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*Extended and Continuous Use of
Contraceptives to Reduce Menstruation*

*A Special Joint Publication of ARHP and
National Association of Nurse Practitioners in
Women's Health (NPWH)*

CA · R · H · P CLINICAL PROCEEDINGS®

A SPECIAL JOINT ISSUE FROM THE
ASSOCIATION OF REPRODUCTIVE HEALTH PROFESSIONALS
AND
NATIONAL ASSOCIATION OF NURSE PRACTITIONERS IN WOMEN'S HEALTH



September 2004

Extended and Continuous Use of Contraceptives to Reduce Menstruation

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ARHP is a non-profit, 501(c)(3) educational organization with a membership of obstetrician/gynecologists and other physicians, advanced practice clinicians, researchers, educators, and other professionals in reproductive health.

Please direct all inquiries to:

ARHP

2401 Pennsylvania Avenue, NW, Suite 350
Washington, DC 20037-1730 USA

Phone: (202) 466-3825 • Fax: (202) 466-3826

E-mail: arhp@arhp.org • Web: www.arhp.org

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Physicians—ARHP is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to sponsor continuing medical education (CME) for physicians. ARHP designates this continuing medical education activity for 2 credit hours in Category 1 of the Physician's Recognition Award of the American Medical Association.

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Menstrual Suppression: Coming of Age?

With the assistance of their clinicians, women have been adjusting their menstrual cycles for years—to avoid bleeding while on their honeymoon, during an athletic event, or to find relief from dysmenorrhea—usually by eliminating the hormone-free week in an oral contraceptive (OC) regimen. Health care providers have also helped women to reduce or eliminate menstruation in the treatment of endometriosis, migraines, and other medical conditions by prescribing the extended use of OCs or depot medroxyprogesterone acetate (DMPA) injections.

In September 2003, a dedicated extended OC regimen, Seasonale[®], was approved by the US Food and Drug Administration (FDA), bringing the concept of menstrual suppression into the mainstream. A number of similar products are being developed or are in clinical trials. This trend is helping to increase the acceptance and popularity of the extended use of OCs among women, health care providers, and third-party payers. Other contraceptive methods for extended use are also available, including DMPA injections (Depo-Provera[®]) and the progestin-releasing intrauterine system (Mirena[®]). Still others are being studied, including extended use of the vaginal contraceptive ring (NuvaRing[®]) and the contraceptive patch (Ortho Evra[®]). Approval by the FDA of a single-rod contraceptive implant (Implanon[™]) would make yet another extended hormonal method available to American women. Different schedules are being investigated as well, including extended regimens (where use of the contraceptive is periodically interrupted for a withdrawal bleed) and continuous regimens.

The topic of extended regimen contraception was first reviewed by the Association of Reproductive Health Professionals (ARHP) and the National Association of Nurse Practitioners in Women's Health (NPWH) in an issue of *Clinical Proceedings*[®] published in April 2003. The current issue provides an update on the subject of the role of extended regimen contraception in light of the release of the dedicated extended regimen OC. It also reviews studies and surveys on the attitudes and practices of health care providers and women concerning the extended use of contraceptives, as well as recent research on extended use of various contraceptive methods. Because counseling represents a key element in women's acceptance and proper use of extended regimens, this monograph also provides educational tools for health care providers to use in counseling their patients.

Extended regimen contraception gives women another reproductive health choice—when and whether to experience menstrual bleeding. We are pleased to help advance the research and practice of extended regimen contraception through this issue of *Clinical Proceedings*.

Wayne C. Shields
ARHP President and CEO

Susan Wysocki, RNC, NP
NPWH President and CEO

LEARNING OBJECTIVES

After completing this *Clinical Proceedings*, participants will be able to:

1. Describe three examples of the impact of menstruation on lifestyle, productivity, and medical conditions.
2. Name four approaches to prescribing extended hormonal contraception.
3. Name five noncontraceptive health advantages of medically suppressing menstruation.
4. Cite two clinical trials that provide data on the endometrial safety of extended regimens of oral contraception.
5. List three obstacles to extended contraceptive regimens and state two recommended approaches to patient counseling.

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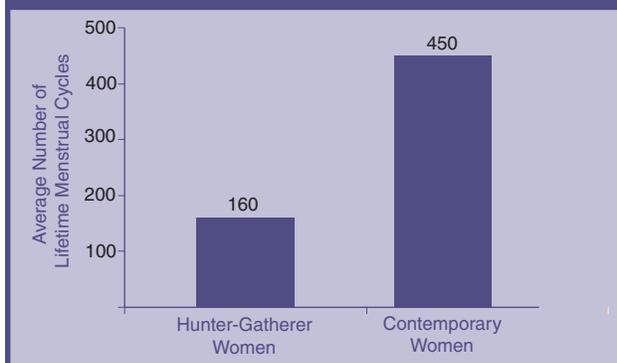


INTRODUCTION

IS REGULAR MENSTRUATION NATURAL OR NECESSARY?

Preagricultural women had about 160 lifetime menstrual cycles, attributable to late menarche, high parity, extended periods of breastfeeding, and early menopause.¹ That number has almost tripled to about 450 cycles for contemporary women who live in industrialized Western nations (see Figure 1).

FIGURE 1. Frequent Menstruation Is a Relatively New Biological State¹



Menstruation can mean many things to different women. For some women, menstruation symbolizes being a woman; they welcome it as a reassuring sign of health and fertility. Others view it with resignation and find bleeding every month to be inconvenient, awkward, messy, and expensive. On the other hand, monthly periods serve important psychological and cultural purposes to some women, who may feel reassured by their periods that they aren't pregnant, find satisfaction in the ritualistic aspects of their monthly cycle, or simply find the concept of transitioning to a period-free life too jarring.

At a minimum, menstruation can be an inconvenience. For many women, monthly menstruation causes substantial distress. Of the 2.5 million women in the United States aged 18–50 years who have menstrual disorders, about 65 percent contact their clinician for menstrual symptoms and 31 percent report spending a mean of 9.6 days in bed each year, resulting in costs to American industry of an estimated 8 percent of the total wage bill.^{2,3} Based on data from a 1999 survey of US women, investigators estimated that women with heavy menstrual flow worked 6.9 percent less, or 3.6 fewer weeks, each year. This translates into

estimated lost wages of about \$1,692 per woman annually.⁴ Menstruation can cause anemia from excessive menstrual volume and can exacerbate preexisting conditions such as iron deficiency anemia and hereditary anemia. It can also cause or increase the severity of pelvic pain, endometriosis, and migraine headaches. Dysfunctional uterine bleeding and menorrhagia represent additional menstrual-related burdens for women. Even though many women and clinicians believe that menstruation is necessary to women's health, no evidence exists that it prevents uterine infections or cancers, or that it improves other parameters of women's health.

In light of these facts, should women's menstrual cycles be suppressed? In the absence of evidence supporting that regular menstruation enhances women's health, the Association of Reproductive Health Professionals and the National Association of Nurse Practitioners in Women's Health believe that medically induced amenorrhea represents an appropriate option for women and an important focus for future research.

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CHOICES ABOUT MENSTRUATION

Advances in contraception are allowing women more choices: whether to alter their menstrual cycle, the type of hormonal contraceptive they use to accomplish this, how often or whether to have a menstrual period at all (extended versus continuous use), and the number of days to menstruate. Some women may want to stop their period for a few months; others, for years. They can also decide to adjust their cycle during particular times and purposes, such as for a vacation, honeymoon, or athletic event; for menstrual conditions that can benefit from amenorrhea (see Table 1);¹⁻³ to relieve discomfort; to reduce the costs associated with hygiene products; or simply for convenience. Women who could benefit from hormonal methods to suppress menstruation include the following:⁴⁻⁸

- Women with menstrual-related medical or gynecologic problems
- Adolescents
- Perimenopausal women
- Athletes
- Females in the military
- Women with mental disabilities
- Women who choose to menstruate less frequently

TABLE 1. Conditions That Can Benefit from Amenorrhea

- Iron deficiency anemia
- Menstrual-related migraine headaches
- Menstrual-related seizures
- Dysmenorrhea
- Premenstrual syndrome and premenstrual dysphoric disorder
- Menorrhagia
 - Idiopathic menorrhagia
 - Uterine fibroids
 - Adenomyosis
 - Coagulation/hematologic problems

“In 1977, I started to extend the use of active oral contraceptives because I had periods every 21–23 days for 7 days. My pattern was to use oral contraceptives continuously for about 4–6 months and then to have a pill-free week. Later, I was diagnosed with endometriosis, so my physician prescribed pills for extended use. I haven’t had a period for 4–5 years and have had no side effects. I really cannot think of a good reason to have a period.”

