

# What Can We Do to Improve the Oral Contraceptive Success Rate?

*One million unintended pregnancies may be avoidable*

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Oral contraceptives (OCs) are among the most extensively studied and commonly prescribed medications used by women in the United States. The combined OC pill is a safe and effective birth control option that is currently being taken by 30% (18 million) of American women who are of reproductive age.

Of the roughly 5 million pregnancies that occur each year in this country, more than half (3.5 million) are unintended; 1 million are related to the use, misuse, or discontinuation of OCs.<sup>1</sup> This is an astonishing number of failures for a contraceptive method known to be 99% effective with ideal use.

Of all OC-related unintended pregnancies, 61% occur in women who discontinue use and fail to substitute a reliable method of contraception (Figure 1). Although 80% of US women use OCs at some point during their lifetimes, the average duration of use is slightly less than 5 years. Approximately half of new users discontinue OCs within the first year.

Another 15% of OC-related unintended pregnan-

**ABSTRACT:** Oral contraception is an important birth control method for many women, but its success depends on many factors. Many unintended pregnancies are attributable to either misuse or discontinuation of oral contraceptives (OCs). Patient characteristics such as adolescence, poor pill-taking techniques, lower socioeconomic status, previous unintended pregnancy, and preexisting fears about the effects of OCs (on appearance or health) are associated with higher failure rates. Side effects (eg, hair growth, nausea, bleeding irregularities) and drug interactions can also limit compliance and effectiveness. With these characteristics in mind, clinicians can identify patients at higher risk for failure and help them learn to use OCs more effectively. (*Women Health Primary Care* 1998;1(10):809-819)

cies occur in women who continue to use these agents but fail to do so properly.<sup>1</sup> It is known that less-consistent OC use is related to an increased risk of unintended pregnancy. It is estimated that 19% of women take their OC pills incorrectly and that adolescents make up a disproportionate share

of these women. Although 47% of sexually active teens rely on OCs as their primary method of birth control, 20% to 50% of those who use OCs do not take them as directed.<sup>2</sup>

The remaining 24% of OC-related unintended pregnancies occur in women who consistently maintain good compliance. Because of the large overall number of women who use OCs, even a low failure rate for this group of users results in a substantial number of unintended pregnancies.

If we are to improve the true effectiveness of this contraceptive method, health care providers must identify and address those characteristics of the patient or of the pill that predict inconsistent use and untimely discontinuation. This article will examine how clinicians can help patients use OCs effectively, why women discontinue use, how to minimize side effects, and how to avoid compromising drug interactions.

## USER CHARACTERISTICS

Product information citing a 3% failure rate for typical use is misleading for most OC users. The pregnancy

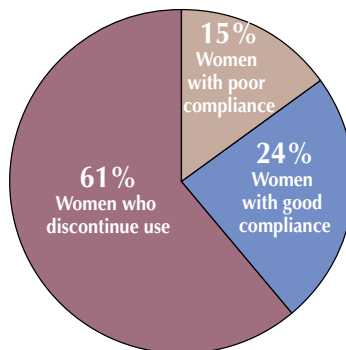
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rate often quoted for typical use is based only on married users; it increases to an overall rate of 7% when single women are included and underreporting of abortions is taken into account.

Typical failure rates for specific sociodemographic subgroups range from 2.8% to 28.8% (Figure 2), but effectiveness is highly variable even within subgroups.<sup>3</sup> The cumulative probability of pregnancy increases over time. Hypothetical long-term pregnancy rates can be estimated by multiplying the probabilities of not getting pregnant each year. Assuming that the risk of pregnancy in the first year of OC use is somewhat higher than in the second and third years of use, the cumulative chance of pregnancy over 3 years of OC use is 7% for married women and 62% for postpartum teens.<sup>4</sup>

Given the wide range of effectiveness of oral contraception, patients need to be counseled that their individual chance of becoming pregnant depends on their own fertility, the frequency and timing of intercourse, and the consistency with which they take their pills.

