

Oral Contraceptive Use and Protective Behavior After Missed Pills

By Deborah Oakley, Linda Potter, Emelita de Leon-Wong and Cynthia Visness

A three-month prospective study of 103 women initiating oral contraceptive use examined how consistently the women took their pills and whether those who missed pills employed other means to avoid pregnancy. The results showed that 52% took each active pill or never missed more than one pill at a time after the first week of the initial cycle, according to electronic devices that recorded the date and time each pill was removed from the blister pack. Another 21% were protected by behaviors that reduce the risk of pregnancy when two or more consecutive pills have been missed: avoiding coitus for the next seven days (18%) or using backup contraception during that period (3%). The remaining 27% were at increased risk of pregnancy. Predictors of increased risk were receiving low partner support for effective pill use, being unmarried and not considering it especially important to avoid pregnancy. Increased risk was most likely during the first seven days and during the third cycle of pill use.

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Depending on their demographic characteristics, 3–27% of U.S. women using oral contraceptives become pregnant during their first 12 months of use.¹ The reasons for such large differentials are not known, but recent data show that women's use-related behaviors merit closer attention than they have so far received.² The risk of pregnancy is lowest for oral contraceptive users who use barrier protection any time they have coitus during the initial seven days of pill-taking and take all of the ac-

tive pills (the first 21 of each 28-day cycle) without interruption. Oral contraceptive protection is expected to decrease when two or more consecutive hormonally active pills are skipped.³

It is not uncommon for prolonged intervals to occur between doses of self-administered medication.⁴ Between one-third and one-half of users of medications in pill form miss enough doses to place themselves at therapeutic risk at least occasionally.⁵ Self-reports have shown that 3–60% of oral contraceptive users, depending on the population studied, miss pills.⁶

An increased risk of unintended pregnancy has been documented among women who have reported missing pills,⁷ but this risk can be modified by two factors: the timing of coitus and the use of backup contraception. The instructions for correct oral contraceptive use that are included in all patient package inserts, which have the approval of the U.S. Food and Drug Administration, state that coitus should be avoided for the first seven days after initiating oral contraceptive use, whenever two or more consecutive active pills are missed and when the hormone-free week is extended by more than one day. They also state that if coitus occurs

during any of these intervals, an additional, backup contraceptive method (such as condoms) should be used until the woman has been taking hormonally active pills again for seven consecutive days.

In this research note, we document the proportion of a sample of women who missed contraceptive pills during the first three months of use, as well as the proportions who were consistently protected against pregnancy by avoiding coitus or using backup contraception after missing pills. We also identify characteristics of women who were at increased risk of pregnancy during their first three months of oral contraceptive use.

Methods

In an earlier study, based on the same sample of women, we compared self-reports and electronic records of presumed pill-taking; details about the sample, methods of data collection and statistical tests are in the previous report.⁸ Briefly, participants were 103 women initiating pill use (for the first time or after six or more months since last using the method) who were recruited from university student health services and Title X-funded clinics in Michigan and North Carolina in 1993–1994.

Upon entering the study, the women completed a baseline questionnaire and received a free cycle of pills in a dispenser with an electronic monitoring device, as well as a monthly diary card on which they were asked to record a variety of information. The women were counseled to use condoms for any act of coitus during their first week of pill use and to use backup contraception for seven days if they missed two or more consecutive active pills. At the end of each of the first two pill cycles, the women completed another questionnaire and received the next free cycle of pills and a new diary card; they completed a final questionnaire at the end of the third cycle.

The questionnaire provided demo-

Deborah Oakley is professor at the Center for Nursing Research, University of Michigan School of Nursing, Ann Arbor. Linda Potter, visiting research collaborator at the Office of Population Research, Princeton University, was principal scientist at Family Health International (FHI), Research Triangle Park, NC, at the time this research was conducted. Emelita de Leon-Wong is senior biostatistician, and Cynthia Visness is research associate, FHI. This analysis was supported by a grant from the Henry J. Kaiser Family Foundation, Menlo Park, CA, and by in-kind donations by Ortho-McNeil Pharmaceuticals, the university health services at the Universities of Michigan and North Carolina, Planned Parenthood Centers of West Michigan, and the Wake County, North Carolina, Health Department. Partial support for this work was also provided by FHI with funds from the U.S. Agency for International Development. The views expressed in this article do not necessarily reflect those of any of the supporting agencies.