—Stella, women’s health physician assistant, age 51

“I had been on the pill for 10 years, and then I started on an extended oral contraceptive regimen to get through my third year of medical school. I have used the extended regimen ever since, taking a pill-free week about every 3 months. And I have never had breakthrough bleeding or a rebound period. It’s convenient for me and also great for overseas travel.”

—Sybil, family practice resident, age 27

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CONSUMER AND CLINICIAN ACCEPTANCE

According to recent surveys, many women—regardless of age and in a variety of populations—would prefer to eliminate menses completely or to reduce its frequency to less than once a month if they had the choice. These surveys suggest that attitudes about extended regimen contraception have changed, as they are in stark contrast to a study performed by the World Health Organization in 1981, which found that most women would prefer to bleed on a monthly basis and were not willing to use a contraceptive method that would induce amenorrhea.¹ Following are summaries of some of the most recent surveys conducted about patient and clinician attitudes toward menstruation and menstrual suppression.

AMENORRHEA ACCEPTABILITY SURVEY

An acceptability survey of 1,001 women attending family planning clinics in China, South Africa, Nigeria, and Scotland was conducted by Glasier et al. from December 2000 to June 2001.² Many of the women surveyed said that they did not like having periods, terming them “inconvenient” and associated with menstrual problems (74 percent in Edinburgh, 25–65 percent in Cape Town, 51 percent in Hong Kong, and 63 percent in Shanghai). Given the choice, many of the women said they would opt to have a menstrual bleed every 3 months or not at all (57 percent in Edinburgh, 36–55 percent in Cape Town, 45 percent in Hong Kong, and 45 percent in Shanghai). The exception was Nigerian women, 81 percent of whom said they liked having periods and 71 percent of whom said they would prefer to bleed monthly “to get rid of bad blood.” A substantial proportion of women said that they would consider using a contraceptive method that induced temporary amenorrhea (65 percent in Edinburgh, 52–64 percent in Cape Town, 37 percent in Hong Kong, 48 percent in Shanghai, and 73 percent in Nigeria).

ARHP MENSTRUAL SUPPRESSION SURVEY

In a 2003 survey from the Association of Reproductive Health Professionals (ARHP), led by Linda Andrist, PhD, RNC, WHNP, associate professor at the MGH Institute of Health Professions, 1,470 women aged 18–40 years at six sites across the United States responded to questions about menstrual suppression.³ Seventy-three percent of these women had never heard of suppressing menstruation with use of oral contraceptives (OCs). Fifty-nine percent said they would be interested in not menstruating on a monthly basis, and one-third said they would choose never to have a period. The survey participants felt that more research should be conducted

on menstrual suppression and said that factors such as long-term health effects, side effects, future fertility, and cost would influence their decision about whether to use extended regimen contraception. The majority of the women said they would use hormonal contraception to reduce menstrual frequency if they believed the practice was safe.

SURVEY OF US MILITARY WOMEN

An anonymous, volunteer survey of 154 women in Army Active Duty or Reserve and the National Guard published in 2003 found that 86 percent of military women would desire menstrual suppression during field training and 83 percent would desire it during deployments.⁴ Despite the interest in temporary amenorrhea, 54 percent of the respondents were unaware that OCs could be used to suppress menstruation, and only 7 percent had used OCs for this purpose. However, 49 percent said they would take advantage of this feature of OCs if it were available.

EUROPEAN SURVEYS

German survey

In 2000, German investigators Wiegatz et al. conducted a survey of 1,195 women between 15 and 49 years of age.⁵ The survey revealed the following.

Desired bleeding patterns. Only 26–35 percent of the German women surveyed desired monthly menstrual bleeding; 37–46 percent preferred no menstrual bleeding. The latter group of women cited less menstrual discomfort, better hygiene, better quality of life, and less blood loss as reasons for desiring amenorrhea. Most of the women (65–78 percent), however, had never used OCs to suppress menstruation. Reasons cited among women using OCs who preferred monthly menstrual bleeding were fear of pregnancy, infertility, adverse effects, and a belief that menstruation was natural.

Interest in menstrual suppression. Of the women surveyed, 32–54 percent said that they would suppress menstruation occasionally, and 11–14 percent said they would suppress it for a longer period of time.

Conventional versus continuous OC regimen. As part of the same German study, 30 women received a 30-mg ethinyl estradiol monophasic combination OC for 6 months after actively requesting extended use for personal reasons, such as to avoid bleeding during holidays, sporting events, or examinations. After a 7-day pill-free interval, they were treated for three cycles with a



conventional OC regimen. Sixty percent chose to take their OCs on a continuous regimen after completion of the study, despite a higher rate of irregular bleeding. The investigators found that bleeding occurred more commonly among new OC users and particularly during administration of the second pill pack. This finding led them to suggest that extended regimens should be recommended for women who have been taking OCs for a number of cycles, rather than for new starts, because it appears that unscheduled bleeding and spotting is less frequent with this approach.

Dutch survey

In a comparable survey conducted with 325 Dutch women in 1996, 71.5 percent of menstruating women desired changes in their bleeding patterns, such as less painful, shorter, and lighter periods, and 9 percent preferred a total absence of menstrual bleeding.⁶ Many women expressed a desire for bleeding once every 3 months or never. The desire to stop menstruation altogether increased with age.

2002 ARHP HARRIS POLL OF US WOMEN

In 2002, ARHP commissioned Harris Interactive, Inc., to conduct telephone interviews of 491 women aged 18–49 years about their preferences on the frequency and characteristics of menstrual bleeding.⁷

- Only 25 percent relied on the occurrence of their menstrual period to indicate whether they were healthy, 24 percent to tell them whether they were able to have children, and 31 percent to tell them whether they were pregnant.
- Overall, 44 percent preferred never to menstruate; this increased to 59 percent for women aged 40–49 years. Twenty-nine percent preferred to menstruate once a month.
- More than one in four women said they had missed professional, social, athletic, or family-oriented events because of their period, menstrual cramps, or other menstrual effects.
- Of the 70 percent of respondents who were using or had used OCs, 15 percent had used pills to delay or stop their periods.

NEED TO BLEED STUDY

In 2002, Linda Andrist and colleagues conducted a pilot study to explore women's attitudes and beliefs about menstruation and menstrual suppression.⁸ Self-administered questionnaires were given to a convenience sample of 221 females aged 18–30 years who were highly educated; most of the respondents were Caucasian. Forty-eight percent were not using a hormonal birth control

method, and 50 percent were using OCs. The following is a summary of the survey results.

Interest in Changing Menstrual Pattern

Sixty-three percent of respondents were interested in reducing menstrual pain and 69 percent were interested in reducing the amount of bleeding. These responses were particularly noted among those who were not using OCs.

Importance of Monthly Menstruation

When asked whether it was necessary to have a period every month, 44 percent said yes, 39 percent said no, and 16 percent were not sure.

Interest in Menstrual Suppression

Fifty-six percent strongly agreed or agreed that they were interested in menstrual suppression, 12 percent neither agreed nor disagreed, and 30 percent disagreed or strongly disagreed. Women not currently using OCs were more interested in using a contraceptive for menstrual suppression than women who were using OCs. Women who were not interested in changing their menstrual pattern said they would be anxious about not bleeding and that not experiencing menstruation would be abnormal.

"I started using the extended regimen when I was a medical intern. I always had horrendous periods, with heavy bleeding and dysmenorrhea, and it was a nuisance to make sure I always had tampons with me. After about 3 months of continuous use, I would start to spot and then take a 1-week break. I think I started spotting when I missed a pill or two. It's hard to remember to take pills.

"The extended regimen is the best-kept secret, although more and more women are asking for it."

—Maria, obstetrician/gynecologist, age 31

PROVIDER ACCEPTABILITY

Amenorrhea Acceptability Survey

In the international study of women, Anna Glasier and colleagues also surveyed clinicians and found that health practitioners tend to overestimate the importance of monthly menstruation to their clients.² Most clinicians reported that they thought it was important for women to menstruate while using contraceptives, and 75 percent thought their patients felt the same way. More than half of the providers surveyed (except those in Shanghai), however, said that they would recommend a contraceptive method that would stop menstrual bleeding.