**Figure 1. One million unintended pregnancies each year are related to oral contraceptives**



**FACTORS AFFECTING QUALITY OF USE**

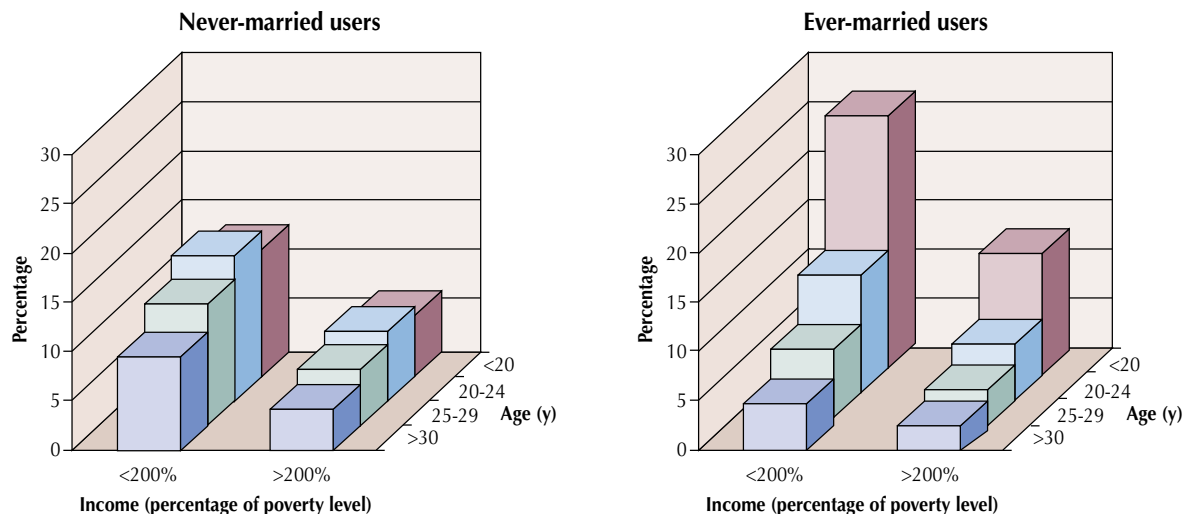
In the largest study to date investigating independent predictors of poor compliance and early discontinuation of OCs, Rosenberg et al<sup>5</sup> analyzed a convenience sample survey of 6,676 European adolescents and women ages 16 through 30. Although 81% of the group used their OCs consistently and effectively, 19% reported missing 1 or more pills per cycle; 10% generally

missed 2 or more pills per cycle.

The survey found that proper use was affected by many factors but that user characteristics most strongly predicted inconsistent use (Table 1). In particular, OC users who did not establish a regular pill-taking routine were 3.3 times more likely to be inconsistent, and those who understood "little or none" of the written package information were 2.2 times more likely to miss pills. Age alone was not found to be a significant predictor of either compliance or discontinuation when these other factors were taken into consideration.

Analysis of data on 1,485 OC users from the 1995 Survey of Family Growth identified other significant markers for poor compliance. Both Hispanic women and non-Hispanic black women were more than twice as likely as other women to report inconsistent use. Women who had initiated pill use within the past 6 months were 2.7 times as likely as long-term users to take pills inconsistently; and women with a previous unintended pregnancy were 1.6 times as likely as nulligravidas to be inconsistent.<sup>6</sup>

**Figure 2. Percentage of oral contraceptive users experiencing unintended pregnancy during the first 12 months of use**



Adapted from Jones EF, Forrest JD. *Fam Plann Perspect.* 1992.<sup>3</sup>

**USE IN ADOLESCENTS**

Adolescents who use OCs have been studied more extensively than any other age group. Their characteristics may not apply to all populations, but it is important to explore the factors contributing to the high failure rates of oral contraception in this population.

In the United States, 10% of women ages 15 through 19 become pregnant each year.<sup>7</sup> This rate is more than double that in any other industrialized country, despite comparable rates of sexual activity. Because most adolescents are at increased risk of OC discontinuation and subsequent pregnancy, careful selection of patients and counseling on all birth control options is essential.

A study of 280 teenagers who had chosen either OCs or levonorgestrel implants after an unplanned pregnancy found that 47% of the OC users stopped within 1 year, compared with 16% of the levonorgestrel implant users. Nearly one quarter of the OC group became pregnant, as compared with none in the other group.<sup>8</sup> In another study comparing depot medroxyprogesterone acetate and OCs in postpartum adolescents, approximately two thirds of young women in each group discontinued use by 12 months. Nevertheless, repeat pregnancy rates at 15 months were higher for those who had chosen OCs (36%) than for those who had received depot medroxyprogesterone acetate (15%).<sup>9</sup>

What influences an adolescent to choose OCs and to use them properly? When 345 teenage girls were interviewed about their beliefs regarding the pill, 3 beliefs were negatively related to both the intention to use OCs and the consistency of OC use during the subsequent year<sup>10</sup>:

- ◆ OCs affect physical appearance.
- ◆ OCs have minor effects on health.
- ◆ OCs have major long-term effects on health.

