td></td>
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</tbody>
</table>

*Except data are available on unmarried women in countries of Asia, Near East and North Africa.

**Sources:** Demographic and Health Surveys, Reproductive Health Surveys, and LS Bureau of the Census International Database, Population Reports.
Figure 1.
Change in Contraceptive Method Mix, Selected Developing Countries, 1978–1998

OCs = Oral Contraceptives
F. Ster. = Female Sterilization
M. Ster. = Male Sterilization
IUD = Intrauterine Device
Inject. = Injectables

Source: Demographic & Health Surveys and World Fertility Survey
In Algeria 44% of married women relied on the pill in 1995—the highest level of pill use in the developing world, accounting for 84% of all contraceptive use. Iraq and Kuwait also report high levels of pill use, at 23% and 24% of married women. In contrast, levels of OC use are low—in Turkey, where overall contraceptive use is 64%, and in Yemen, where overall use is about 21%.

In Morocco pill use has risen substantially, from 14% of married women in 1980 to 32% in 1995. In Egypt, however, OC use fell from 17% of married women in 1980 to 10% in 1995. In the 1990s many Egyptian women shifted to IUDs (168), which have been more promoted. (See Figure 1.)

Latin America and the Caribbean. In Latin America and the Caribbean, OCs are the second most widely used method among married women, following female sterilization. About 14% of married women use the pill—nearly one in every seven married women, or one in every five family planning users. Some of the world's highest levels of current OC use, as well as ever use, are found in Latin American countries. For example, in Brazil 6 million women use the pill in numbers fourth in the world after China, Germany, and Indonesia. Some 21% of married women used OCs in 1996, over one-fourth of all Brazilian women using family planning. Brazilian women overwhelmingly use either the pill or female sterilization. Access to the IUD is limited, and a 1995 rating of access to family planning methods found that the condom was readily accessible to less than 20% of couples in Brazil (73).

In some Latin American countries contraceptive use shifted from the 1980s through the mid-1990s. Smaller percentages used OCs as the use of female sterilization and IUDs grew. Overall, OC use rates dropped from one in every six married women in 1987 to one in every seven in 2000. In Colombia, for example, prevalence of OC use fell from 7% of married women in 1986/1987 to 13% in 1995 (see Figure 1). In Mexico OC use declined from 14% in 1987 to 8% in 1995. At the same time, overall contraceptive use increased from 44% to 72%.

Researchers studying Mexican data conclude that the shift from OCs to other methods is occurring because more family planning users are older women choosing IUDs and sterilization once they have had all the children they want (519).

In Latin America the pill is the most popular way for sexually active unmarried women to avoid pregnancy. One-fourth of sexually active unmarried women use the pill. Use is highest in Brazil, at 36%.

Sub-Saharan Africa. Pill use accounts for about one-quarter of all contraceptive use among both married and unmarried women in sub-Saharan Africa. Overall, about 15% of married women use family planning, and slightly less than 4% use the pill. Among sexually active unmarried women, about 4% use some contraceptive method, and 10% use the pill.

In some African countries levels of OC use are among the world's highest. For example, in Zimbabwe 33% of married women and 32% of sexually active unmarried women were using OCs in 1994. In Zimbabwe access to the pill is generally good, while access to the IUD and to female and male sterilization is considerably more difficult (73). Also, in Reunion 40% of married women use OCs, in Mauritius 21%, and in Botswana and Cape Verde about 18%. Among sexually active unmarried women, about 17% in both Mali and Niger are using the pill, and about 20% in Botswana and South Africa.

In Bangladesh a village health worker discusses family planning with a client. In this country oral contraceptives have become the most widely used contraceptive, used by about 21% of married women.

Nevertheless, high levels of pill use are more the exception than the rule in sub-Saharan Africa. In five countries of the region, 1% or less of married women use the pill. In another eight countries use is between 1% and 2%.

Asia. In Asia contraceptive prevalence averages 59% of married women of reproductive age, but only 4.5% use the pill. This low percentage for OCs reflects the massive influence of populous China and India. In the most recent surveys only 3% of married women in China and 1% of married women in India reported using the pill. With China and India removed from the estimate, 10% of married women in Asia currently rely on the pill—nearly one-quarter of all family planning users.

Prevalence of OC use is highest in southeast Asia, led by Thailand, where an estimated 27% of married women of reproductive age use OCs in 1993. Despite the low percentage who use the pill, China has more pill users than any other country—about 7.6 million. Indonesia, the world's fourth-largest country, has 6.1 million pill users. Few data are available about contraceptive use among unmarried women in Asia.

In a few Asian countries OC use among married women has increased considerably in recent years. In Bangladesh, for example, OCs have become the most widely used contraceptive method, taken by nearly 21% of married women of reproductive age in 1996–97 compared with 3% in 1984. (See Figure 1). Pill use also has grown recently in Sri Lanka and Vietnam.

For country-by-country statistics on OC use, see the Internet website of the Johns Hopkins Center for Communication Programs at <http://www.jhuccp.org/go/09/89สถาท.html>.
Menstrual Benefits

The menstrual benefits of OCs include:

- Less iron deficiency anemia, due to lighter menstrual bleeding.
- More regular menstrual cycles.
- Less dysmenorrhea.
- Less severe premenstrual symptoms.

Less iron deficiency anemia, because their menstrual flow is reduced, OC users may find only one third to one half the blood from that other women lose during menstruation. For example, a 1992 Danish study found that women using or having used the pill had significantly fewer blood iron levels than non-users and that iron levels increased with the number of years of pill use (307). Studies in Chile (243) and Egypt (401) also have found higher iron levels in OC users than in non-users. Taking the iron-containing pills packaged at placebos in some brands of 28-day pill packets also may help. A study of Mexican women who were found that both hemoglobin and serum iron levels increased significantly after one year of OC cycles consisting of active combined pills for 21 days and placebo pills for 7 days (387).

Because of higher blood iron levels, OC users are less likely than non-users to develop iron deficiency anemia (147, 328, 460). Also, by preventing unintended pregnancies, OCs--like other contraceptives--prevent anemia associated with pregnancy (404). In developing countries anemia is a serious health problem among women, many of whom suffer from inadequate diets, parasitic infections, and the strain of repeated pregnancies. As many as half of women of reproductive age in developing countries may have subnormal levels of hemoglobin, the iron-containing pigment of red blood cells (328, 536). Some 60% to 80% of women who use OCs bleed less heavily than before starting OCs, and on average OC users lose 50% to 60% as much blood per cycle as other women (147, 260, 302, 328, 382, 433, 438). A 1992 Swedish study found that a low-dose OC containing 30 mg ethinyl estradiol and 0.15 mg desogestrel, reduced menstrual blood loss to 56% of previous levels (260). OCs

More regular menstrual cycles. Oral contraceptives generally improve menstrual patterns (179). For example, a UK study of 2,115 women ages 18 to 49 found that most OC users had shorter, lighter periods that occurred at more regular intervals (49). Only 7% of OC users reported irregular periods, compared with 10% of RU users, 11% of women relying on female sterilization, and 12% of women using other methods of use. The Oxford University Family Planning Association (Oxford FPA) cohort study found that, compared with non-users, OC users on secodn OCs (users with the previous 12 months were two times as likely to be referred to a hospital for treatment for irregular periods (695).

Protection from Some Cancers

Oral contraceptives help protect women from two cancers of the reproductive organs:

- Endometrial cancer (cancer of the lining of the uterus) and
- Epithelial ovarian cancer.

Studies in the UK and the US suggest that these cancers are about half as common in current users of OCs as among other women (59, 196, 210, 234, 236, 375, 516).

Combined OCs probably help protect against these cancers by reducing the size of cell division in the endometrial lining and the ovaries. In the case of the uterine endometrium, the
In the CASH study women using OCs for 10 years or more reduced their risk of ovarian cancer to 20% of that among nonusers. The CASH study also found that protection against epithelial ovarian cancer persists long after women stop using OCs. Even women who had stopped using OCs 15 or more years earlier faced just half the risk that never-users faced. Each of the 11 pill formulations studied offered similar protection, whether the formulation was high- or low-dose (59).

The protective effect of OCs against epithelial ovarian cancer may grow in importance in the coming years. All studies to date have focused on women younger than 50, since most OC users and former users are in this age group. Ovarian cancer is more common in women over age 60. However, since the protective effect of OC use apparently persists for many years, widespread OC use may eventually result in a decline in the incidence of this frequently fatal disease. Epithelial ovarian cancer is far the most common type of ovarian cancer (58).

Progestin component in the pill is thought to counteract the effects of estrogen, which would otherwise encourage cell division. OCs may protect against ovarian cancer by reducing gonadotropin production by the pituitary gland, thus reducing the effects of gonadotropin stimulation of the surface cells of the ovaries (62, 359).

Endometrial cancer. Even as little as one year's use of combined OCs cuts the risk of endometrial cancer substantially, and protection lasts long after women stop using OCs. A combined analysis of eight case-control studies and two cohort studies found that longer use significantly increased protection (409, 535). One year of OC use reduced risk to 77% of that among nonusers, 2 years to 62%, 5 years to 45%, 8 years to 36%, and 12 years to 80%. Earlier studies reported protection persisting from 3 to 10 years (195, 210, 234, 516).

It is uncertain whether the degree of protection against endometrial cancer varies with estrogen and/or progestin dose. The 1985 US Centers for Disease Control's Cancer and Steroid Hormone (CASH) study found no relationship between progestin dose and the degree of protection (58). Although the number of women using any one formulation in the CASH study was too small to allow an analysis by formulation, both high- and low-dose pills had a protective effect. In contrast, a 1991 WHO study suggested that protection was greater for users of formulations containing high estrogen doses (164, 247, 250, 278, 416). A retrospective study of 2,297 women, 76% of whom were premenopausal, found that women with high bone density were significantly more likely to have used OCs than were women with low bone density. Bone mineral density increased with duration of use (247). Clinical studies suggest that the bone mass benefits of OC use are related to the estrogen dose, with estrogen doses below 15 μg resulting in a net loss of bone mass and doses greater than 25 μg resulting in a net gain (109). Therefore some very low-dose pills may not help prevent loss of bone density.