ARHP Menstrual Suppression Survey

The ARHP Menstrual Suppression Survey included a sample of 512 providers to determine clinicians' attitudes toward menstrual suppression.³ This survey found that only 7 percent of providers believed it was physically necessary for women to have a menstrual period every month; in fact, 44 percent of the sample felt that menstrual suppression was a good idea. Fifty-seven percent of the providers said that their patients do not ask them about extended use of OCs. Fifty-two percent said that they prescribe them. These latter respondents cited dysmenorrhea, menorrhagia, and endometriosis as medical indications for prescription; extended OCs were also prescribed upon patient request. Like patients, providers said that more research should be conducted, particularly in regard to long-term health effects, side effects, future fertility, and the cost of extended regimen contraception.

2003 ACOG Survey of Female Fellows

A Gallup telephone survey of female obstetrician/gynecologists conducted for the American College of Obstetricians and Gynecologists (ACOG) in September 2003 revealed that 99 percent of these clinicians believe that menstrual suppression is a safe practice for their patients, 69 percent believe that long-term suppression with OCs is safe, and 30 percent believe that it is safe if used occasionally.⁹ Fifty-three percent of the female obstetrician/gynecologists had tried menstrual suppression themselves, with a higher percentage of practitioners under the age of 40 reporting personal experience.

German Survey

In the German study conducted by Wiegratz et al., gynecologists were sent surveys to evaluate their professional attitudes and experiences with suppression of menstruation and extended use of OCs.⁵ Of the 1,152 questionnaires that were evaluable, 99.5 percent of gynecologists had prescribed OCs for the postponement of menstrual bleeding; 97 percent had prescribed extended-cycle OCs for at least a limited time to suppress bleeding for medical reasons (menstruation-related disorders or complaints, endometriosis, polycystic ovary syndrome) or at the request of their patients. These clinicians rated the experience of suppressing menstruation as good (60 percent) or very good (28 percent). Sixty-one percent prescribed a regimen consisting of three packs (63 pills) of OCs followed by a hormone-free week.

ARHP and NPWH Annual Meeting Registrant Clinician Survey

ARHP and the National Association of Nurse Practitioners in Women's Health (NPWH) surveyed 117 annual meeting registrants in August-September 2002 (before US Food and Drug Administration approval of a

dedicated extended regimen OC) to determine their practices concerning prescription of extended OCs.¹⁰ Seventy-eight percent of the respondents specialized in obstetrics/gynecology. Forty-eight percent of the respondents were nurse practitioners, 16 percent were physicians, and 33 percent were in private practice.

Seventy-seven percent of the survey participants prescribed extended regimen OCs. The prescription patterns included more than 21 active pills per cycle and a shortened pill-free interval (15 percent); 42 active pills followed by a 7-day pill-free interval (29 percent); 63 active pills followed by a 7-day pill-free interval (72 percent); continuous active pills with instructions for the patient to take a 7-day pill-free interval if spotting occurred with uninterrupted use (35 percent); or other regimens (12 percent).

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USING ORAL CONTRACEPTIVES TO REDUCE MENSTRUAL BLEEDING

The most common method used to reduce or suppress menstruation is to change the way in which a monophasic oral contraceptive (OC) is taken. With this method, the placebo week from the standard 21/7-day cycle (i.e., 21 days of active pills followed by 7 days of placebo) is eliminated. Two types of regimens may be used to suppress menstruation with OCs: extended use and continuous use. *Extended use* refers to a variety of patterns. For instance, Seasonale® is a dedicated extended regimen OC product indicated for 84 days of active pills followed by a 7-day pill-free interval to induce withdrawal bleeding.¹ In contrast, in the 2002 surveys by the Association of Reproductive Health Professionals and the National Association of Nurse Practitioners in Women's Health of annual meeting registrants (performed before Seasonale was available), 72 percent of the respondents who prescribe extended OC regimens indicated that they prescribe 63 active pills followed by a 7-day pill-free interval.² (The use of this regimen is probably explained by the fact that three continuous cycles of available contraceptives would be 21 times 3, or 63 active pills.) *Continuous use* refers to the administration of OCs for an unlimited time without interruption to eliminate menstrual periods; this regimen is currently under investigation.

For most women, the use of today's pills carries low risks and substantial health benefits. Women who take OCs are less likely to develop osteoporosis, ovarian or endometrial cancer, benign breast changes, and pelvic inflammatory disease.³ A recent major study confirms that current or previous use of the pill does not affect the risk of breast cancer among women aged 35–64 years.⁴ OCs can also help to ease menstrual-related disorders, such as dysmenorrhea and menorrhagia, premenstrual syndrome, and perimenopausal symptoms (e.g., hot flashes, night sweats, and irregular monthly periods).^{3,5}

However, some women should not take OCs. A complete list of contraindications to OC use is available at the World Health Organization's International Web site at http://www.who.int/reproductive-health/family_planning.

EXTENDED USE OF OCs

Researchers have studied extending the use of OCs to reduce menstrual bleeding since the late 1970s. Presented here are data from recent studies.

Extending the Cycle from 28 to 49 Days with Conventional OCs

A study comparing a traditional 28-day cycle with an extended 49-day cycle of a 30-mg ethinyl estradiol (EE)/300-mg norgestrel monophasic birth control regimen (Lo/Ovral® 28) was conducted from April 1998 to April 2000.⁶ The objective was to compare the two regimens in terms of differences in bleeding patterns, symptoms, need for sanitary protection (pads or tampons), and overall patient satisfaction. Patients were randomly assigned to either 21/7-day or 42/7-day cycles over four 84-day reference periods or trimesters. During this time, they kept diaries on bleeding, pill taking, and symptoms. Of the 90 women who began the study, 24 (54.5 percent) using the 28-day cycle and 29 (63 percent) using the 49-day cycle completed the study. The two groups were similar in demographics and continuation rates.

Bleeding and Spotting. For the two treatment arms, there were no significant differences in amenorrhea, frequent menses (more than four episodes of bleeding per trimester), or prolonged withdrawal bleeding. In the first trimester, the number of bleeding days was significantly reduced with the extended OC cycle: the mean number of bleeding days was 10.9 for the 21/7-day cycle and 6.4 for the 42/7-day cycle ($p = 0.00$). The number of spotting days in the first trimester was similar between schedules (mean number of spotting days = 4.8 for the 28-day regimen and 3.7 for the 49-day regimen; $p = 0.24$); spotting was reduced by the fourth trimester (3.4 days for the 28-day regimen and 2.9 days for the 49-day regimen; $p = 0.30$).

Hygiene Product Use. Women using the extended regimen spent significantly less on hygiene products and needed them for significantly fewer days.

Satisfaction. Women's satisfaction with their pill schedules was similar for the two regimens.

Continued Contraceptive Use. At the study exit, 52.4 percent of women who had been assigned to the extended regimen wished to continue with it and 16.7 percent who had been assigned to the 28-day regimen wished to switch to the extended regimen.

Extending the Conventional 21/7-Day Regimen to Individualized Schedules

Sulak and colleagues conducted a retrospective survey to assess how women accepted changing the 21/7-day OC regimen to delay menses and to reduce hormone withdrawal symptoms.⁷ Records of 318 patients who were counseled about extended OC use from December 1993



through October 2000 were reviewed. Of these, 292 patients had documented follow-up. These women were counseled about extending their use of active pills to 6, 9, or 12 weeks or until breakthrough bleeding or spotting developed, as well as shortening the hormone-free interval to 3–7 days. All women used a monophasic OC formulation with 30–35 mg of EE plus norethindrone, levonorgestrel (LNG), norgestimate, or desogestrel. At baseline the women reported having headaches, dysmenorrhea, hypermenorrhea, or premenstrual symptoms during the hormone-free week.

Fifty-nine percent of the women chose to continue on an extended regimen and used an average cycle of 12 weeks of active pills followed by 6 pill-free days. No unintended pregnancies occurred during the study.

Extended 84/7-Day Contraceptive (Seasonale®)

The largest trial to date of an extended regimen OC was conducted with the dedicated 84/7-day monophasic OC Seasonale, consisting of 30 mg of EE and 150 mg of LNG.⁸ Seasonale was approved by the US Food and Drug Administration in late 2003.¹ A 47-site, randomized, parallel, open-label, 1-year study examined its safety and efficacy. In this study, a total of 682 healthy women aged 18–40 years who desired oral contraception were randomly assigned to Seasonale or to a conventional cycle regimen of Nordette® (30 mg of EE/150 mg of LNG). The women taking Seasonale received four consecutive cycles of the 91-day extended cycle pills (84 days of active pills with a 7-day pill-free interval), and those on Nordette received 13 consecutive cycles of the 28-day cycle pills (21 days of active pills with a 7-day pill-free interval). Through electronic diaries, researchers measured daily compliance, bleeding and spotting, and menstrual-related symptoms.