Neither intentions toward abortion nor intentions to use condoms were related to subsequent OC use, but teens who intended to use withdrawal as a contraceptive measure were less likely to use the pill in the following year.<sup>10</sup> Other studies have found that the following factors are predictive of poor OC compliance among teens<sup>11</sup>:

- ◆ Multiple sex partners.
- ◆ Low evaluation of personal health.
- ◆ Worry about becoming pregnant.
- ◆ Previous abortion.
- ◆ Feelings of guilt about sexual activity.

Although parental involvement

is a factor in this method and guide counseling efforts. Factors that relate to the pill itself also may play a role in OC failure by decreasing effectiveness and hindering compliance. Understanding how to prescribe OCs correctly, anticipate drug interactions, and minimize side effects helps providers and their patients succeed in preventing unwanted pregnancies.

Newer formulations of OCs using lower doses of estrogen and progesterone greatly reduce the risk of some serious cardiovascular and thromboembolic complications but do so at the cost of a more narrow pharmacodynamic

**Table 1. Risk indicators for missing pills**

Risk indicator	Relative risk
<b>User characteristic</b>	
Not taking pill at same time each day	3.3
Reading/understanding little or none of package information	2.2
Not receiving adequate information from provider	1.5
Previous pregnancies	1.4
Single, with no regular sex partner	1.3
Working-class status (referent to professional class)	1.2
<b>Side effect</b>	
Hair growth	2.1
Nausea	1.4
Bleeding irregularities	1.3
Breast tenderness	1.2
Data extracted from Rosenberg MJ, et al. <i>Contraception</i> . 1995. <sup>5</sup>	

has been shown to improve adolescent compliance with asthma medications, diabetic diet, and antibiotics, results are mixed regarding the effect of parental involvement in contraceptive compliance.

**METHOD CHARACTERISTICS**

Patient-specific characteristics can clearly influence the risk of unintended or mistimed pregnancy in OC users. Recognizing patients who may be at high risk for discontinuation or poor compliance can assist appropriate patient se-

lection for this method and guide counseling efforts. With these drugs, it is more important than ever for women to adhere to consistent timing of daily doses to avoid unintended pregnancy or the bothersome side effect of irregular bleeding. Tablets that are missed just before or just after the pill-free interval are more likely to result in unintended pregnancy, because increasing the pill-free interval increases the chances of follicular development. It is unclear, however, precisely what dosing interval is safe at any given point in the

**Table 2. Androgenic activity of oral contraceptive progestins**

	Progestin*		Ethinyl Estradiol* (µg)	Examples
	Type	Dose (mg)		
<b>Low</b>	Desogestrel	0.15	30	Desogen Ortho-Cept
	Levonorgestrel	0.10	20	Alesse
	Norethindrone	0.5	35	Brevicon Modicon
	Norgestimate	0.250	35	Ortho-Cyclen
	Norgestimate	0.180, 0.215, 0.250	35	Ortho Tri-Cyclen
<b>Medium</b>	Ethinodiol diacetate	1.0	35	Demulen 1/35
	Levonorgestrel	0.050, 0.075, 0.125	30, 40, 30	Tri-Levlen Triphasil
	Norethindrone	1.0	35	Norinyl 1+35 Ortho-Novum 1/35
	Norethindrone	0.5, 0.75, 1.0	35	Ortho-Novum 7/7/7
	Norethindrone	0.5, 1.0, 0.5	35	Tri-Norinyl
<b>High</b>	Levonorgestrel	0.15	30	Levlen Nordette
	Norgestrel	0.3	30	Lo/Ovral
	Norgestrel	0.5	50	Ovral

\* In instances where multiple doses are given, the amount of progestin or ethinyl estradiol varies throughout the cycle.

cycle.<sup>12</sup> Therefore, women should be strongly encouraged not to miss or mistime any of their pills.

**DRUG INTERACTIONS**

The effectiveness of OCs may be compromised by a small number of clinically significant drug interactions. Medications that induce microsomal liver enzymes (such as the antibiotic rifampin or the anti-convulsants phenobarbital, phenytoin, carbamazepine, primidone, and ethosuximide) increase the breakdown of estrogen and progesterone. For women receiving these medications, contraceptive efficacy can be restored by using a higher dose OC containing 50 µg ethinyl estradiol, with another increase in dosage if breakthrough bleeding occurs.