It has not been demonstrated that the effect of OCs on bone density makes a practical difference. Neither of the two major British cohort studies, the Royal College of General Practitioners study or the Oxford/FPA study, found that pill use helped to protect premenopausal women from bone fractures (87, 492). Low-dose combination OCs may help to protect postmenopausal women from bone fractures (87, 492), even if women stop using OCs 15 or more years after initially starting them. In the CASH study women using OCs for 10 years or more reduced their risk of osteoporotic hip fractures (87, 492) by 50% compared with nonusers. The CASH study also showed that protection against osteoporotic hip fractures was greatest among women who had used OCs for 10 years or more and for combined OCs (87, 492). The Oxford/FPA cohort study found that the risk of hip fractures was 30% lower among women using OCs than among those who never used them or had used them for less than 10 years (493).

Ovarian cysts. Several early studies indicated that high-dose OCs—those containing 50 μg or more of estrogen—protect women from functional ovarian cysts (334, 397, 493). The Oxford/FPA cohort study found that the risk of follicular ovarian cysts in current OC users was about half that in users of nonhormonal methods. The protection from corpus luteum cysts was even greater. Users of combined OCs faced about one-fifth the risk that other women faced (493). Low-dose combined and multiphasic OCs, even though they prevent ovulation effectively, may permit some follicular development and thus offer less protection against cysts (155, 436) or perhaps none at all (174, 207, 258).

In the CASH study women using OCs for 10 years or more reduced their risk of ovarian cancer to 20% of that among nonusers. The CASH study also found that protection against epithelial ovarian cancer persists long after women stop using OCs. Even women who had stopped using OCs 15 or more years earlier faced just half the risk that never-users faced. Each of the 11 pill formulations studied offered similar protection, whether the formulation was high- or low-dose (59).

The protective effect of OCs against epithelial ovarian cancer may grow in importance in the coming years. All studies to date have focused on women younger than 50, since most OC users and former users are in this age group. Ovarian cancer is more common in women over age 60. However, since the protective effect of OC use apparently persists for many years, widespread OC use may eventually result in a decline in the incidence of this frequently fatal disease. Epithelial ovarian cancer is far the most common type of ovarian cancer (58).

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Benign breast disease. Studies of women using older, higher-dose formulations found that OC use protected against myo-adenoma and fibrocystic breast disease. OC users had from one-quarter to one-half the risk of nonusers (45, 335, 398). Protection against benign breast disease may depend on the progestin content of the pill, with more progestin offering more protection. The Oxford/IFPA cohort study compared women using pills with the same amount of estrogen but with different amounts of the same progestin. Women using pills containing 2.5 or 3.0 mg of the progestin medroxyprogesterone acetate had half the incidence of fibrocystic breast disease as women who used pills containing 1.0 mg of the same acetate. Also, protection increased with length of pill use (45). Since more OCs now in use contain lower amounts of progestin than in this study, they may offer less protection against benign breast disease (29, 265).

Colorectal cancer. Some studies have found that OC use reduces the risk of colorectal cancer (26, 135, 148, 293, 364). The largest case-control study to date found that women who had ever used OCs reduced their risk of colorectal cancer to 60% of that of nonusers and that OC use for over two years reduced risk to 50% (135). Other studies, however, have found no protective effect (252, 468, 514).

Colorectal cancer is the fifth most common cancer among women worldwide (148, 342).

**Health Risks of Oral Contraceptives**

Modern oral contraceptives are safe for the great majority of women. The health risks of using OCs are much less than the risks of pregnancy and childbearing for almost all women, especially in countries with high maternal mortality rates. Except for thromboembolism, increased risks among OC users were concentrated in older women who smoked or had other risk factors such as high blood pressure. To reduce the risk of circulatory system disease, the second- and third-generation OCs contain less estrogen. Third-generation OCs are pills containing an estrogen dose of less than 50 μg and either of two newest progestins—desogestrel or gestodene. All other pills containing less than 50 μg of estrogen are considered second-generation OCs except those containing cyproterone acetate or norgestimate, which are difficult progestins to categorize (122, 463, 540).

Heart attack. Ischemic heart disease results from an impediment to circulation that deprives the heart of adequate blood supply. Myocardial infarction—heart attack—is the resulting death of heart muscle cells. Ischemic heart disease can develop gradually from atherosclerosis, in which deposits on the walls of coronary arteries restrict blood flow to the heart muscle, or it can result from a thrombus, or clot, that suddenly blocks a coronary artery. Myocardial infarction is rare in young women who do not smoke or have other clinical risk factors (122, 463, 540).

**Circulatory System Diseases**

Evidently that combined OCs increased the risks of venous thromboembolism, heart attack, and stroke first appeared in the mid-1970s. The research involved OCs that contained 50 μg or more of estrogen along with a progestin. These circulatory system disorders are rare in young women. Except for thromboembolism, increased risks among OC users were concentrated in older women who smoked or had other risk factors such as high blood pressure. To reduce the risk of circulatory system disease, the second- and third-generation OCs contain less estrogen. Third-generation OCs are pills containing an estrogen dose of less than 50 μg and either of two newest progestins—desogestrel or gestodene. All other pills containing less than 50 μg of estrogen are considered second-generation OCs except those containing cyproterone acetate or norgestimate, which are difficult progestins to categorize (122, 463, 540).

Modern oral contraceptives are safe for the great majority of women. The health risks of using OCs are much less than the risks of pregnancy and childbearing for almost all women, especially in countries with high maternal mortality rates. This functional pointer points to high effectiveness and low side effects with low-dose oral contraception.
Among nonsmoking OC users who had their blood pressure checked before starting OCs and had no other risk factors for heart attack, there was no appreciable increase in risk in those who do not smoke, who have their blood pressure checked, and who do not have diabetes are at no increased risk of myocardial infarction. Relative risk is a measure of how much a particular factor influences the risk of a specified outcome. For example, a relative risk of 2 associated with a factor means that people with the factor face twice the risk of the specified outcome that people without the factor have (a protective effect). The WHO study found the relative risk of heart attack associated with OC use was highest among women who had not had their blood pressure checked before starting to use OCs—presumably because some of them did have high blood pressure, whereas the group of OC users who had been screened excluded most women with high blood pressure (539).

Among nonsmoking OC users who had their blood pressure checked before starting OCs and had no other risk factors for heart attack, there was no appreciable increase in risk in those who do not smoke, who have their blood pressure checked, and who do not have hypertension or diabetes are at no increased risk of myocardial infarction if they use combined oral contraceptives, regardless of age. There is no increase in the risk of myocardial infarction with increasing duration of use of combined oral contraceptives. There is no increase in the relative risk of myocardial infarction in past users of oral contraceptives. These conclusions appear to apply equally to women in developed and developing countries (540).

Relative risk is a measure of how much a particular factor influences the risk of a specified outcome. For example, a relative risk of 2 associated with a factor means that people with the factor face twice the risk of having a specified outcome that people without the factor have. A relative risk of 0.5 means that people with the factor face half the risk of the specified outcome that people without the factor have (a protective effect).

### Table 3. Myocardial Infarction

<table>
<thead>
<tr>
<th>No History of Hypertension</th>
<th>History of Hypertension</th>
<th>Non-users</th>
<th>Light Smokers</th>
<th>Heavy Smokers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Developing-country hospitals</td>
<td>4.0</td>
<td>15.3</td>
<td>4.5</td>
<td>10.7</td>
</tr>
<tr>
<td>European hospitals</td>
<td>5.0</td>
<td>6.0</td>
<td>4.0</td>
<td>5.0</td>
</tr>
<tr>
<td>Overall</td>
<td>4.8</td>
<td>15.3</td>
<td>4.5</td>
<td>10.7</td>
</tr>
</tbody>
</table>

*Among women with no history of hypertension other than that associated with pregnancy, diabetes, atheromatous heart disease, or abnormal blood lipids.

### Table 4. Ischemic Stroke

<table>
<thead>
<tr>
<th>No History of Hypertension</th>
<th>History of Hypertension</th>
<th>Non-users</th>
<th>Light Smokers</th>
<th>Heavy Smokers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Developing-country hospitals</td>
<td>2.7</td>
<td>10.7</td>
<td>2.2</td>
<td>4.0</td>
</tr>
<tr>
<td>European hospitals</td>
<td>2.8</td>
<td>3.9</td>
<td>2.2</td>
<td>2.5</td>
</tr>
<tr>
<td>Overall</td>
<td>2.9</td>
<td>10.7</td>
<td>2.2</td>
<td>4.0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Age 35 and Over</th>
<th>All Ages</th>
<th>Age 35 and Over</th>
<th>All Ages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Under</td>
<td>7.0</td>
<td>Past</td>
<td>7.0</td>
</tr>
<tr>
<td>Age 35</td>
<td>5.9</td>
<td>Current</td>
<td>5.9</td>
</tr>
</tbody>
</table>

*Source: Pirkle 1976 (527), WHO 1997 (540)*
Recent studies have suggested no increased risk of myocardial infarction among users of third-generation OCs with no other risk factors (222, 268, 270). The risk increases in women of reproductive age in subarachnoid hemorrhage, in which blood from the ruptured vessel enters the space below the brain’s arachnoidal membranes, and spreads through cerebrospinal fluid pathways. Hemorrhagic stroke is more likely to be fatal than ischemic stroke (281, 282, 441).