The two groups were similar in terms of demographics. Over 60 percent of the patients were already using OCs, 30 percent had previously used OCs, and <10 percent of patients in each group had not previously used OCs.

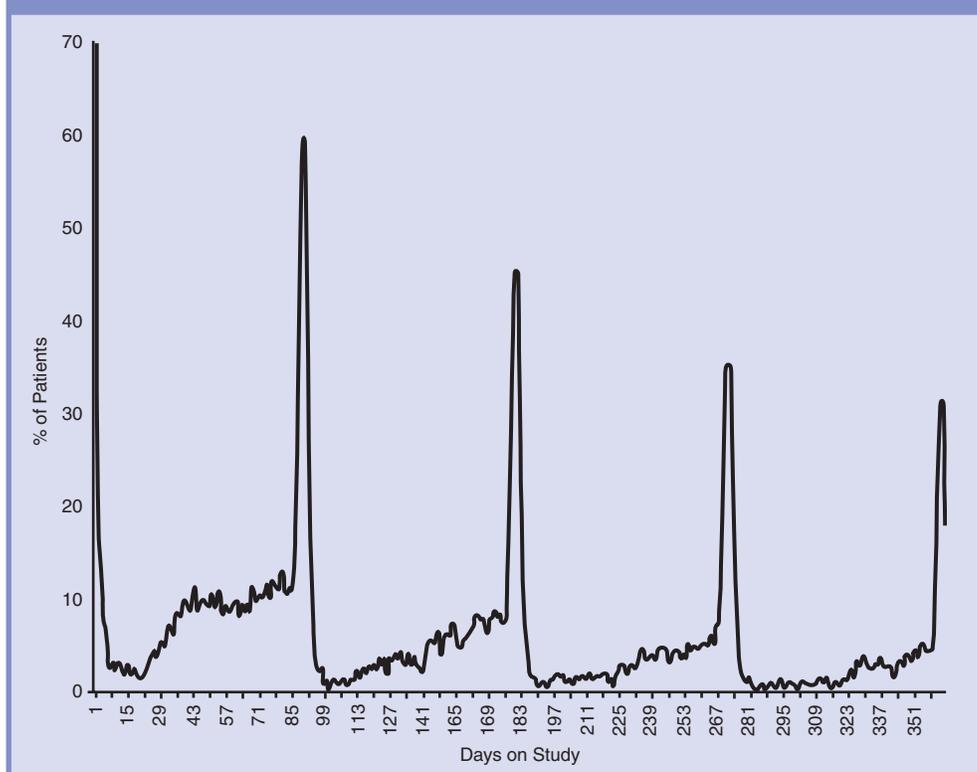
The high rates of compliance in both groups (94.5 percent in the Seasonale group and 93.4 percent in the Nordette group) was probably partially attributable to daily reminders to take the pills via the use of the electronic diaries. The investigators noted that compliance may be more of an issue when patients are transitioning from one pill pack to the next and suggested that the reduction in pill packs from 13 per year on the conventional regimen to only four per year on the extended regimen may improve adherence to the regimen.

Fifty-nine percent of Seasonale patients and 71.2 percent of Nordette patients completed the 1-year study. Adverse events, individual patient decision, and patients lost to follow-up accounted for most of the discontinuations; 7.7 percent of the extended-cycle patients and 1.8 percent of the conventional-cycle patients reported “unacceptable bleeding” as their reason for discontinuing. The rate of discontinuation for unacceptable bleeding in the Seasonale group decreased after two extended cycles of pills (after week 26).

Following are other results of the study:

- Seasonale was as effective in preventing pregnancy as conventional 21/7-day combination OC use (Pearl index = 0.60 for Seasonale and 1.78 for Nordette).

FIGURE 2. Percent of extended cycle regimen patients reporting bleeding by study day.⁸





- Duration of withdrawal bleeding was comparable between Seasonale and conventional-schedule OCs. The frequency of unscheduled bleeding episodes was initially higher with Seasonale than with Nordette but declined with each successive cycle (see Figure 2). With the extended regimen, there were 12 days of breakthrough bleeding in cycle 1, which decreased to 4 days by cycle 4. By cycle 4, breakthrough bleeding was comparable to that in the conventional regimen group. More than half of the days of unscheduled bleeding episodes in the Seasonale group consisted of spotting.

CONTINUOUS USE OF OCs

Researchers are currently investigating continuous (uninterrupted) administration of OC tablets. Two studies have been reported in the literature.

Comparing a 28-Day OC Cycle with Continuous OC Use

Researchers randomized 79 women to either 28-day cycles or continuous use of the same 20-mg EE/100-mg LNG formulation for 12 study cycles (336 days).⁹ They found that women assigned to continuous OC use had significantly fewer bleeding days than women assigned to conventional 21/7 cycles. During cycles 1–3, 68 percent of continuous users experienced amenorrhea or infrequent bleeding; this figure increased to 88 percent during cycles 10–12. Increased spotting was initially reported by continuous users but decreased over time; by 9 months, continuous users reported less spotting than cyclic users.

Comparing a 28-Day OC Cycle with a 168-Day Cycle: the Oregon Data

Marni Kwiecien and colleagues compared bleeding patterns and patient acceptability with continuous use of a 20-mg EE/100-mg LNG pill (168 days without a pill-free interval) or

with standard use (six 28-day cycles).¹⁰ Thirty-two patients in Oregon seeking oral contraception were enrolled in the study and 28 completed this randomized, controlled trial, returning completed daily bleeding calendars that documented bleeding events and side effects.

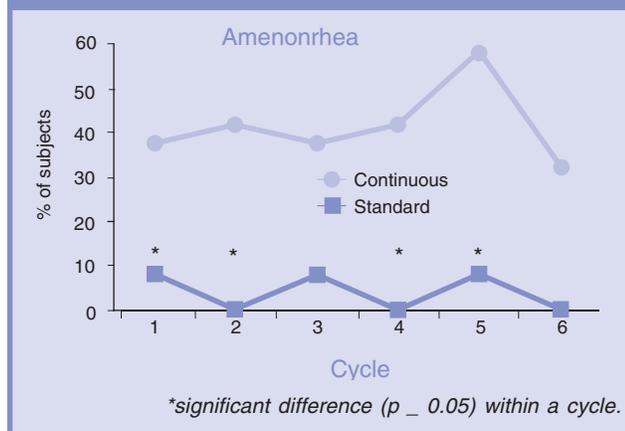
The results were as follows:

- Women in the continuous group had nine fewer total bleeding and spotting days (34.9 days) than those in the cyclic group (29.2 days) over the course of the study ($p = 0.33$) and required less sanitary protection for bleeding.
- Women in the continuous group were more likely to be amenorrheic than those in the cyclic group (see Figure 3).
- Subjects in both groups reported a high level of satisfaction with their bleeding patterns and side effect profiles (headache, nausea, breast tenderness, depression, premenstrual syndrome, and bloating).

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FIGURE 3. Percent of subjects reporting no bleeding in each treatment cycle.¹⁰





USING EXTENDED REGIMEN ORAL CONTRACEPTIVES FOR NONMENSTRUAL BENEFITS

Beyond the obvious benefits of extended and continuous regimen oral contraceptive (OC) use to reduce bleeding, practitioners and patients are using OCs in this manner to relieve menstruation-related complaints, such as breast tenderness, bloating, headache, and premenstrual syndrome or premenstrual dysphoric disorder, as well as medical conditions such as endometriosis.