Table 1. Percentage distribution of pill users, by pregnancy protection status, according to cycle of pill use

Status	All cycles* (N=103)	Cycle 1* (N=103)	Cycle 2 (N=95)	Cycle 3 (N=89)
Always protected	72.8	93.2	87.4	75.3
No missed pills	52.4	84.5	79.0	60.7
Coitus avoided after missed pills	17.5	7.8	7.4	12.4
Backup used after missed pills	2.9	1.0	1.0	2.2
Ever at risk†	27.2	6.8	2.6	24.7
Total	100.0	100.0	100.0	100.0

*Excluding the first seven days of cycle one. †Missed pills, but took no protective action. Notes: Three women, each with one missed-pills episode, did not provide complete diary card data during those episodes; thus, their protection status with respect to coital activity and the use of backup contraception is unknown. The days for which protection status is unknown were deleted from this analysis. Ns differ by cycle because some women did not participate in the study for all three cycles.

graphic, reproductive and psychosocial information. Demographic variables included the woman's age, race, level of education and marital status. Reproductive factors included her prior use of oral contraceptives and number of pregnancies. Psychosocial variables included the importance to the woman of avoiding pregnancy now and her degree of comfort with discussing pill use, perceived likelihood of becoming pregnant if pills were not used, degree of planning in other aspects of life, expected ease of pill use and perception of her partner's support for effective pill use.

A microchip concealed in the bottom of the pill dispenser recorded the time and date when each pill was pushed out of the blister pack. The diary card, a commonly used tool to study pill-taking in a number of therapeutic areas,⁹ was formatted as a page from a calendar with a box for each day, and included a place to record the number of pills taken, whether or not the woman had had intercourse each day and what backup method, if any, she had used. Following procedures recommended to enhance the quality of diary card data,¹⁰ we gave careful instructions to participants at the beginning of the study.

For days when a woman had not had a sexual encounter, no information was collected about the reason. Thus, we cannot determine if she was avoiding intercourse on those days to prevent pregnancy. No data were collected about the identity of sexual partners, so it is not possible to know whether a woman's coital patterns and method use were related, for example, to whether or not she had a regular partner or to her number of partners.

*These include five episodes that occurred during the women's first seven days of pill use and were not included in the earlier report (see reference 2).

When a backup method was used, the participants were not asked whether this was for extra protection against pregnancy, to avoid sexually transmitted diseases or for both reasons. Condoms were the most commonly reported backup method; other methods were reported only occasionally. A few women recorded use of condoms for every or almost every coital act, presumably for protection against sexually

transmitted diseases. However, in most cases, additional methods were noted only when two or more consecutive pills had been missed—that is, for pregnancy prevention. Although electronic data show that self-reports underestimate pill-taking errors,¹¹ and self-reports of condom use have shortcomings,¹² daily self-report is the current standard source of information on coital acts and the use of backup methods of contraception.

Pill package inserts advise users that missing two pills consecutively or extending the seven-day hormone-free interval to nine or more days could put them at increased risk of pregnancy. Therefore, we defined each set of two or more pills missed consecutively and each hormone-free interval that was extended by at least two days, whether the days were missed at the beginning or the end of the interval, as a missed-pills episode. (We did not count a one-day extension of the hormone-free interval as a missed-pills episode, because it would have no effect on levels of follicle-stimulating hormone, a key indicator of ovulation.¹³)

For the first seven days of resumed use after a missed-pills episode, women were defined as not being fully protected hormonally. If another missed-pills episode occurred within those seven days, the seven-day count began again. Also, since the women had not been using the pill before entering the study, they were considered not fully protected hormonally during the first seven days, because it can take up to a week for the pill to suppress ovulation.¹⁴ Women who had at least one seven-day period (excluding the first week) when they were not fully protected hormonally but had coitus without using a backup method were categorized as ever having been at increased risk of pregnancy during the study period.

Results

The electronic records showed that half of the women never missed more than a single pill at a time during the study (in other words, they had no missed-pills episodes). Roughly one-quarter each had one missed-pills episode (26%) or two or more such episodes (24%); these 52 women had a total of 93 missed-pills episodes.* Forty-four missed-pills episodes occurred when women extended the hormone-free week; of these extended hormone-free intervals, 73% were early terminations (that is, active pills were missed just before the hormone-free week).

To what extent did use-related behaviors other than missed-pills episodes affect the likelihood that women were ever exposed to an increased risk of pregnancy? During the first seven days of the first cycle of pill use, 39% of the women did not have coitus and another 28% always used backup contraception. Therefore, 33% were technically at increased risk of pregnancy because contraceptive protection may not have been fully established; however, the women started pill-taking during the first week after starting to menstruate, and ovulation is unlikely until two weeks into the cycle.

Overall, 73% of the women were protected against an increased risk of pregnancy throughout the study, excluding the first seven days of cycle one (Table 1). Once these first seven days were excluded from the calculations, 52% were protected by their pill-taking alone, 18% because they never had coitus during the seven days after a missed-pills episode and 3% because they always used backup contraception during sexual encounters in the seven days after a missed-pills episode.