The first studies of the health risks of OC use, conducted in the 1960s and 1970s, suggested about a fivefold greater risk of any type of stroke among OC users than among nonusers (81, 213, 224, 264, 375, 441, 490). Now, based on the results of a multi-center WHO study (367) and other recent studies (192, 354, 412), the estimated risk of ischemic stroke among OC users is about 2.5 times greater than the risk among nonusers (131). The more recent studies provide more information on ischemic stroke than on hemorrhagic stroke.

Lower doses appear to have reduced the risk. For example, in the Oxford/FPA cohort study, the relative risk of stroke for OC users appeared to drop as the study progressed. In 1964 the study reported relative risks of 1.5 to 2.0 for subarachnoid hemorrhage and 2.3 to 3.2 for other types of stroke among OC users compared with nonusers (490), down from 5.0 for all types in 1970 (490).

The multicenter WHO study—the largest case-control study of stroke and OCs by far—found an overall relative risk of ischemic stroke of about 3 among OC users. As with heart attacks, other risk factors make a big difference to the risk of OC use (see Table 4). Current OC users who did not smoke, 2nd their blood pressure checked, and did not have high blood pressure were at 1.5 times greater risk than nonusers. In contrast, OC users who smoked faced a higher risk—about two times greater than among nonusers among OC users in the developing countries studied and about 3.5 times greater in Europe. Current OC users with a history of hypertension faced the greatest risk—about five and six times greater than for other OC users. As in the WHO study of heart attack, the risk of ischemic stroke was lower among women who reported having their blood pressure checked before starting OCs than among those who did not (367).

The WHO study produced conflicting findings on the relationship between dosage and ischemic stroke risk. In Europe lower doses meant lower risks; while in the developing countries the pattern was reversed. The researchers suggest that the opposing patterns reflect different levels of other risk factors for ischemic stroke. In both Europe and the developing countries, however, risk did not rise significantly with continuing OC use, and elevated risk did not appear to persist after women stopped using OCs (367).

Migraine headaches have been linked to twofold or greater increased risk of ischemic stroke. Several studies have found that OC users with a history of migraine are two to four times more likely to have an ischemic stroke than women with a history of migraine who do not use OCs (69, 272, 273, 274, 411, 475). For example, a case-control study conducted in European hospitals from the WHO study of cardiovascular disease and hormonal contraceptives found that, compared with women not using OCs and having no history of migraine, ischemic stroke was 6.6 times more likely among OC users with a history of migraine, and 2.3 times more likely among nonusers with a history of migraine (69). Studies suggest risk is greater among women who have severe migraine headaches with "aura"—focal neurologic symptoms such as blurred vision, temporary loss of vision, seeing flashing lights or zigzag lines, or trouble speaking or moving (61, 69, 411, 475). The recent studies (61, 69, 273, 475) led a March 2000 meeting of experts convened by WHO to recommend that a woman who has migraine headaches with focal neurologic symptoms should not start combined OCs. The group recommended that a woman who has migraine headaches without focal neurologic symptoms should not start combined OCs. The group recommended that a woman who has migraine headaches without focal neurologic symptoms should not start combined OCs. The group recommended that a woman who has migraine headaches without focal neurologic symptoms should not start combined OCs.

For hemorrhagic stroke, the WHO study found a slightly increased risk among OC users in general (see Table 5). The
Table 5. Hemorrhagic Stroke

<table>
<thead>
<tr>
<th>Table 5. Hemorrhagic Stroke</th>
<th>Relative Risk Among Current Users of Oral Contraceptives Compared with Nonusers, by History of Hypertension and by Smoking Behavior and Age</th>
</tr>
</thead>
<tbody>
<tr>
<td>Developing-country hospitals</td>
<td>European hospitals</td>
</tr>
<tr>
<td>Crude Risk</td>
<td>Nonusers</td>
</tr>
<tr>
<td></td>
<td>Overall Age 35 and Over All Ages</td>
</tr>
<tr>
<td>Developing-country hospitals</td>
<td>European hospitals</td>
</tr>
<tr>
<td>Crude Risk</td>
<td>Nonusers</td>
</tr>
<tr>
<td></td>
<td>Overall Age 35 and Over All Ages</td>
</tr>
</tbody>
</table>

Population Reports

Difference was statistically significant in developing countries but not in the European countries. In both developing and European countries, current OC users age 35 or over had a significantly increased risk of hemorrhagic stroke, with relative risks of 2.5 and 2.2, respectively, compared with nonusers of OCs. The relative risk among current OC users who smoked was three to four times that of nonusers who did not smoke. Also, current users with a history of hypertension faced a substantially higher relative risk than nonusers with no such history. As with ischemic stroke, the duration of OC use did not affect the risk of hemorrhagic stroke, and the elevated risk did not persist after OC use ended. Risk did not vary with estrogen dose or with progestin dose or type (537, 540).

Because, in combination, hypertension and OC use increased the risk of stroke and myocardial infarction far more than would either risk factor alone, WHO medical eligibility criteria for OC use were recently revised to recommend that women who know that they have high blood pressure—systolic pressure of 140 mm Hg or higher and/or diastolic pressure of 90 or higher—or, where blood pressure cannot be evaluated, who have a history of hypertension should choose another contraceptive method (537). Blood pressure must be properly taken, and one reading is not enough to diagnose high blood pressure.

In areas where medical services are limited, blood pressure checks for OC users may be impractical. In these service areas, maternal morbidity and mortality tend to be greater risks than any risks associated with OC use (540).

In any case, the benefit of screening potential combined OC users for high blood pressure and withholding OCs from women with high blood pressure would not be substantial if hypertension itself cannot be treated. A recent analysis conducted for WHO pointed out that this screening would prevent only about 10% of stroke and heart attack cases attributable to OC use. In particular, screening women under age 35 for high blood pressure would not prevent an appreciable number of cardiovascular disease cases or deaths attributable to OC use. At the same time, "false positive" diagnoses of hypertension would needlessly prevent some women from using OCs (556). Because it is dangerous to withhold OCs from women who are truly hypertensive,

From a public health perspective, the impact of cardiovascular disease attributable to OC use is slight, particularly since most OC users are young and do not have other risk factors for cardiovascular disease. The analysis for WHO points out that the additional number of cardiovascular disease cases and deaths among OC users depends greatly on age. For example, among one million OC users under age 35, 20% of whom smoke, fewer than 20 deaths annually would be due to OC use. By comparison, among one million OC users over age 35, 20% of whom smoke, 24 to 96 deaths annually would be attributable to OC use, depending on the region (556).

Thrombembolism. Thrombembolism is an obstruction of a blood vessel by a blood clot. The most common thrombembolic disorder in OC users—known as venous thromboembolism (VTE), or deep vein thrombosis—involves clots that form in veins deep in the leg. These clots sometimes circulate to the lungs, where they become potentially fatal pulmonary embolisms. A multinational study by WHO, conducted from 1989 to 1993 (366), and three smaller studies in the mid-1990s (134, 221, 440) found that modern low-dose OCs pose less risk of thromboembolism than indicated by earlier studies that involved mostly first-generation pills.

The new case-control studies reported a risk of VTE about three times greater among users of second-generation OCs than among women not using OCs and about six times greater among users of third-generation OCs containing desogestrel and gestodene (131). There is debate about whether the difference in risk between second- and third-generation pills is real or due to bias in the studies (188, 131, 132, 194, 233, 267, 269, 275, 368, 440, 447, 503, 540, 554).

When the findings were released in 1993, they caused a "fear scare" in the news media of the UK and other European countries where third-generation OCs are most widely used. Responding to the publicity, many women switched to other OCs or stopped taking pills altogether. In the months following, the number of unintended pregnancies and abortions increased substantially (15, 75, 76, 118, 218, 257, 376, 528).

The estimated risk of VTE is low with all modern low-dose OCs—including those containing desogestrel and gestodene—and all low-dose OCs pose less risk of VTE than previous higher-dose formulations. For users of high-dose OCs, early studies suggested that about 80 cases of VTE per 100,000 women per year could be attributed to OC use (197, 221, 358, 441). By comparison, recent studies estimate that the annual number of VTE cases attributable to second-generation OCs ranges from about 6.5 cases per 100,000 women per year at ages 20 to 24 to 12 cases per 100,000 per year at ages 40 to 44. The number attributable to third-generation OCs ranges from about 16 cases per 100,000 at ages 20 to 24 to 30 cases per 100,000 at ages 40 to 44 (111). VTE risk associated with pregnancy is about 60 cases per 100,000 pregnancies (86).

The risk of death from VTE is slight. Worldwide, among women not using OCs, an estimated 0.6 to 1.2 deaths per million self-reported deaths in 1989-1990 was attributed to VTE. In the United States, VTE deaths were estimated to be about 0.2 per 100,000 women aged 15-44.

(Text continues on page 25.)
The US Food and Drug Administration declared in 1997 that six brands of combined oral contraceptives could be used safely and effectively as ECPs.
safety, and effectively as ECPs (481). Several more have been approved since. In 1998 USFDA approved Preven, the first progestin-estradiol regimen marketed in the US specifically as ECPs. USFDA approval for a two-pill progestin-only regimen, Plan B, came in 1999; it had already been approved in 39 other countries.

ECPs are becoming increasingly available around the world. In some countries combined and progestin-only OCS are packaged specifically for use as emergency contraception. These packages contain the appropriate dosage along with instructions for the user and the provider. In some places ECPs are sold over-the-counter or with the referral of a pharmacist, while other places require a physician's prescription.

Effectiveness of ECPs

Progestin-only ECPs may be more effective than combined pills. ECPs containing estrogen probably prevent at least three-fourths of pregnancies that would have otherwise occurred (472). Typically, if 100 women had unprotected sex once during the second or third week of their menstrual cycle, 8 of them would become pregnant. If these same women all used ECPs containing estrogen, however, only two would become pregnant (518).