Other antibiotics may decrease OC effectiveness by increasing fecal or urinary estrogen excretion or decreasing enterohepatic recirculation. Anecdotal reports of OC failures in women using most antibiotics have not been substantiated by firm pharmacokinetic evidence of altered steroid blood levels. Any medication with side effects such as nausea, diarrhea, or drowsiness may decrease OC effectiveness by interfering with compliance or absorption.<sup>13</sup>

**THE IMPACT OF SIDE EFFECTS**

Most women who discontinue OC use while still wanting to avoid pregnancy do so because of side effects. Although user characteristics were the strongest predictors of poor compliance in Rosenberg’s

survey of 6,676 women,<sup>5</sup> early discontinuation was more strongly associated with the occurrence of side effects. Strongest predictors were nausea (relative risk [RR], 2.1), bleeding (RR, 1.9), breast tenderness (RR, 1.8), mood changes (RR, 1.8), and weight gain (RR, 1.4). Women reporting 2 side effects were more than twice as likely to stop taking their OCs, and women with 3 side effects were more than 3 times as likely to stop.<sup>5</sup> Since irregular bleeding can be either a side effect or a marker of poor compliance, women should be asked about this symptom in particular at follow-up visits.

**MINIMIZING SIDE EFFECTS**

In general, clinicians should prescribe a combination OC with the lowest doses of estrogen and progestin that will maintain contraceptive efficacy and minimize side effects. Estrogen-related side effects (eg, hypertension, nausea, and breast tenderness) are less common in women who take pills containing less than 50 µg ethinyl estradiol, and most patients should take low-dose formulations containing less than 35 µg.

Because so many of the available combination pills contain less than 35 µg ethinyl estradiol, the choice of a particular agent is influenced primarily by the progestin component and its relative androgenicity, as outlined in Table 2.<sup>14</sup> Some OC formulations may contain one of the new progestins; a brief description of these appears on page 815.

Brand names of pills listed in this article and its tables are designed to be not a comprehensive listing of all of the pills available, but rather a representative sampling of commonly available pill brands. Clinicians are encouraged to use the equivalent preparations that are available at the lowest cost to their patients.

#### ACNE AND HIRSUTISM

All low-dose combined pills tend to improve preexisting acne and hirsutism because they suppress a woman's own testosterone production. This benefit is greatest with low-androgenic preparations. If your patient experiences acne while taking OCs, try switching to an agent that contains one of the new progestins or to a pill with 35 µg estrogen (such as Ovcon-35, Brevicon, Modicon, or Demulen 1/35) to raise the sex hormone-binding globulin level.

#### WEIGHT GAIN

Significant weight gain is rare with the new progestins, with a mean gain of only 1 pound after 1 year. Most studies, in fact, show little or no effect on weight regardless of the formulation of the pill. Though it is usually unrelated to OC use, a patient who experiences weight gain may benefit from switching to a low-androgenic formulation.<sup>14</sup>

#### HEADACHE

OCs do not appear to influence the frequency or intensity of tension-type headaches, but they are one of the most common pharmacologic triggers for migraine. Women who have classic migraines with focal symptoms are not good candidates for OCs, because they may be at increased risk of thrombotic stroke. If a patient experiences tolerable headaches, advise her to continue taking OCs for 3 months because the headaches will most likely subside. If headaches continue, changing to a lower-dose estrogen preparation may be helpful.<sup>14</sup>

#### NAUSEA AND BREAST TENDERNESS

These are estrogen-related effects that usually abate with continued OC use. Nausea and breast tenderness may also improve if the patient is given a lower-estrogen formulation, such as Alesse (which has 20 µg of ethinyl estradiol) or Desogen or Ortho-Cept (both of

eliminating caffeine from the diet, wearing a support bra, or taking vitamin E supplements.

#### IRREGULAR BLEEDING

The frequency of breakthrough bleeding has increased as estrogen doses have decreased to make OCs safer. Patients should be reassured

that this side effect usually subsides over the first few cycles of use. Encourage your patient to take her pill at the same time each day to avoid this problem.

If irregular bleeding persists after 3 or 4 months of use, it is important to rule out cervical infection or cancer, uterine fibroids, pregnancy, and endometriosis. Smoking has also been shown to promote spotting and breakthrough bleeding. It may be helpful to increase the progestin potency by switching to formulations such as those found in Lo/Ovral, Nordette, or Levlen. The clinician may also increase the estrogen potency during the time of breakthrough bleeding by daily supplementation with ethinyl estradiol (20 µg) or conjugated estrogen (0.625 mg).<sup>13</sup>

#### IMPROVING EFFECTIVENESS

Characteristics specific to both the patient and the pill affect the likelihood of success with OCs. Provid-

ers can use this information to better select and counsel patients about OC use. Several concrete suggestions emerge from the literature on OC failures.