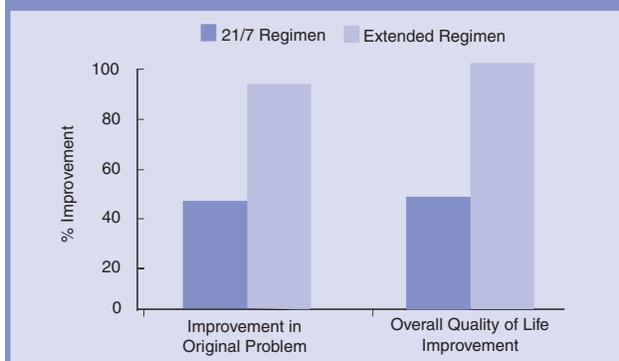
EXTENDED USE TO REDUCE HORMONE WITHDRAWAL SYMPTOMS

In a retrospective study by Patsy Sulak and colleagues, women with hormone withdrawal symptoms were counseled to extend the standard 21/7-day regimen to 6, 9, or 12 weeks or until breakthrough bleeding or spotting occurred.¹ Reasons for using an extended OC regimen included decreased symptoms of headache (35 percent), dysmenorrhea (21 percent), hypermenorrhea (19 percent), and premenstrual symptoms (13 percent). The remaining 12 percent listed convenience, endometriosis, and other menstrual-related problems, such as acne. This was the first large series of extended use of OCs among patients complaining of hormone withdrawal symptoms. The study yielded 7 years of follow-up data for 292 patients (92 percent of the original 318 patients).

Symptom Improvement and Quality of Life

As shown in Figure 4, in this nonrandomized series, 86 percent of women using the extended regimen and 41 percent using the 21/7-day regimen reported that their symptoms improved. Ninety-four percent of the women using the extended regimen and 43 percent using the 21/7-day regimen reported that their overall quality of life improved. A potential limitation of this uncontrolled series is that a charismatic physician who strongly supports extended OC regimens supervised the care of these women.

FIGURE 4. Symptomatic with Extended OCs vs. 21/7 Regimen¹



Shortening the Hormone-Free Interval

In the first few years of the study, after an extended cycle of use, patients were instructed to discontinue pill-taking for the standard 7 days; most elected to do so after a typical cycle of 12 weeks (median 9 weeks). Although extended use of OCs effectively delayed hormone withdrawal symptoms, subjects often experienced a recurrence of symptoms (headache, premenstrual symptoms) during the 7-day hormone-free interval. The investigators subsequently advised patients to shorten the hormone-free interval to 4–5 days, and many avoided withdrawal side effects. The investigators suggested that this practice may concurrently increase contraceptive effectiveness via enhanced ovarian follicular suppression.

DROSPIRENONE EXTENDED-USE TRIAL

In a 6-month prospective, open-label, observational trial conducted in Germany, 175 women who chose to take an extended regimen of 30 mg of ethinyl estradiol (EE) and 3 mg of drospirenone (marketed as Yasmin® in the United States) for 42–126 days were compared with 1,221 women who took the same OC using the standard 21/7-day regimen.² The aim of the study was to determine whether taking the OC for an extended cycle would affect menstrual-related symptoms such as swelling of the extremities, body weight, breast tenderness, feeling of bloating, acne, dysmenorrhea, breakthrough bleeding, and withdrawal bleeding.

Effect on Edema, Breast Tenderness, Weight Gain, and Feeling of Bloating

Of the women using the extended regimen, 49 percent experienced a reduction in edema and 2 percent experienced an increase in this symptom. This was in contrast to the women using the 21/7-day regimen, 34 percent of whom had a decrease and 3 percent had an increase in edema. This difference was significant between the groups at $p < 0.001$. Of women using the extended OC regimen, 50 percent had decreased breast tenderness and 5 percent had an increase in this symptom. In contrast, among women using the traditional regimen, 40 percent had decreased breast tenderness and 7 percent had an increase in this symptom (significant difference between groups, $p = 0.046$). Women using the extended regimen experienced a 0.57-kg mean decrease in weight, whereas those using the standard regimen had a 0.61-kg mean decrease, a difference that was neither clinically nor statistically significant between groups. A feeling of bloating improved among 37 percent of women on the extended regimen and 29 percent on the 21/7-day regimen, but there was no significant difference between groups.



Improvement in Skin Problems

At the start of the trial, 35 percent of the women using extended regimen OCs and 33 percent of women using the 21/7-day regimen reported moderate to severe skin problems. After 6 months of therapy, only 5 percent of women taking the extended regimen and 8 percent taking the 21/7-day regimen reported these problems. (Statistical testing was not reported by the authors for this comparison.)

Dysmenorrhea and Bleeding Patterns

After 6 months of therapy, 65 percent of women using the extended OC regimen and 50 percent using the standard regimen reported an improvement in dysmenorrhea, whereas 2 and 3 percent, respectively, reported worsening; these differences were statistically significant in favor of the extended regimen ($p = 0.0016$). Breakthrough bleeding occurred in 15 percent of subjects using the extended regimen and 6 percent using the 21/7-day regimen. Duration and severity of bleeding were similar between the two groups, but the number of total withdrawal bleeding episodes was less in the extended regimen group. (Statistical testing was not reported by the authors for these comparisons.)

Well-Being

Among women using the extended regimen, 85 percent reported that they felt better or much better after 6 months and 2 percent felt worse, compared with 66 and 3 percent, respectively, of women using the standard regimen ($p < 0.0001$). Ninety-seven percent of women using the extended regimen and 91 percent using the 21/7-day regimen said that they would recommend the preparation.

OREGON CONTINUOUS USE TRIAL

In a randomized study, Kwiecien et al. compared the use of a 20-mg EE/100-mg levonorgestrel pill (168 days without a pill-free interval) with standard use (six 28-day cycles).³ Subjects were asked to record subjective side effects on a daily basis. There were no significant differences between groups in regard to the incidence of nausea, depression, and premenstrual syndrome. However, subjects in the continuous group had significantly less bloating (mean = 0.7 days in the continuous group and 11.1 days in the cyclic group; $p = 0.04$) and less menstrual pain (mean = 1.9 days in the continuous group and 13.3 days in the cyclic group; $p < 0.01$) than those in the cyclic group. In addition, continuous users reported approximately half as many days of headache (mean = 3.1 days in the continuous group and 9.6 days in the cyclic group) and breast tenderness (mean = 2.6 days in the continuous group and 7.1 days in the cyclic group) as cyclic users over the 168-day study, although these differences were not statistically significant.⁴ Interestingly, although the number of headache days reported by users of standard cycles remained about the same during each month of observation, users of the

continuous regimen reported successively fewer headache days for each cycle. Weight decreased slightly and skin satisfaction was comparable and high in both groups.

TREATMENT OF ENDOMETRIOSIS-RELATED PAIN

An open-label, 6-month, randomized clinical trial of 90 women with recurrent moderate or severe pelvic pain after conservative surgery for endometriosis was conducted in Italy.⁵ This study compared continuous use of an OC containing 20 mg of EE and 150 mg of desogestrel with oral cyproterone acetate, 12.5 mg/day. Both drugs substantially reduced dysmenorrhea, deep dyspareunia, and nonmenstrual pelvic pain scores and significantly improved health-related quality of life, psychiatric profile, and sexual satisfaction.

In a separate prospective, self-controlled clinical trial of 50 women who had undergone conservative surgery for endometriosis in the previous year but continued to experience dysmenorrhea with conventional cyclic OC use, the same investigators looked at continuous use of an OC containing 20 mg of EE and 150 mg of desogestrel for 2 years.⁶ They found that continuous use significantly reduced the frequency and severity of dysmenorrhea, and 80 percent of the women were satisfied or very satisfied with the treatment.

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OTHER HORMONAL METHODS FOR REDUCING MENSTRUATION

In addition to oral contraceptives, other hormonal contraceptives can be used to reduce bleeding. Some of these approaches reduce the frequency of bleeding on a cyclical basis, whereas others (such as Depo-Provera[®], Mirena[®], and Implanon[™]) are continuous and reduce or eliminate bleeding. See Table 2 for a list of these latter methods.

Two newer, longer-acting, combination hormonal contraceptives represent potential methods for suppressing menstruation.¹

CONTRACEPTIVE VAGINAL RING

Extended use of the NuvaRing[®], a combination estrogen-progestin method approved for contraception in October 2001,² presents an appealing concept. This ring is approved for 3-weeks-in, 1-week-out use. In a small pharmacokinetic study on the effects of the vaginal ring after extended use (worn in the vagina for 5 weeks rather than the conventional 3 weeks), investigators determined that ovulation continued to be inhibited, and there were no unfavorable safety observations.³ Because these results may not be found in a larger population of women of different body weights, ages, and other characteristics, the authors did not recommend the use of the ring beyond 3 weeks.

TRANSDERMAL CONTRACEPTIVE PATCH

Ortho Evra[®], a combination hormonal method, approved as a contraceptive in November 2001,⁴ also has appeal to women and clinicians for extended use. Conventionally, the patch is worn for 3 of 4 weeks each month, on a traditional oral contraceptive 21/7-day schedule. For extended use, it could be replaced every week for 4 weeks without a patch-free interval.