A recent WHO study found that women using progestinonly ECPs were one-third as likely to become pregnant as women using combined ECPs (453). Thus, if the same 100 women used progestin-only ECPs, only 1 would become pregnant. This is an 80% reduction in the chance of pregnancy compared with not using ECPs (469). It is important to remember that these failure rates are per use and cannot be compared with failure rates for ongoing contraception, including daily use of OCS.

How Do ECPs Work?

The precise mode of action of ECPs is uncertain and may be related to the time they are used in a woman's cycle (133, 471). It is thought that in the beginning of the cycle they may prevent ovulation just as OCS taken daily would, or they may delay ovulation. After ovulation, they may interfere with fertilization and/or, in theory, prevent implantation of a fertilized egg in the wall of the uterus (175, 448, 518). ECPs are not effective once the process of implantation has begun.

ECPs will not disrupt an established pregnancy. Furthermore, there is no evidence that combined or progestin-only contraceptives harm a developing fetus (133, 160, 518). Studies examining the effects of exposure to oral contraceptives early in pregnancy have not linked such exposure to congenital malformations (40). Only one study has looked specifically at pregnancy outcomes after failed emergency contraception. It found no evidence that ECPs would adversely affect a fetus (60).

ECPs offer no protection against sexually transmitted infections (STIs). When indicated, as in cases of rape, preventive STI treatment should be provided (190).

Timing of ECP Use

The sooner treatment is started, the better. The first dose should be taken no later than 72 hours after intercourse. The second dose should follow 12 hours after the first dose. A recent study found that, even within the 72-hour period, effectiveness decreased dramatically as time since intercourse increased (453). With each additional 12 hours, the chances of pregnancy increased by almost 50%. Thus, ECPs were eight times more effective when begun in the first 12 hours than when begun 60 to 72 hours after intercourse (557).

How effective ECPs would be if started 72 hours or more after intercourse has not been well studied. It is biologically plausible that ECPs would be effective after 72 hours because there are approximately six days between ovulation and implantation (175, 456). Women who request ECPs more than 72 hours after unprotected intercourse may be given pills, but they should be told that pregnancy may already have begun, and therefore ECPs may not be effective (133, 517). For women who request emergency contraception between 72 and 120 hours and are appropriate IUD candidates, a copper IUD may be a better option (517). An international study, conducted by the Population Council and partner clinics, is underway to determine more accurately the effectiveness of ECPs beyond 72 hours. The study also seeks to determine whether pills containing the progestin norethindrone may be used for emergency contraception and whether the second dose is really necessary (370).

Safety and Side Effects

ECPs are safe for virtually all women, including those who may have health conditions that rule out daily use of OCS. ECPs have not been found to increase the risk of the complications associated with ongoing OCS use (85, 123, 456, 486). One study specifically examined the risk of venous thrombembolism—which is associated with continued use of combined OCS (see p. 166) —and found no increase in risk among ECP users (488). WHO medical eligibility criteria for contraceptive use list no medical conditions that rule out use of ECPs (557).

Women taking ECPs sometimes experience nausea, dizzi-

ness, fatigue, headache, defecation, or light menstrual bleed-

ning, breast tenderness, and/or abdominal pain. These side

effects usually subside within a day or two. In the WHO

study, about 50% of women using combined ECPs report

nausea compared with 25% of women using progestin-

only ECPs. Approximately 20% of women who used com-

bined OCS and 6% of those who used progestin-only pills

vomited (453). Arthralgia and pain, cold, headache, body

aches, or dizziness may be associated with the use of

medroxyprogesterone, levonorgestrel, or norethisterone.

Taking the pills with food or milk also may help (133, 541).

If a woman vomits within two hours after taking ECPs, she

should take another dose. For women who vomit more
What are Emergency Contraceptive Pills (ECPs)?

- ECPs can be taken after unprotected sex to help prevent unintended pregnancy. They contain some of the same hormones as pills used for daily oral contraception. ECPs are sometimes packaged especially for emergency use (dedicated products), or they can be special doses taken out of a regular pill pack.

What are reasons to use emergency contraception?

- A woman has had unprotected sex, and she wants to prevent pregnancy. For example:
  - She did not expect to have sex and was not using contraception.
  - Sex was forced.
  - A condom broke or slipped.
  - She ran out of oral contraceptives, started a new packet of pills several days late, or missed three or more active pills in a row, and she did not use condoms or spermicide.
  - She is late for a contraceptive injection—more than two weeks late for depo medroxyprogesterone acetate (Depo-Provera), more than one week late for norethindrone enanthate (Noristerat), or more than three days late for a monthly injection (such as Cyclofem or Medigyno).

In short, any reason that a woman is concerned that she might become pregnant is an appropriate reason.

Questions and Answers

What pills can be used as ECPs?

- Four types of pills can be used. All four types contain the progestin levonorgestrel, or norgestrel.
  - Progestin-only dedicated products,
  - Progestin-only oral contraceptives,
  - Combined oral contraceptives,
  - Combined progestin-estrogen dedicated products (see table on p. 21).

Progestin-only pills are more effective and cause much less nausea and vomiting than combined pills.

How effective are ECPs?

- Among 100 women, if each has sex once in the second or third week of her menstrual cycle without using contraception, 8 women are likely to become pregnant. If all 100 women use progestin-only ECPs, only one is likely to become pregnant. If all 100 women use combined OCs for emergency contraception, only two are likely to become pregnant. ECPs are appropriate in emergency situations, but they are not as effective as an ongoing use of most modern contraceptives.

When should ECPs be taken?

- As soon as possible after unprotected intercourse. The first dose should be taken within 72 hours after intercourse.

Are there side effects?

- Yes, some women have nausea, vomiting, dizziness, headache, breast tenderness, abdominal pain, or a heavier or lighter menstrual period. Nausea and vomiting are most common. With combined pills about 20% of women vomit. With progestin-only pills about 6% vomit. Antinausea medications can help (see p. 22).

Do ECPs cause abortion?

- No. ECPs will not disrupt an established pregnancy. They are not effective once the process of implantation has begun.
Questions and Answers

Q: Do any medical conditions rule out use of ECPs?
A: No medical conditions rule out ECPs. Medical conditions that rule out continuing use of oral contraceptives do not apply to ECPs. Furthermore, there is no suggestion that ECPs increase the risk of complications—such as certain circulatory system diseases—associated with ongoing OC use.

Q: After using ECPs, when can a woman start an ongoing method of contraception?
A: ECPs do not provide continuing protection from pregnancy. Therefore it is important to start an ongoing method of contraception after ECP use. Most methods can be started at once. For example:
- Condoms and spermicides can be started at once. A woman who wants to start another method later needs to use these methods if she has sex before then.
- If a woman chooses to use oral contraceptives regularly, she should take the first pill on the next day after she finishes the ECPs. She should also use condoms for the next seven days.
- A woman who wants an IUD for ongoing contraception can have it inserted within five days of unprotected intercourse in place of taking ECPs.
- Injectable and implants can be started within seven days after the beginning of the next menstrual cycle. The woman should use condoms until then.
- Couples who want to use a fertility awareness-based method such as periodic abstinence may need to abstain or use condoms at first and wait one or two cycles until the woman's menstrual cycle becomes regular.

All guidelines also apply to switching to another method after regular use of oral contraceptives.

Q: Where should ECPs be offered?
A: Anywhere that women can get ECPs easily, including chemists' shops and convenience stores, as well as at clinics, emergency rooms, shelters, and private health care providers' offices.

Q: Where should women find out how to use ECPs?
A: Information can come from a pharmacist, a community-based provider, a doctor, a nurse, or from radio, television, newspapers, magazines, package inserts, flyers, telephone recordings, or the Internet.

PRACTICAL GUIDE TO

Providing ECPs: Suggested Steps for Health Care Providers

Most important is to see that the woman gets the pills and knows how to take them. If possible, these steps are useful:

1. Help the client feel at ease. Let her know that you understand her needs, you will not judge her behavior, and you will keep her visit confidential.

2. Ask when unprotected sex took place. ECPs should be started as soon as possible within 72 hours after unprotected intercourse.

3. Give the woman the pills. Explain how to take them (see next page), and point to the pills as you explain. She can take the first dose at once.

4. Tell her that, if she vomits within two hours of taking the pills, she may take another dose either by mouth or vaginally.

5. Explain and discuss important points about ECPs (see p. 22).

6. Discuss the woman's need for ongoing contraception.
- If she expects to have sex and wants to avoid pregnancy, it is best if she can choose an ongoing method. In some circumstances—for example, if her partner prevents it—she may not be able to use an ongoing method. In any case, consider offering an extra supply of ECPs for future use.
- Even if she does not expect to have sex, offer her condoms or spermicide just in case. You also can offer her oral contraceptives, with instructions on when to start them, in case she changes her mind.

7. When there is a chance that she might have acquired a sexually transmitted infection (STI), she should be treated for the most common STIs.
To use progestin-only pills for emergency contraception, a woman must take:

- A total of 0.75 mg of levonorgestrel within 72 hours after intercourse, and then a second dose of 0.75 mg 12 hours later. (See table below for numbers of pills to take.)

To use combined OCs for emergency contraception, a woman should take pills totaling 0.5 mg levonorgestrel (or 1.0 mg norgestrel) and 100 pg ethinyl estradiol within 72 hours after intercourse, and the same dose 12 hours later. For example:

- Two pills containing 50 pg ethinyl estradiol and 0.25 mg levonorgestrel (or 0.50 mg norgestrel), and then two more of these same pills 12 hours later, OR

- Usually four "low-dose" combined pills, each containing less than 50 pg of ethinyl estradiol and 0.15 mg levonorgestrel (or 0.30 mg norgestrel), and then four more of these same pills 12 hours later. (A few brands differ; see table below.)