*Individualize the contraceptive choices:* Your patient's background, beliefs, and lifestyle influence her

## The new progestins

Norgestimate, desogestrel, and gestodene (not yet available in the United States) are the newest progestins; they increase serum levels of sex hormone-binding globulin, decrease free testosterone concentrations, and have a greater affinity to progesterone binding sites. Several studies have suggested that this decreased androgenic potential minimizes side effects such as amenorrhea, weight gain, acne, and hirsutism. OCs containing these progestins may also better ameliorate preexisting acne and hirsutism than do older formulations, without producing a higher incidence of irregular bleeding, headache, nausea, breast tenderness, or mood changes.

In contrast to the older OCs, which produced adverse effects on lipid metabolism, the new progestins lead to an increase in HDL cholesterol and a decrease in LDL cholesterol levels. However, they do not appear to offer any major advantages over formulations using the lowest doses of norethindrone in terms of androgenic symptoms or metabolic effects.<sup>13</sup> It is not yet known whether the decrease in androgenic potency will have any undesirable side effects, particularly in regard to libido. Furthermore, controversial observational data suggest a slightly increased risk of venous thromboembolism in users of gestodene and desogestrel. Therefore, some clinicians have suggested avoiding use of these agents in women who have not previously used OCs.

which contain 30 µg of that hormone). A progestin-only pill could be used as a last resort.

Patients experiencing nausea should be advised to take their pills after meals or at bedtime. Anecdotal reports suggest that breast pain may be reduced or alleviated by

chance of successful OC use. Address her particular risk factors, needs, and concerns to improve her likelihood of proper use and continuation.

*Discuss possible side effects:* Reassure your patient that she can expect most side effects to be transient. Encourage her to let you know if side effects are interfering with compliance.

*Dispel common misperceptions:* While some studies have suggested that OC use carries a possible increased risk of breast, cervical, or liver cancer, any such risks are well balanced by a proven decrease in the risk of ovarian and endometrial cancer. Other noncontraceptive

benefits include some protection against pelvic inflammatory disease and endometriosis, alleviation of perimenstrual symptoms, and decreased incidence of functional ovarian cysts and benign breast tumors. It is safe for nonsmokers without cardiovascular disease to use OCs into their 50s.

*Give specific instructions:* Instruct your patient to take her pill at the same time each day to improve effectiveness and decrease breakthrough bleeding. Provide her with clear instructions about what to do if pills are missed, and reinforce the guidelines provided in package inserts.


*Have a backup plan:* Identify

an alternative contraceptive method that is readily available if OCs are discontinued by your patients.

*Encourage condom use:* Remind your patients that OCs do not protect against HIV, cervical cancer, or other sexually transmitted infections.

*Provide written material:* Make sure it is easy to understand, and encourage your patient to read it!

*Talk about emergency contraception:* Educate all women about emergency postcoital contraception should the need for it arise. Two doses of enough tablets to provide at least 100 µg ethinyl estradiol each, taken 12 hours apart, are usually effective if begun within 72 hours after unprotected intercourse. An antiemetic should be taken a half hour before each dose. Consider supplying your patient with a prescription for an antiemetic and with specific instructions for using the contraceptive pills she has on hand.

Recently, the Food and Drug Administration approved an emergency postcoital contraceptive kit. The Preven Emergency Contraceptive Kit consists of 4 tablets that each contain 0.25 mg levonorgestrel and 0.05 mg ethinyl estradiol. Also included in the kit is a urine pregnancy test, for use prior to taking the tablets (to confirm that pregnancy has not occurred earlier in the cycle). Two tablets are taken within 72 hours of unprotected intercourse and 2 tablets are taken 12 hours later. An antiemetic medication should also be used with this product. 

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## PRIMARY POINTS

## Oral Contraceptives

Although 47% of sexually active teens rely on OCs as their primary method of birth control, 20% to 50% of those who use OCs do not use them as directed.

Patients need to be counseled that their individual chance of becoming pregnant depends on their own fertility, the frequency and timing of intercourse, and the consistency with which they take their pills.

The majority of women who discontinue OC use while still wanting to avoid pregnancy do so because of adverse side effects. Women should be reassured that most of these side effects are transient or can be alleviated by a change in the OC formulation.

Any medication with side effects such as nausea, diarrhea, or drowsiness may decrease OC effectiveness by interfering with patient compliance or drug absorption.

Careful patient compliance is crucial for successful OC use. Misconceptions about OCs must be dispelled, and patients should be instructed in how and when to take the pills, and what to do if pills are missed.

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