Although clinical trials on the extended use of NuvaRing and Ortho Evra have been conducted, these data have not been published to date.

“I started using an extended oral contraceptive regimen in my residency so I would have one less thing to deal with. Initially, after 2–3 months of continuous oral contraceptives, I had some breast tenderness and some breakthrough bleeding. At that point, I started a pill-free week. On those placebo days, my mood dropped. I am now using the NuvaRing and use it continuously. I have had spotting only once in the last 7 months.”

—Patricia, ob/gyn physician, age 30

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TABLE 2. Other Therapeutic Options for Suppressing Menses⁵⁻¹⁰

Methods	Injectable progestin-only contraceptives (Depo-Provera [®])	Levonorgestrel intrauterine system (Mirena [®])	Norethindroneacetate tablets (Aygestin [®]) ^a	Danocrine (Danazol [®])	GnRH, leuprolide acetate (Lupron Depot [®]) ^c	Etonogestrel implantable contraceptive (Implanon [™] ; FDA approval pending as of July 2004)
Description and Dosage	Injectable progestin-only contraceptive: 150 mg every 3 months. A subcutaneous injection is pending FDA approval as of July 2004.	Progestin-releasing IUD: releases 20 mg of LNG daily; effective for 5 years	Oral progestins: 5 mg, 1–3 tablets daily	Gonadotropin inhibitor with progestational and androgenic properties: Danazol, 100–200 mg twice daily (optional titration to lowest dose sufficient to maintain amenorrhea)	Delivery methods and dosages vary	Single-rod implantable contraceptive containing 68 mg of etonogestrel; effective for 3 years
Contraception Provided	Yes	Yes	Yes (but not FDA approved for contraception)	No	No	Yes
Medical Uses^b Effects on Menstrual	Menorrhagia, dysmenorrhea, endometriosis, anemia, PMS, menstrual migraines	Menorrhagia	Menorrhagia, dysmenorrhea, endometriosis, anemia, PMS, menstrual migraines	Endometriosis, fibrocystic breast changes, menorrhagia	Menorrhagia, dysmenorrhea, endometriosis, anemia, PMS, menstrual migraines	Insufficient experience to draw from as yet
Blood Loss	Amenorrhea common with long-term use—50% with 1 year of use, 90% with 2 years	80–90% decrease in blood loss; ~20% of users are amenorrheic by 1 year	Reduces bleeding by 87% after 3 months of use	Produces amenorrhea	Produces amenorrhea	21% of users are amenorrheic in any 90-day reference period
Adverse Effects	Irregular bleeding or spotting, possible weight gain, transient loss in bone mineral density, delayed return to fertility	Intermenstrual bleeding, ovarian cysts, acne	Mood changes, bloating, weight gain	Androgenic effects, such as weight gain and acne; hypoestrogenic reactions, such as flushing, sweating, vaginal dryness and irritation	Hypoestrogenic effects; these may be counteracted with add-back progestin and/or estrogen/progestin	Breakthrough bleeding/spotting, acne, headache, breast pain
Cost	Cost-effective; less expensive than alternatives	Initial high cost, but becomes cost-effective with extended use	More costly than extended OC regimen	Expensive	Very expensive	Cost not yet known

FDA = Food and Drug Administration

GnRH = gonadotropin-releasing hormone

IUD = intrauterine device

LNG = levonorgestrel

OC = oral contraceptive

PMS = premenstrual syndrome.

a. Approved for the treatment of endometriosis.

b. None of the medical noncontraceptive uses listed are FDA-approved indications, except as noted.

c. Approved for the treatment of endometriosis and menorrhagia-induced anemia in women with fibroids.

Other GnRH agonists approved for the treatment of endometriosis include Synarel[®] and Zoladex[®].



OBSTACLES TO USING EXTENDED CONTRACEPTIVE REGIMENS

Obstacles to health care providers' prescribing and women's use of extended regimen contraception include lack of third-party coverage, concerns about safety, and off-label use of existing contraceptives.¹ With the availability of Seasonale®, an extended oral contraceptive (OC) regimen, these obstacles are easier to address. Other obstacles, including health care providers' lack of time and skills to adequately counsel their patients, may be alleviated with better counseling tools and consumer and provider education.¹

"I suggest this regimen to patients, especially those who have menstrual migraines. In counseling patients, I make sure I tell them to expect breakthrough bleeding. The key barriers to more widespread use of this regimen are that women think they need to have a period and that health [care] providers think that it builds up the endometrium."

—Rosa, nurse practitioner, age 44

THIRD-PARTY COVERAGE

Coverage of OCs varies among third-party payers. With extended use of OCs, four extra packs of pills per year (17 instead of 13) are needed. These additional packs of OCs are more likely to be covered for medical purposes, such as endometriosis and dysmenorrhea, than for convenience. Coverage for Seasonale also varies; in some cases, insurance covers it but requires three co-pays for one pack.

Medicaid coverage for OCs also differs from state to state. For example, in Delaware, both public and private providers of hormonal contraceptives can issue up to three cycles of pills at a time but can bill for only one cycle per month. However, Medicaid pays by the tablet, so if an OC prescription is written "daily for 63 days" and indicated as a medical necessity, Medicaid will be more likely to cover it.

According to an expert at the American Association of Health Plans, when a provider writes a prescription for more than one pack of pills per month, the pharmacist can fill the prescription easily when the woman pays out of pocket. However, when the insurance company pays, the prescription needs to be justified by the consumer or sometimes the provider. Approval varies according to the insurance company.

SAFETY

Patients and providers have expressed concerns about the safety of extended regimen contraception in regard to long-term health effects, side effects, and future fertility.² Earlier studies of women taking an extended OC regimen have not shown adverse health consequences. The 1-year trial of extended use of Seasonale³ and the 6-month trial of continuous use of a 20-mg ethinyl estradiol/100-mg levonorgestrel OC conducted in Oregon⁴ offer reassurance that no untoward effects on the endometrium occur with these regimens. In the Seasonale trial, some patients underwent endometrial biopsy at the start and finish of therapy to assess the effects of the extended regimen on the endometrium; no instances of endometrial hyperplasia or carcinoma were observed. In the Oregon trial, investigators conducted transvaginal ultrasound examinations to document endometrial stripe thickness on 14 subjects using the continuous regimen. All women with endometrial stripe thicknesses of >5 mm were to be asked to consent to endometrial biopsy; this proved unnecessary, however, as mean thickness ranged from 2 to 4 mm with a mean of 3.3 mm (standard deviation = 0.73). The investigators suggested that "continuous use of oral contraceptives results in an inactive endometrium, similar to that obtained with combined continuous hormone replacement therapy."

Concerns about breast cancer and thrombosis as a result of extended or continuous use of OCs can be answered only by large postmarketing observational studies. However, data on conventional use of pills—including epidemiologic data on doses of OCs higher than are usually used—are reassuring with respect to breast cancer.⁵

In regard to fertility, a German trial suggests that return to fertility after discontinuation is rapid: Patients who switched from the extended regimen to the conventional regimen experienced a rapid reversal of amenorrhea, and those who desired pregnancy conceived soon after discontinuation.⁶ In addition, in the Oregon trial, one subject became pregnant the week after discontinuation of continuous OCs.⁴

Depo-Provera® injections and the Mirena® intrauterine system have been used by millions of women and have excellent safety records. Nevertheless, additional studies on long-term use of extended OCs and other extended contraceptive methods would be welcome.



WOMEN'S BELIEFS AND CULTURAL MYTHS

Many women want or feel that it is necessary to menstruate. Some believe that menstruation cleans out toxins, is “natural,” makes them feel feminine, or helps connects them to the “cycle of life.” Some use menstruation as a way to determine whether they are pregnant, as a reason to avoid sex, or to ascertain fertility; others continue to menstruate because of pressure from family and friends, and still others avoid contraceptives because of religious beliefs.⁷

Women's customs, values, and beliefs about menstruation and contraception differ among societies. According to Castaneda et al., researchers with the National Institute of Public Health in Mexico, “every society builds complex belief systems in relation to the reproductive system.”⁸ This concept is illuminated in the researchers' study of fertility and menstruation in rural Mexico. Here are some quotes from women in the study:

“A period is like a wound which opens in the woman and the womb has to vent itself.”

Menstrual blood “...collects in the belly, because it no longer circulates in the body and it has to come out.”

Menstrual blood is “something which ripens and must be thrown out.”