### Dosages for Emergency Contraceptive Pills

<table>
<thead>
<tr>
<th>If you are using:</th>
<th>Number of pills to swallow as soon as possible (within 72 hours)</th>
<th>Number of pills to swallow 12 hours later</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Dedicated Progestin-Only ECPs</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Plan B</td>
<td>1 pill</td>
<td>1 pill</td>
</tr>
<tr>
<td>NorLevo</td>
<td>1 pill</td>
<td>1 pill</td>
</tr>
<tr>
<td><strong>Dedicated Combined ECPs</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preven</td>
<td>2 pills</td>
<td>2 pills</td>
</tr>
<tr>
<td>E-Gen-C</td>
<td>2 pills</td>
<td>2 pills</td>
</tr>
<tr>
<td>Schering-PC-4</td>
<td>2 pills</td>
<td>2 pills</td>
</tr>
<tr>
<td>NeoPrimovlar</td>
<td>2 pills</td>
<td>2 pills</td>
</tr>
<tr>
<td>Tetragynon</td>
<td>2 pills</td>
<td>2 pills</td>
</tr>
<tr>
<td>Imediat</td>
<td>2 pills</td>
<td>2 pills</td>
</tr>
<tr>
<td><strong>Progesterin-Only OCs</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Microval</td>
<td>25 pills</td>
<td>25 pills</td>
</tr>
<tr>
<td>Ovrette</td>
<td>20 pills</td>
<td>20 pills</td>
</tr>
<tr>
<td><strong>Combined OCs</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alesse</td>
<td>5 pink pills</td>
<td>3 white pills</td>
</tr>
<tr>
<td>Bipyrone</td>
<td>3 white pills</td>
<td>5 pink pills</td>
</tr>
<tr>
<td>Levlen</td>
<td>4 light-orange pills</td>
<td>4 white pills</td>
</tr>
<tr>
<td>Levile</td>
<td>5 pink pills</td>
<td>4 light-orange pills</td>
</tr>
<tr>
<td>Levora</td>
<td>4 white pills</td>
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<tr>
<td>Levonal</td>
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</tr>
<tr>
<td>Micronor</td>
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</tr>
<tr>
<td>Lof-Ovral</td>
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<td>4 white pills</td>
</tr>
<tr>
<td>Norlestrin</td>
<td>4 light-orange pills</td>
<td>4 light-orange pills</td>
</tr>
<tr>
<td>Ovral</td>
<td>2 pills</td>
<td>2 pills</td>
</tr>
<tr>
<td>Ovral</td>
<td>2 white pills</td>
<td>4 pills</td>
</tr>
<tr>
<td>Regylation</td>
<td>4 yellow pills</td>
<td>4 yellow pills</td>
</tr>
<tr>
<td>Tri-Levon</td>
<td>4 yellow pills</td>
<td>4 yellow pills</td>
</tr>
<tr>
<td>Tripill</td>
<td>4 pink pills</td>
<td>4 pink pills</td>
</tr>
<tr>
<td>Trilora</td>
<td>4 white pills</td>
<td>4 pink pills</td>
</tr>
<tr>
<td>Remember that in 28-day pill packs the last 7 pills are not &quot;active&quot; pills and therefore cannot be used for ECP.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Brochures in many languages, available from reproductive health centers.
What Women Should Know About ECPs

- The first dose of ECPs should be taken as soon as possible within 72 hours after unprotected intercourse. The second dose should be taken 12 hours later. The sooner ECPs are started, the more effective they will be.

- ECPs will not protect against other acts of unprotected intercourse later in the menstrual cycle. In fact, ECPs can delay ovulation, so a woman might still get pregnant later in the same cycle. To keep avoiding pregnancy, a woman should start an ongoing method of contraception as soon as possible.

- ECPs are not as effective as consistent, correct, and ongoing use of OCs or many other modern family planning methods.

- ECPs do not protect against sexually transmitted infections, including HIV, which causes AIDS.

- Especially with combined pills, many women have nausea (upset stomach), and some women vomit after taking ECPs. Taking an anti-nausea medication containing medazine hydrochloride can help. Anti-nausea medication should be taken 30 minutes to one hour before the first dose of ECPs and repeated as directed on the package.

- Taking more than the recommended dosage of ECPs will NOT make ECPs more effective. The extra pills will only cause more nausea.

- The pills will not make menstruation start immediately. A woman's next period may come a few days earlier or later than expected. This is not harmful and not a reason to worry. She should suspect pregnancy, however, if:
  - Her period is more than one week later than expected, or
  - She has not menstruated within three weeks after treatment, or
  - Her period is unusually light.

- ECPs are not 100% effective. If they fail, however, the available research suggests that ECPs will not harm the fetus or the course of pregnancy.
than two hours after taking ECPs, another dose is not necessary (380, 517). This advice is based on the medical care providers' best guess rather than scientific data and is, therefore, a topic of debate (450, 517). In cases of severe vomiting, vaginal administration of a second dose of ECPs has been recommended (450).

Little research has been done on possible drug interactions involving ECPs. Continuing oral contraception is known to be less effective for women taking carbamazepine, paracetamol, phenytoin, or phenobarbital (for seizures), rifampin (for tuberculosis), or griseofulvin (for fungal infections) (see p. 26). Some experts recommend assuming that the same interactions occur with ECPs and therefore double the dose of ECPs (85). It is unlikely that broad-spectrum antibiotics reduce the efficacy of ECPs (456).

**Increasing Access to ECPs**

More women and more providers need to know about ECPs. Also, access to ECPs should be improved both for women in general and for groups with special needs.

**Educate about ECPs**

Women. The public—and women in particular—need to know about ECPs and how to get them. Emergency contraception should be discussed with women at routine health care visits, although at this point it seldom is (229). A study of US college students found that those who had correct information about ECPs—particularly about their ingredients and side effects—had more favorable attitudes toward their use (186, 453). The mass media can help the public by avoiding this "new" way to avoid unwanted pregnancy, explain where to get ECPs and how to use them, stress the need to take the first dose as soon as possible and within 72 hours after intercourse, and clarify that ECPs do NOT cause abortion. Health care providers can tell women how to use their usual brands of OCPs as emergency contraception, if their brand contains norethisterone or levonorgestrel. Women can be encouraged to keep an extra packet of pills on hand specifically for emergency use if needed. Where prescriptions are required for OCPs and ECPs, the prescriptions can be provided ahead of time. Providers may give women an Emergency Contraception Kit consisting of instructions and pills or else a prescription that can be filled either immediately or when needed (516).

Providers. All women's health care providers should know about ECPs, including which pills to use, correct regimens, and possible side effects. In some places, however, many health care providers do not know that some of the same pills used for ongoing contraception can also be used for emergency contraception. Other providers may confuse ECPs with abortion-inducing drugs, which, in contrast to ECPs, act after implantation to disrupt an established pregnancy (9, 79, 110, 149, 157, 231, 259, 316, 326, 406, 513). In either case women may be denied information or access to ECPs because providers are not well informed. As facilities that provide ECPs, all staff members—including those who first greet clients—should know that ECPs are available.

Make access to ECPs easy. Make referrals simple. Easy referrals lead to quicker treatment. Where telephones are widely accessible, hotlines can provide information about ECPs and referrals to providers. In the US and Mexico, nationwide 24-hour-a-day, toll-free hotlines provide information and referrals: 1-888-NOT-2-LATE in the US and 01-800-EN-3-DIAS in Mexico. The British Pregnancy Advisory Service maintains an "action line"—09457 304303—that offers referrals. In China hospitals have set up their own information and referral lines (322). Women in Sri Lanka can dial 501 315 on weekdays between 3:00 am and 4:30 pm for ECP information and referrals (1).

Train a range of providers. Pharmacists, as well as others, can provide ECPs on a woman's request. A pilot project in the US state of Washington allows pharmacists to provide ECPs according to a clear written protocol. Within the first several months the pharmacists had prescribed over 2,000 courses of ECPs, and users reported no adverse outcomes (85, 212, 226). A survey of women who had received ECPs through these pharmacists found that half obtained them on a weekend or in the evening—times when they could not usually visit a doctor's office for a prescription (212). A similar pilot project is underway in the UK, where chemists in 16 pharmacies have undergone training and are giving ECPs to women according to a specific protocol. The project will be evaluated, and a decision will be made whether to extend it (197).

Remove unnecessary medical barriers to access. Some providers continue to require a gynecological examination and/or pregnancy test before dispensing ECPs. These procedures are costly, use precious time, and may actually discourage some women from using ECPs (477). Likewise, the inclusion of a urine pregnancy test in commercial emergency contraception kits may deter some women from using ECPs. The test adds to the cost of the kit, requires instructions that may confuse or discourage women with limited literacy, or, if the test is negative, may falsely reassure women that their recent act of unprotected intercourse did not result in pregnancy (174).

Offer ECPs over the counter. Most women decide for themselves when they need emergency contraception, and a physical exam is not necessary. Therefore, well-labeled ECPs should not require a prescription and can be offered over the counter (123, 473). Over-the-counter access can make treatment more effective because women can get ECPs sooner. On June 1, 1999, the progestin-only ECP NorLevo was granted over-the-counter status in France. This is the first dedicated EC product to become available over the counter in a major market (32). A study conducted by the Population Council in India found strong support for over-the-counter provision of ECPs among women themselves (230). Some argue that contact with a health care provider for ECPs is an important point of entry into the health care system for some women, as well as an opportunity to discuss ongoing contraceptive needs (23). While counseling is valuable when providing any contraceptive method, access to ECPs should
not be denied because a health care provider cannot counsel the woman face to face. Women can learn about ECPS in other ways. If necessary, pharmacists can give women ECPS and refer them elsewhere, if they wish, for later counseling about ongoing contraception.