The proportion of women who were always protected in some way declined from 93% in cycle one to 87% in cycle two and 75% in cycle three. Protection from pills alone declined from almost 85% in cycle one to 61% in cycle three. Only a few women consistently used backup contraception after a missed-pills episode. Therefore, avoiding coitus during the seven days following a missed-pills episode was the second most important source of protection.

Using multiple logistic regression techniques, we explored predictors of risk status in two stages. In the first stage, we examined which factors predicted whether or not a woman was ever at increased risk during the study. The results showed that demographic and psychosocial characteristics had no significant effects, but that the number of days on which a woman had had intercourse was a significant factor. Women who had ever been at risk had

had coitus on 22 days, on average, whereas those who had always been protected had had intercourse on 11 days. Women who had ever been at increased risk were also more likely to have had unprotected coitus during the first seven days of the study and during cycle three. These results were duplicated even when the 12 women who reported no sexual activity during the study were excluded from the analysis.

In the second stage, we used SUDAAN multiple logistic regression¹⁵ to determine predictors of unprotected intercourse among women who had had coitus at least once during the study. SUDAAN groups the observations by woman, thereby adjusting for the correlations among each woman's responses. The dependent variable becomes whether or not the woman was at risk on each day she had coital activity, taking into account her use of backup contraception and pill-taking patterns. This analysis showed that three groups of women had a significantly elevated number of unprotected days: those with a lower level of perceived partner support for effective pill use, unmarried women and those who considered it not especially important to avoid pregnancy now (Table 2). As in the first stage of the analysis, the chance that a woman had unprotected intercourse was highest during the first seven study days and during cycle three.

Discussion

The pill-taking patterns documented here are similar to those in reports of medication-taking in general,¹⁶ despite two important advantages the pill has over other medications: The dial pack's day-of-the-week labeling for each pill provides visual cues as to whether a pill has been taken on a given day, and alternative forms of protection are available when pills are missed. Half of the women in this study never missed two or more pills in a row. The timing of coitus protected another 18%, but backup contraception played a negligible role in compensating for missed pills. This infrequent use of backup methods stands in sharp contrast to the results of a recent study in which 38% of pill users reported having used dual methods at last intercourse.¹⁷ However, our data refer to backup contraception after every missed-pills episode, a more stringent measure than use at last intercourse.

The likelihood of unprotected coitus during the first week of use is higher in part because women were defined as being unprotected hormonally throughout those days. Thus, only women who had no coitus or who used backup con-

traception were considered protected. Those who had coitus without using a backup method may have decided that they were unlikely to become pregnant. Since they started pill-taking early in the menstrual cycle, their reasoning may have been justified.

The poor record of consistent pill-taking during the third cycle is of greater concern. By this time, new users should have had time to settle into the routine of pill-taking. However, their vigilance may have lessened over time. And those with multiple missed-pills episodes may have felt less vulnerable each time they missed pills without becoming pregnant. Further follow-up was not possible, so we do not know whether or not missed-pills episodes in cycle three were a prelude to discontinuation.

In the first three cycles after initiating pill use, three out of four women in this study were always protected against pregnancy. Although the demographic and psychosocial variables that were tested did not predict the subgroups at increased risk, considering it not especially important to avoid pregnancy, perceiving a low level of partner support for pill use and being unmarried all predicted being at increased risk.

Clinicians can support effective pill use by understanding that using oral contraceptives daily is a complex process. Clinicians need to provide information that is relevant to a woman's particular situation (e.g., marital status) that can help her estimate her risk of becoming pregnant, taking into account coital frequency.¹⁸ Clinicians also need to provide individualized care that is focused on maximizing women's ability to identify and solve future problems in their use of the contraceptive methods they have chosen.¹⁹

Changes in how oral contraceptives are prescribed and packaged also may be helpful. Shortening the hormone-free interval to 4–5 days could reduce the proportion of users who are not fully protected hormonally. A shortened hormone-free interval is beginning to be discussed in the United States and is already routinely used in some countries.²⁰ Adopting such modifications would mean, for instance, packaging 24 hormonal pills and only four placebo pills in each pack.

In addition, for the one woman out of four who does not take the pill consistently and also does not use a backup method, other alternatives should be considered. Emergency contraception is a reliable last resort for an occasional lapse, preventing 75% of pregnancies that might otherwise occur.²¹ Women who miss pills more often

Table 2. Logistic regression coefficients (and standard errors) showing the likelihood that pill users ever engaged in unprotected intercourse, by variable

Variable	Coefficient
First seven days of study	4.12 (1.00)*
Cycle three	1.13 (0.33)*
Married	-0.81 (0.36)*
Importance of not getting pregnant	-0.87 (0.33)*
Perceived partner support	-0.05 (0.24)*
Days in study	0.06 (0.05)
Intercept	3.18 (2.89)

*p<.05.

may benefit from rethinking the relative advantages of reversible methods such as the implant, injectables and IUDs.²²

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