“Blood comes with menstruation because it is going into heat.”

“Most girls with a strong nature were born under a full moon and their first menstruation will come with a full moon, whereas weak ones have their first menstruation when there is no moon or a new moon.”

In a study of indigenous Alaskan women, researchers found that Eskimo women were uninterested in tracking their periods to find out when their next period was due, the usual interval between periods, or the average duration of the period.⁹ Suha Kridli, PhD, RN, reviewed studies of Arab women's beliefs about menstruation and family planning.¹⁰ Some Arab American women think that they should not shower until the end of their menstrual periods. The researcher said that women might have this belief because according to Islamic religion, a menstruating woman is not considered *tahra*, which is Arabic for *clean*. Many Kuwaiti women believe that OCs cause obesity and twin pregnancies. Some Jordanian women think that OCs cause serious side effects, such as cancer, hair loss, and back pain.

HEALTH CARE PROVIDER AWARENESS AND BELIEFS

Some health care providers believe that women need to have regular menstrual periods for medical reasons and that safety issues concerning the extended use of contraceptives have not been adequately researched.^{2,11,12} Many health care providers have never questioned the reasons for the 21/7 regimen and may have assumed that there was a scientific rationale for scheduling OCs in this manner. Some providers also mistakenly confuse amenorrhea that normally accompanies hormonal methods—particularly Depo-Provera, Mirena, and extended regimen OCs—with amenorrhea associated with endometrial pathology (i.e., hyperplasia). Once they learn about the physiological differences between amenorrhea induced by hormonal methods versus that associated with pathology, they should be reassured.

Some providers are concerned with the long-term effect of menstrual suppression for extended periods. Although long-term use of extended regimens has not been studied, it is reassuring that there have been no reports of harm among thousands of patients who have used extended regimens to treat endometriosis and other menstrual-related problems. It is also reassuring that recent studies have shown that concern about endometrial proliferation from extended use is unfounded.^{3,4}

“For 5 years, I took oral contraceptives, continuously. I stop taking them about every 3 months for about 5 days because my doctor suggested this pattern. It seems to me that nurse practitioners know more about continuous oral contraceptives than physicians. They learn about and discuss this regimen at conferences and then go back and talk to the physicians they work with. But there does seem to be confusion about how often you should have a pill-free interval. Some say twice a year, others every 3 months. I would like to know even more about this regimen to gain confidence in prescribing it. It's difficult convincing women that they don't need to bleed.”

—Kate, nurse practitioner in physician's office, age 41

PERCEPTION THAT EXTRA COUNSELING IS REQUIRED

Women need counseling on how to take and what to expect with extended regimen contraception. Health care providers often have little time to counsel their patients adequately for conventional-use methods. They also do not have the patient education tools to assist them in



counseling about changes in bleeding patterns with hormonal methods.¹ Because all women initiating a contraceptive hormonal method experience changes in menstrual patterns, counseling women on continuous use may not take much more time than counseling on conventional use.

CORRECT USE OF CONTRACEPTIVE METHOD

The regimen for any contraceptive method—whether it is conventional or extended use—must be followed closely to lessen side effects and prevent pregnancy. Many contraceptive methods rely on the woman's memory and willingness to follow the contraceptive schedule. For example, with OCs, women should take the pill at the same time every day, yet it is difficult for many people to remember consistently to do so.

SIDE EFFECTS

In a study of 1,675 women, the most common reason cited for discontinuing OCs was bleeding irregularities.¹³ Unscheduled bleeding is initially more common with an extended OC regimen than with a conventional OC regimen. However, after 3–4 months, the number of days of unscheduled bleeding or spotting with extended OCs is comparable to that with conventional OCs. With both regimens, the bleeding decreases over time.

OFF-LABEL USE

Some providers are uncomfortable with prescribing conventional contraceptives for extended use because these formulations have not been approved by the US Food and Drug Administration for that purpose.¹ Public clinics often use the labeling on contraceptives to prepare practice protocols. It is noteworthy, however, that most clinicians prescribe OCs for women with dysfunctional uterine bleeding, menorrhagia, and dysmenorrhea, even though OCs are not approved for these indications. As mentioned previously, third-party payers are reluctant to cover extended contraceptives because of this “off-label” use. The current availability of Seasonale, a dedicated extended OC regimen, addresses some of these off-label concerns.

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PATIENT COUNSELING STRATEGIES

One of the most common reasons that women stop using any hormonal contraceptive is that they are ill informed about breakthrough bleeding: when to expect it and what it means. It may be of particular concern when the oral contraceptive (OC) regimen is unfamiliar. Counseling can help allay patients' fears and concerns.

To tailor counseling messages on extended or continuous contraceptive regimens to each woman, it is helpful for the health care provider to be familiar with patients' frames of reference, such as their cultural and religious beliefs, family members' views, and expectations of how the regimen would benefit them.

Presented below are some strategies for introducing the concept of extended or continuous hormonal use to patients, as well as how to counsel patients who have elected to use such a method. Following these strategies is a patient handout that answers commonly asked questions.

INTRODUCING THE CONCEPT

Overall Concept

- There is no medical or health reason to bleed while on hormonal contraceptives.
- Periods on the pill are "false periods" that were designed to make bleeding with the pill seem like a natural cycle. In women using birth control hormones, the uterine lining does not build up or need to be shed.
- Menstrual blood does not build up when women are using hormonal birth control.

Safety

- No serious side effects have been found in nine studies involving some 2,000 women.
- Three trials have shown that there is no harmful effect on the uterine lining.
- Conventional pill-use data are reassuring regarding breast cancer, although only future postmarketing studies will show if the same holds true for extended use.
- A return to fertility after discontinuation is expected to be the same as for conventional OC use.

ADVANTAGES

- Extended regimen contraception can help alleviate conditions such as painful periods, excessive bleeding, premenstrual syndrome, and menstrual-related migraine headaches.
- With conventional-use OCs, more side effects, such as bloating, headaches, and breast tenderness, may occur during the pill-free interval than during the active pill phase. Reducing or eliminating this pill-free interval may reduce these side effects.
- Extended and continuous regimens are more convenient in general and during particular occasions, such as vacations and athletic activities.
- Extended regimen contraception eliminates the need to purchase and carry as many hygiene products.
- These regimens (e.g., the vaginal ring) may be less costly.

Disadvantages

- Unpredictable breakthrough bleeding is initially more common than with conventional OCs. Bleeding will lessen as the body adjusts to the new hormone balance.
- It often takes a few months before the desired effect of reduced bleeding is achieved. If the method is being used to eliminate menstruation for a specific event, such as a honeymoon, it should be initiated well in advance of the event.
- It may be more difficult to tell whether you are pregnant. Look for other signs of pregnancy besides a skipped menstrual period, such as breast tenderness, nausea, fatigue, and other signs. If necessary, pregnancy tests can be performed.
- The regimens (e.g., pills, patches) may be more costly.



Female Reproduction Anatomy and Menstrual Physiology (See Patient Pull-Out)

- Roles of estrogen and progesterone and how they relate to the menstrual cycle
- How the standard birth control method works (see Patient Pull-Out for OCs)
- How extended regimen contraception works (see Patient Pull-Out for OCs)
- Hormonal options

DISCUSSION AFTER DECISION IS MADE

How to Use Contraceptive Method for Extended Use

- When to have hormone-free days, if any
- Schedule of method, such as taking OCs at the same time every day

What to Expect

- Spotting
- Blood may be dark brown (oxidized due to remaining in vagina longer) rather than red (blood noted with active bleeding)
- Blood may have different texture

When to Call Provider

- Side effects such as heavy bleeding, nausea, vomiting, bloating, mood changes, headaches

Pregnancy Signs and Symptoms Other Than a Missed Period

- Breast tenderness
- Fatigue
- Nausea
- Frequent urination



FREQUENTLY ASKED QUESTIONS ON EXTENDED CONTRACEPTION

Following are answers to questions patients commonly ask about extended or continuous regimen contraception. This page may be reproduced, and handed out to patients as an educational tool.

1. Is it safe to use contraceptives continuously?

- ♦ The studies on Seasonale®, the new extended OC regimen, showed that side effects were comparable with the conventional 21/7 regimen. Extended OCs were also found to be safe with respect to the uterus (womb and its lining).
- ♦ Taking the pill continuously is not any riskier than taking monthly birth control pills, which are safe for most women.
- ♦ Today's low-dose OCs have much less estrogen than they did years ago. They now cause fewer side effects, such as nausea and fluid retention. They also remain very effective in preventing pregnancy.
- ♦ Some women should not take the pill, including those with liver disease, severe high blood pressure, previous problems with blood clots in the legs or lungs, and women over 35 who smoke.