Serve groups with special needs

Youth. There are many reasons that adolescents especially need ready access to ECPS. The psychological, social, and health risks of an unwanted pregnancy are especially great for adolescents (298, 541). At the same time, sexual activity among youth tends to be more sporadic and less likely to be planned for than among adults, and young people may be more likely to take risks. Furthermore, as US research finds, adolescents tend to wait some time between starting sexual activity and seeking reproductive health care, including contraception (46, 136). Because family, school, and society at large often disapprove of adolescent sexual activity, many young people lack adequate and appropriate information on sexuality and family planning as well as access to reproductive health care (541). Not only can emergency contraception help prevent unwanted pregnancies and abortions in this vulnerable group, but also providing ECPS sometimes can create opportunities to offer other reproductive health services and counseling about healthy sexual behavior (53, 541).

Women suffering domestic violence. Emergency contraception is a pressing need for many battered women (33). Women abused by their husbands or boyfriends often are unable to negotiate the timing or the terms of sexual intercourse (see Population Reports, Ending Violence Against Women, Series L, No. 11, December 1999). A violent sexual partner may prevent a woman from using ongoing contraception, thus putting her at risk of an unintended pregnancy (292). Some women cannot discuss contraception with their partners for fear that it would spark abuse (193). An unintended pregnancy can also prompt a violent episode from an abusive partner (266). Thus access to ECPS is especially critical for battered women. ECPS should be available whenever women may seek help or refuge, such as hospital emergency rooms, counseling centers, and women's shelters (129).

Refugees. Refugees often are cut off from a supply of contraception. Furthermore, women are targets for sexual violence while both fleeing and once they arrive in refugee camps. For example, an International Rescue Committee assessment of Burundian refugees in an established camp found that 26% of women ages 12 to 49 had experienced sexual violence since becoming refugees (322). Thus emergency contraception should be available as a part of reproductive and mental health services for refugees (165). Humanitarian aid groups increasingly are making ECPS available in times of crisis (151, 470). The WHO New Emergency Health Kit (NEHK) and the Minimal Initial Service Package (MISP) both include written guidelines and supplies for emergency contraception (338). The High Commissioner for Refugees, the United Nations Population Fund, and WHO have produced a refugee reproductive health manual that includes guidelines for counseling and treating refugee women who are victims of sexual violence. The manual covers provision of ECPS (477).

For More Information

The Committee for Emergency Contraception operates an Internet website in English, French, Spanish, and Portuguese. The site offers information and advocacy materials as well as a newsletter on the status of ECPS worldwide (http://www.paxth.org). The Committee also produces Emergency Contraceptive Pills: A Resistance Packet for Health Care Providers and Program Managers. This packet contains a training curriculum, sample client brochures, a medical guide, answers to common questions about EC, guidelines for instruction, and a list of selected references. Contact: Elisa Wells, Contraception Coordinator, 1224 Purdue Street, Anchorage, AK 99504, USA. By email: paxth@paxth.org.

Princeton University Office of Population Research operates a website with information on emergency contraception, a guide to US clinicians who provide emergency contraception, and country-specific information on dosage of commonly available contraceptive and any specific methods of emergency use (http://www.princeton.edu/~paxth or http://www.not-2-time.org).

MEXFAM runs a website in Spanish and English with information on contraception, including ECPS. The site also includes dosages and instructions for emergency use of pills commonly used in Mexico (http://www.mexfam.org.mx).

Pathfinder International publishes a comprehensive reproductive health and family planning training curriculum with a module 53 that specifically addresses emergency contraception. The manual is available on the Pathfinder International website (http://www.pathfinder.org) or by writing to its Medical Services, Education, Pathfinder International, 5 Calle Street Suite 217, Worcester, MA 01612, USA.

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Other Health Risks

OCs have been associated with changes in carbohydrate metabolism and with increased risk of gallbladder disease and noncancerous liver tumors.

Carbohydrate metabolism and diabetes. Combined oral contraceptives may affect carbohydrate metabolism in two ways. The estrogen component is thought to increase glucose levels and supplies the insulin response to them. The higher the dose, the more pronounced (23, 156, 540). The progesterone component has been hypothesized to stimulate overproduction of insulin, a suspected risk factor for atherosclerosis (96, 544, 545). In low-dose OC users with initially normal glucose levels, these responses seldom exceed the normal range. These women face no apparent risk of developing diabetes (143, 152, 158, 171, 185, 385).

Can women with diabetes use combined OCs? Diabetics, whose insulin response to increases in glucose is already suppressed, may still be able to use low-dose OCs, depending on the severity of their diabetes. If they are insulin-dependent, their insulin requirement may increase, although with low-dose pills this does not appear to happen often (48, 303). Diabetics may choose a form of contraception that avoids continuing the oral contraceptive pill and who have had diabetes for over 20 years (and therefore may have suffered vascular damage) generally should choose another family planning method (557). Women with a history of diabetes in pregnancy or a family history of diabetes can safely use combined OCs without special medical supervision (48, 177, 189, 190, 228, 280, 530).

Gallbladder disease. OCs probably do not cause gallbladder disease, but instead they may accelerate the development of gallstones in already susceptible women. Gallstones are caused by abnormalities high saturation of bile with cholesterol. Cholesterol saturation is higher in OC users than nonusers, possibly due to estrogen (432, 526).

After finding a higher risk during the early years of OC use, the major cohort studies did not detect any elevated risk of gallbladder disease among long-term OC users. The lack of long-term risk suggests an acceleration effect in women with already high cholesterol saturation (318, 375, 494, 526). An analysis of the results of several studies from the 1970s and early 1980s concluded that OC use is associated with only a slight increase in the risk of gallbladder disease (458).

There may be little or no increased risk with low-dose formulations (458, 494). More recent analyses have found either no increased risk of gallbladder disease or, at most, a small, transitory increased risk among current OC users. An analysis of 25 epidemiologic studies concluded that only nine studies used rigorous methodology. These nine studies detected a 30% to 40% increased risk of gallbladder disease in OC users, although the increases were not statistically significant. Since 1982 no studies have reported relative risks as high as 1.5 (458).

Because of concerns that OCs may worsen existing gallbladder disease, WHO recommends that women with current symptoms of the disease should choose another method if possible (530).

Noncancerous liver tumors. Noncancerous liver tumors (hepatocellular adenomas), which are rare, are somewhat more frequent in OC users than in nonusers. They can be fatal (61). Their incidence increases with higher estrogen dose and longer OC use. Studies in the 1970s of women using higher-dose pills estimated that three cases attributable to OCs would occur per 100,000 users per year. With today's low-dose OCs, this rate may be lower (277), but new studies have not been conducted. (See p. 31 for discussion of liver cancer and OCs.)
Drug Interactions
Contraceptive hormones can interact with certain other drugs, reducing the effectiveness of OCs or modifying the effects of the other drugs. Pregnancies and breakthrough bleeding due to interference with contraceptive hormones have been reported in OC users taking:
- The anticonvulsant drugs carbamazepine, ethosuximide, methylenephobarbital, phenobarbital, and phenytoin, primidone, and topiramate;
- The antitubercular antibiotic rifampicin; and
- The antifungal drug griseofulvin.
Although anecdotal reports have suggested that broad-spectrum antibiotics such as amoxicillin and tetacycline might also interfere with OC effectiveness, research has not demonstrated this. (18, 19, 23, 333, 377, 418-422, 450, 500).

If a user of low-dose OCs is taking any of these drugs, she can increase her contraceptive protection by using an additional method of contraception while continuing with her daily pill, or she can change to an OC with 50 µg estrogen. If she uses the drug for less than a month, she should continue using her back-up contraceptive method or different pill regimen for at least 3 weeks after stopping the drug. If her cycle of 21 contraceptive pills ends during this week, for best protection she can start the next cycle of pills immediately. If she is using 28-day pill cycles, she can skip the seven placebo or iron tablets and start the next cycle of pills immediately (178, 189).

Unresolved Health Issues
OCs have proved safe for most women. Still, several important health issues remain unresolved, even though the perspective of these issues has become clearer. Of particular concern are associations between OC use and neoplasia of the cervix and breast. Women who use OCs may have slightly elevated risks of being diagnosed with cervical neoplasia and early occurring breast cancer—risks which disappear within 10 years after discontinuing use. In both cases screening bias cannot be ruled out as an explanation for the apparent risks. The OC users studied tended to have more regular gynecological care than other women, and thus early cancer may be more likely to be detected in these women. OC use has been linked to an increased risk of certain reproductive tract infections, including HIV. While an association is biologically plausible, possible methodological problems make interpretation difficult. Finally, results of recent studies conflict as to whether OCs are linked to hepatocellular carcinoma, a rare form of liver cancer.

Cervical Cancer
Certain strains of human papillomavirus (HPV) are widely considered to be the primary initiator of cervical cancer. Epidemiologic evidence remains inconclusive on whether OCs play any associative role in the development of cervical cancer. Most early studies found no link between OC use and malignant or premalignant cervical neoplasms. In general, the earlier studies did not include long-term OC users (491). Recent studies have been fairly consistent in finding somewhat greater risk of cervical cancer or its precursors among users of combined OCs than among other women (112). Whether this reflects a cause-and-effect relationship is not clear, however.

Epidemiologic findings on preinvasive lesions, most studies in the past 10 years have found an association between OC use and cervical intraepithelial neoplasia (CIN) and carcinoma in situ (CIS), collectively described as preinvasive lesions. Preinvasive lesions fall into two general categories: LSIL (low-grade squamous intraepithelial lesions), which correspond to mild dysplasia (abnormal tissue development), and HSIL (high-grade squamous intraepithelial lesions), which correspond to moderate and severe dysplasia and CIS (44).
Preventing Cervical Cancer

Cervical infection with some types of human papillomavirus (HPV) appears to cause most, if not all, cases of cervical cancer (126, 372). A recent analysis of 1,000 cervical cancer specimens collected worldwide found evidence of HPV infection in 98.7% of the samples (502). Many women develop HPV infections, but few go on to develop cervical neoplasia. HPV infection usually is transient and clears without treatment (199). Apparently, cancer arises from infections that persist—perhaps those lasting six months or more (203, 383).

Avoiding HPV

Primary prevention of cervical cancer is the ideal, and that means minimizing exposure to HPV. A woman can reduce her exposure to HPV and other sexually transmitted disease organisms by using a barrier method of contraception—preferably condoms, but perhaps also diaphragms and spermicides—whether or not she also uses another family planning method such as OCs. Abstinence and delaying first sexual intercourse also reduce the risk (173). The behavior of women's sexual partners is important. Men who were young when they first had sexual intercourse, who have multiple sexual partners, or who visit prostitutes regularly increase their partners' risk of cervical cancer significantly (107, 317, 402).

It may be particularly difficult for a sexually active woman to avoid HPV. Identifying an uninfected sexual partner—and knowing one's own status—is not possible without testing. Moreover, the types of HPV that cause cervical cancer do not cause warts (235) or any other obvious symptom. At the same time, the virus is very common. Condoms are helpful, but HPV can spread through contact between areas of the body near the anus or genitals that a condom does not cover (423). HPV vaccines are being developed, but the availability of a safe and effective vaccine is probably over a decade away (215, 372).

Relative risks of pre-invasive lesions were for the most part less than 2.0—for example, 1.3 for ever-use (54601, 1.4 for past users (169), and 1.8 for low-grade lesions (323). A Swedish study found curious use of OCs to be associated with a fourfold increase in risk of pre-invasive lesions overall; risk increased with duration of use (547). One recent study, however, found no association between OC use and pre-invasive lesions (180). For women who had used OCs for five years or more, several recent studies report about a doubling of risk compared with women not using the pill (46, 47, 245, 546). Studies that have looked at various grades of pre-invasive lesions, however, have reported inconsistent findings (46, 251, 323).

Epidemiologic findings on invasive cancer. As with pre-invasive lesions, most studies in the past decade have found that long-term OC use is associated with a slight increase in risk of invasive cervical cancer (304). In many of these studies risk increased with duration of use (43). An analysis of 14 studies found relative risks of invasive cervical cancer to be 1.37, 1.60, and 1.77 for 4, 8, and 12 years of OC use (410).

While HPV infection may initiate most or all cervical cancers, cigarette smoking poses an increased risk (532, 527), and avoiding smoking will limit risk. A diet rich in vitamin C may also help (173).

Screening

Since most women cannot eliminate all chances of exposure to HPV, where feasible, women should be screened for cervical lesions. The Pap test (Pap smear) is the current standard screening method. Pap smears can identify cervical neoplasia at early stages, when treatment is almost always effective. Countries that have instituted national screening programs have seen declines from cervical cancer decline to one-third or less of previous levels (384). Unfortunately, comprehensive Pap screening is practically nonexistent in developing countries, where cervical cancer is the most common type of cancer among women.

A more feasible screening technique appears to be on the horizon. Visual inspection of the cervix after an acidic acid (vaginal) wash—also known as cervicovaginal or VIA—offers a low-cost, low-tech alternative to the Pap smear. Lesions appear white after application of vinegar and can be seen with a flashlight (220). In Zimbabwe nurse-midwives using this method accurately detected more than 75% of pre-invasive lesions compared with 44% with Pap smears (479). Similarly, in India paramedical personnel could accurately detect pre-invasive and invasive lesions using VIA (402). In India, VIA was as specific—able to detect accurately women who do not have pre-invasive or invasive lesions—as a Pap smear (402), while in Zimbabwe VIA was less specific than a Pap smear (479). Early detection allows for early treatment with low-cost, easy methods such as cryotherapy—freezing the cervix with a liquid coolant to destroy abnormal tissue—that some midwives and many other health care providers can administer (220).

Some evidence suggests that OCs accelerate the progression of precancerous lesions to invasive cancers. Any increased risk may be concentrated in women who have sexual partners with risk factors that increase susceptibility to HPV, where feasible, where the women are young when they first have sexual intercourse, who have multiple sexual partners, or who visit prostitutes regularly increase their partners' risk of cervical cancer significantly (107, 317, 402).

Integrating the findings. A number of biological mechanisms have been proposed to explain an association between OCs and cervical neoplasia. Currently, no firm evidence favors any one of these mechanisms. There has been suggested that OCs might: (1) promote the growth of existing lesions, (2) change cervical mucus to increase tissue susceptibility to HPV (491), (3) alter immune response to HPV to increase susceptibility to HPV, (4) produce a folate deficiency in the cervix that could stimulate development of abnormal lesions (183, 216, 350, 426).

27
There is fairly strong evidence associating cervical neoplasia and OCs may reflect the difficulties of studying the issue rather than causal relationships. First, OC use may be part of larger behavior patterns that also increase the risk of cervical cancer (46-48). Second, cervical neoplasia may be more easily detected in OC users than in other women (detection bias). These difficulties are hard to overcome completely. Furthermore, the biological factors that influence the development of cervical cancer are complex.

Behavioral factors. Studies of cervical cancer and OCs may need to take account of both sexual behavior and smoking. Sexual behavior, particularly age of first intercourse, lifetime number of sexual partners, and use of barrier contraception, are known to affect the risk of developing cervical cancer. Younger age at first intercourse and more partners raise risks. Condom use lowers risks. If women choose OCs because they start sexual activity early or have many sex partners, and they do not use condoms, studies would find a noncausal association between OC use and cervical cancer (46).

There is fairly strong evidence associating cervical cancer and cigarette smoking (523, 527). Several studies suggest about a twofold increase in risk for smokers compared with nonsmokers (46, 102, 168, 547). A Danish study suggested that OC users who smoke are at particularly high risk of cervical cancer. Among women using OCs for six years or more, smokers had a relative risk of 6.0 compared with 2.2.

Detection bias. In developed countries OC users tend to have more Papanicolaou (Pap) smears than other women do to test for cervical cancer and its precursors (523). Therefore, asymptomatic cervical neoplasia may be detected earlier among OC users, and false positive diagnoses may be more common. Changes in the cervix induced by OCs may make pre-invasive lesions easier to detect; or they might make OC users more susceptible to vaginal infections that can be mistaken for pre-invasive lesions (116, 118). In either case the result would be detection of more lesions in OC users, but not necessarily progression.

Biological factors. Cervical cancer develops slowly. Invasive cancer apparently occurs at the end of a slow progression from pre-invasive lesions. But must mild, and many moderate, pre-invasive lesions regress spontaneously (193, 209). Very few go to invasive cancer (321, 384). Risk factors for progression at each stage—and for progression to invasive cancer—may vary (441). Hypothetically, OC use could have an independent effect or act as a cofactor at any stage. Thus a causal link between OC use and preinvasive lesions—if established—would not necessarily imply a link to invasive cancer (184, 346). Research needs to explore why some preinvasive lesions progress while most regress, and what role, if any, OCs play in progression. Because HPV is the primary cause of cervical cancer (see box, p. 27), researchers have looked for a connection between OCs and the risk of acquiring HPV infection. Findings are mixed. Some studies have reported that OC users are significantly more likely to acquire or have an HPV infection (539, 271, 283, 323, 395, 459, 487). Others have not (51, 198, 213, 279, 367, 436, 489). Some studies have not consistently controlled for sexual behavior, however. HPV targets cervical cells that are actively dividing (344). OCs increase cervical ectopy—the expression of sensitive columnar epithelial cells from the cervix into the vaginal surface of the cervix. Thus it is possible that OCs could enhance susceptibility of the cervix to HPV infection (210).

Breast Cancer

The possible role of OCs in the development of breast cancer has been debated for over 30 years. Some breast cancers are hormone-dependent, and breast cancer is an increasingly common cause of death among older women, particularly in developed countries. Thus many studies have sought to find out if OC use affects the risk of developing breast cancer (321). In 1996 the Collaborative Group on Hormonal Factors in Breast Cancer published an analysis that pooled epidemiologic evidence from 54 studies in 25 countries (82, 83). Covering over 53,000 women with breast cancer and over 100,000 without breast cancer, these 54 studies constituted more than 90% of the epidemiologic evidence available at the time. The analysis examined a great many characteristics of OC use and users. The observation was concise and sober: "Women who had used OCs for at least 5 years had slightly (5-10%) higher breast cancer risk than nonusers." Findings from the pooled analysis include:

- Overall, women currently taking OCs or who have quit within the past 10 years were slightly more likely than nonusers to be diagnosed with breast cancer.
- St. Paul
• Risk was greater for current users and decreased with time between last use and diagnosis. Relative risk was 1.24 for current users, 1.16 for women who had stopped use within one to four years before diagnosis, and 1.07 for women who had stopped use five to nine years before diagnosis.

• There was no additional risk for OC users who discontinued use 10 to 19 years before diagnosis. In some subgroups former OC users faced less risk than nonusers.

• The excess risk of breast cancer diagnoses in OC users was solely for cancers that were localized. OC users actually had a reduced risk of cancers that had spread beyond the breast.

• Women who used OCs before age 20 faced somewhat higher relative risk, when compared with nonusers of the same age, than women who used OCs later in life.

• Whether a woman first used OCs before or after she first gave birth did not appear to make much difference.

• For women with a family history of breast cancer, OC use did not seem to increase risk particularly.

• Duration of OC use did not affect risk.

• Data were limited, but risk did not appear to be related to the type of estrogen or progestin, and the only dose-related difference was a reduction in breast cancer among women who had used the highest dose pills more than 10 years before.

This pattern of findings suggests two possible explanations of a relationship between OC use and breast cancer. First, OCs may promote the growth of an already existing tumor. The observations that relative risk is greatest during and soon after OC use and that duration of OC use has no effect on risk argue that OCs do not initiate new tumors. Second, OC users may simply have more frequent and more careful breast exams than other women, and thus their tumors may be found at an earlier stage. The fact that the entire excess risk of breast cancer diagnosis occurs for tumors that are localized and that OC users actually have a reduced risk of cancers that are spread beyond the breast strongly supports this possibility.

The Collaborative Group researchers comment:

The relation observed between breast cancer risk and hormone exposure is unusual, and it is not possible to infer from these data whether it is due to an earlier diagnosis of breast cancer in users, the biological effects of hormonal contraceptives, or a combination of both factors (82). The finding that the modest additional risk is greatest during OC use and eventually disappears after a woman stops OCs has important public health implications (521). Because most women use OCs when they are young, and breast cancer is extremely rare at young ages, the number of breast cancer cases attributable to OC use would be quite small. The Collaborative Group's estimate, among 10,000 European or North American women using OCs from ages 16 to 19, an additional 0.5 cases of breast cancer would be diagnosed in the 10 years after these women quit OC use—among those using OCs from ages 20 to 24, 1.5 additional cases; and among those using OCs from ages 25 to 29, 4.2 additional cases. Because of this age gradient, earlier OC use in a population does not lead to more cancers diagnosed overall (82). Generally, the numbers of additional cases would be smaller in developing countries, where breast cancer is less common (83). By 20 years after stopping OC use, there was no significant difference between women who used OCs at these ages and nonusers in the cumulative number of breast cancer cases diagnosed.

Since the Collaborative Group's analysis in 1996, OCs and breast cancer continue to be studied. A US study involving 744 breast cancer patients found effects largely compatible with the findings of the Collaborative Group, but for the most part increased risks were not statistically significant (480). A small case-control study in Nigeria found that women diagnosed with breast cancer were more likely to have used OCs. The analysis did not control for other risk factors such as age at first birth, however, and information about duration of use and pill formulation could not be obtained (51). Like the Collaborative Group analysis, the German Breast Cancer Study Group found that the breast tumors of OC users tended to be smaller at diagnosis. OC use did not significantly affect the length of recurrence-free survival or of overall survival, however (405).

Reproductive Tract Infections

The relationships between OC use and reproductive tract infections (RTIs), which include both those that are sexually transmitted and those that are not, are varied and complex.

A parade float promotes social marketed Nova brand oral contraceptives and injectables in Pakistan.
Greater risk of chlamydial infection among pill users could be due largely to cervical ectopy. Cervical ectopy is the extension of sensitive columnar epithelial cells from the cervical canal to the vaginal surface of the cervix. It is known to occur in OC users (121). Cervical ectopy may make columnar cells easier targets for C. trachomatis (17, 30, 94, 392). Several studies confirm a link between ectopy and chlamydial infection (284, 347, 374). These studies, however, could not determine which came first—ectopy or infection—and so it is not clear whether ectopy leads to infection or infection leads to ectopy. Similarly, in studies of chlamydial infection and OCs, it is possible that ectopy simply makes it easier to detect the infection (17, 505).

Chlamydial pelvic inflammatory disease (PID). For more than 10 years there has been considerable speculation about whether or not OCs actually offer some protection against PID caused by the ascent of chlamydial infection from the cervix to the fallopian tubes. Although OC users seem more susceptible to chlamydial infection than other women do, they are less likely to experience symptomatic chlamydial PID. For example, two recent studies found that pill users faced 20% to 30% as much risk of chlamydial PID as women using nonhormonal methods (242, 439).

How could OCs help protect against chlamydial PID? Possible explanations include reduced permeability of cervical mucus, reduced uterine contractions during menstruation, and alteration of immunological response (136). Whether any of these mechanisms apply, however, is not certain.

Furthermore, most studies of PID have involved only women hospitalized for PID, which accounts for less than one-quarter of cases (42). Women hospitalized for PID are not representative of all women who have PID. Chlamydial PID, moreover, is less likely to lead to hospitalization than other forms of PID because chlamydial PID tends to be milder and less often noticed (340).

Other reproductive tract infections. Possible associations between OCs and other RTIs have also been studied, although not as extensively as OCs and chlamydial infection. The use of OCs has been reported to increase the risk of gonorrheal infection by 70% (294, 392) and the risk of candidiasis, a common yeast infection that is not necessarily sexually transmitted, by 50% to 80% (467, 392). Findings on OCs and bacterial vaginosis are conflicting. One study found a significant increase in risk (647); some have found a significant decrease (116, 424); and another found no relationship between OC use and risk of bacterial vaginosis (178). There is some evidence that OCs help protect against Trichomomas vaginalis, a common cause of vaginitis (22), although not all studies have found a protective effect (331).

Human immunodeficiency virus (HIV). Studies fail to show clear and consistent associations between OC use and HIV infection. Studies of the risk factors for HIV infection vary widely in quality and methodology and are difficult to compare directly. For many, OC use was only one of a number of variables that were examined, and the potential relationship between OC use and HIV was not the focus of the study. Individual studies often showed elevated, although not statistically significant, risk of HIV infection among OC users. A recent analysis that pooled the results of all studies published or presented between 1985 and 1998 found a significant association between use of OCs and the incidence or prevalence of HIV infection. Based on these studies considered methodologically most sound, OC use was associated with
a 60% increase in risk (504). Studies of OCs and HIV may not be suitable for a pooled analysis, however. One recent review of the literature on the association between OCs and HIV infection concludes that studies to date suffer from methodological biases that make them inappropriate for combined statistical analysis (445).

Most individual studies have not found a statistically significant association between OC use and HIV infection (8, 63, 115, 128, 314, 403, 429). A study that examined the chances of infection per sexual contact found that HIV infection was less likely, although not significantly so, among OC users than among women who were not OC users and were not using a barrier method (319).

Several recent studies have found a significant association between OCs and HIV among various subgroups after adjusting for a variety of confounding factors. A perspective study of 435 HIV-negative Kenyan sex workers found that OC users were more likely to become HIV-positive than women not using OCs (291). One study of a Nairobi antenatal clinic—a group considered at low risk of HIV infection—found that OC users were 3.5 times more likely to be infected with HIV than women using other methods of contraception or no contraception at all. The association persisted after adjustments for variables such as frequency of intercourse, number of partners, and history of STI symptoms. Few of these women used condoms (429).

A cross-sectional study in Nairobi suggests that OC use increases the risk of HIV infection only among women with genital ulcers. OC use alone did not increase HIV risk. Women who had used OCs longer than 12 months and had genital ulcer disease, however, were 2.5 times more likely to be infected with HIV than women who did not use OCs and did not have genital ulcers. This finding was based on 196 women who were long-term OC users and had genital ulcer disease, 80% of whom were infected with HIV (362).

Some evidence has led to speculation that HIV-infected OC users could infect their partners more readily than other contraceptive users. A recent study of women who were long-term OC users and had genital ulcer disease found more often in the cervical and vaginal secretions of OC-users than in other HIV-infected women (77). Not all studies have found a link between OCs and HIV DNA levels, however (249).

The presence of another STI increases the risk of HIV infection by two- to sixfold (56, 91, 108, 114, 205, 232, 238, 256, 303, 339, 363). Bacterial vaginosis, which is often but not always sexually transmitted (201), also has been linked to increased HIV risk (414, 451, 507). If other STIs make women more susceptible to HIV infection, and OCs make women more susceptible to other STIs, then OCs might indirectly increase HIV risk (66, 217).

Liver Cancer

A number of case-control studies in developed countries have detected increased risks of a rare liver cancer, hepatocellular carcinoma, in OC users (139, 196, 254, 324, 454, 548). These studies reported risks among OC users about 2 to 20 times greater than risks among nonusers. The largest of these studies found that women using OCs for eight years or more were four times more likely to develop this liver cancer than nonusers (324). A recent study in six European countries (191) and a study of South African women (248) found no increased risk of hepatocellular carcinoma among short-term or long-term users.

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More research is needed in developing countries. Hepatitis B and C, which are the most important risk factors for liver cancer, are much more common in developing countries than elsewhere (191). It is not known whether or not OCs might interact with hepatitis infection to further increase the risk of liver cancer. A WHO study in eight developing countries where hepatitis infection is widespread found no increase in risk of liver cancer associated with short-term OC use. Few women in the WHO study had used OCs for more than three years (444).

Liver cancer is quite rare, but it is usually fatal within a year of diagnosis. Therefore, OCs significantly increased the risk of liver cancer, both incidence of the disease and mortality from it should have been noticed since the 1960s, when OCs were introduced. A recent study, however, found no evidence of increased incidence or mortality either in the US or in Sweden, two countries where OCs have been used extensively since the 1960s. Instead, the study found a gradual increase in incidence of liver cancer and resulting mortality in Japan, where OCs are seldom used (501).

Despite some lingering uncertainties, the benefits of oral contraceptives far outweigh the risks for the vast majority of women. Continuing research has made it possible to identify more clearly the few women who face substantial risks and should choose another method of contraception. Forty years after their introduction, OCs remain popular for their convenience, effectiveness, and safety.


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PAPeRPOPuLATIoN REGuLATIONS


The vast majority of current oral contraceptive users are women of reproductive age. Oral contraceptives are used to prevent pregnancy and may also provide other health benefits. However, they can have side effects and risks, including bleeding disorders, blood clots, and other serious health issues. It is important for users to be aware of these risks and to consult with healthcare providers regularly. The World Health Organization (WHO) has published guidelines on the use of oral contraceptives, and healthcare providers should review these guidelines with their patients. Additionally, providers should be aware of the potential for interactions between oral contraceptives and other medications. It is important to monitor patients for signs of adverse reactions and to follow up with them regularly to ensure their continued safety and health.
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