2. Is it safe not to have a period every month?

- ♦ Health care providers have stopped women's periods—through the continuous use of contraceptives—to treat a condition called *endometriosis* for years. No significant problems with this have been reported.
- ♦ There were no health problems in the studies on Seasonale.

3. What happens to the blood when I don't have a period?

- ♦ In women who are not using hormones, every month female hormones signal the uterus to build up its lining and blood supply to make a healthy, nurturing place for a fertilized egg to grow. If the egg does not join with a sperm to start a pregnancy, the lining is no longer needed, so you have a period. The blood that comes out is the built-up lining of the uterus.
- ♦ Birth control pills and other contraceptives contain hormones that stop the egg from being released from the ovary and stop the lining of the uterus from building up. This leaves little or nothing to be released from the uterus. Taking contraceptives continuously keeps the normal uterine lining from breaking down and bleeding. The lining remains thin and does not need to be flushed out each month.

4. What should I do if I have spotting?

- ♦ Spotting is from some of the thinned-out uterine lining breaking down. It is not a period. Spotting is normal and common at first, as your body adjusts to the steady hormone levels. Eventually spotting stops.

- ♦ Spotting can happen on and off for around months, sometimes for a little longer.
- ♦ The important thing is to take the pill or other contraceptive as I suggested. With the pill, it is important to take it as close as possible to the same time every day. If the spotting continues beyond a few months, seems heavy, is overly bothersome, or you have any other concerns, call me.

5. How often do I need to get a period?

- ♦ Women who take hormonal contraceptives do not need to have a period.
- ♦ In fact, women who breastfeed and don't supplement feedings usually don't get a period. They do not ovulate, so the lining of the uterus does not thicken.
- ♦ In some cultures, women breastfeed for two or three years continuously. During this time, they do not get a period. This is perfectly normal.

6. How will I know if I'm pregnant?

- ♦ Pregnancies are rare in women who take their contraceptive correctly. If you think you may be pregnant, you should have a pregnancy test. Use either a home pregnancy test that you can buy at the drug store or come in for a test. Most home pregnancy tests can tell you if you are pregnant after about 10 days of pregnancy. Many women suspect they are pregnant before they miss a period. Symptoms such as breast tenderness, feeling overly tired, and nausea can happen early in pregnancy—often before the first period is missed.

7. What are the differences between the health effects of hormone therapy (HT) and birth control pills?

- ♦ HT and the pill both release the hormones estrogen and progesterin into the body.
- ♦ BUT: Women who take HT are generally older than women who use birth control pills, and older women have a higher risk for medical problems, such as heart disease, stroke, blood clots, and breast cancer. The Women's Health Initiative showed that adding estrogen and progesterin to their systems slightly increases these risks. Use of the pill is safe for most women.
- ♦ Premenopausal women whose bodies still make estrogen and progesterone can better handle the effects of added synthetic hormones that you get from the pill.



SUMMARY AND RECOMMENDATIONS

Many women are becoming interested in reducing or eliminating their periods.¹ For example, sizeable numbers of women in the international amenorrhea acceptability study,² the German study,³ the Association of Reproductive Health Professionals' (ARHP) Menstrual Suppression Survey,⁴ and the women interviewed through the Harris poll in 2002⁵ preferred to menstruate less than once a month or never. According to research by Sulak and colleagues,⁶ Miller and Notter,⁷ and Anderson and colleagues,⁸ many women who try an extended regimen choose to continue with it.

Providers are also recognizing the benefit of extended and continuous contraception. Of 117 ARHP and National Association of Nurse Practitioners in Women's Health meeting registrants who were surveyed, 77 percent said they prescribed extended contraceptives.⁹ In ARHP's Menstrual Suppression Survey, half of providers surveyed said they prescribed extended contraception, many upon patient request.⁴ In the American College of Obstetricians and Gynecologists' survey of female obstetrician/gynecologists, 99 percent believed that menstrual suppression is safe and over half had suppressed their own periods.¹⁰

Yet numerous barriers to menstrual suppression remain. The release of Seasonale®—a dedicated product for extended contraceptive use—in 2003 has raised awareness of menstrual suppression among clinicians and women. However, it is also essential to provide ongoing education of health care providers and women about extended contraceptives and to create counseling tools for providers. Recommendations include the following.

Educate providers about menstrual suppression:

- Benefits and effects of regulating menstruation
- Surveys on women's attitudes and beliefs about menstruation and its suppression
- Various hormonal therapies to adjust menstruation and related research
- Different cultural values and beliefs about menstruation

Improve patient counseling:

- Explaining the female reproductive system and the effect of extended regimen contraception on the system
- Addressing myths about the need to menstruate during use of hormonal contraception

- Developing better counseling tools for providers
- Describing the endometrial safety of extended use of combination hormone therapy

Increase the awareness and knowledge of women about extended regimen contraception through provider counseling and media venues:

- No need to menstruate while on hormonal contraception
- Ways to change menstruation
- Health and lifestyle advantages to suppressing menstruation
- Research findings on health effects of extended contraceptive methods

Conduct further research to answer questions: Extended and Continuous Regimen Methods

- What patterns of bleeding can women expect with extended or continuous use over time?
- Are there differences in bleeding patterns between new oral contraceptive (OC) extended or continuous regimen users and users who are switching from a traditional regimen to an extended or continuous regimen?
- What strategies might reduce or eliminate spotting and irregular bleeding during the early cycles of extended or continuous use contraceptives?
- What are the safety issues and noncontraceptive benefits associated with use of extended or continuous contraceptives?

Counseling

- How can health care providers counsel women to improve consistent use of OCs?
- What are the cultural differences in how women and families view menstruation?
- How do women feel about spotting with extended or continuous regimens?



Facilitating an Extended Regimen

- How can providers best integrate the use of extended regimen contraception into their practices?
- How can pills be packaged to make them easier to take?
- How can the cost of extended OC regimens be reduced?

Women should be able to choose whether and how to suppress their menstrual cycles. To enable them to choose, they and their providers need to be knowledgeable about the benefits and risks of various extended contraceptive regimens. Providing women with this choice has the potential to improve not only their reproductive health, but also the quality of life during their reproductive years.

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Association of Reproductive Health Professionals
2401 Pennsylvania Avenue, NW, Suite 350
Washington, DC 20037-1730 USA
Phone: (202) 466-3825 ♦ Fax: (202) 466-3826
E-Mail: arhp@arhp.org ♦ Web: www.arhp.org

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503 Capitol Court, NE, Suite 300
Washington, DC 20002 USA
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CLINICAL ADVISORS

ARHP would like to thank the following clinical experts for their assistance in preparing this monograph.

Linda Andrist, PhD, RNC, WHNP

Associate Professor and Coordinator
Women's Health NP Program
MGH Institute of Health Professions
Boston, MA

Jeffrey T. Jensen, MD, MPH

Leon Speroff Professor of Obstetrics and Gynecology
Oregon Health and Science University
Portland, OR

Andrew M. Kaunitz, MD, co-chair

Professor and Assistant Chairman
Department of Obstetrics and Gynecology
University of Florida, Health Science Center
Jacksonville, FL

Susan Wysocki, RN-C, NP, co-chair

President and CEO
National Association of Nurse Practitioners
in Women's Health
Washington, DC

FINANCIAL DISCLOSURE INFORMATION

Andrist: Advisory board for Berlex Laboratories.

Jensen: Receives grant/research support from Berlex Laboratories; National Institute of Child Health and Human Development, National Institutes of Health; Organon Pharmaceuticals USA, Inc.; Pfizer, Inc.; Warner Chilcott, Inc.; and Wyeth Pharmaceuticals. Speaker for Organon Pharmaceuticals USA, Inc.; Pfizer, Inc.; and Wyeth Pharmaceuticals. Advisory board for Wyeth Pharmaceuticals.

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Extended and Continuous Use of Contraceptives to Reduce Menstruation

POST-TEST

Please circle the single most appropriate answer below.

1. Surveys of consumers conducted in the United States and Europe indicate that:
 - a. many menstruating women would prefer to have monthly periods
 - b. many menstruating women would prefer not to have monthly periods
 - c. many menstruating women would prefer to have periods twice a year
 - d. many menstruating women would prefer to have periods once a year
2. According to the Association of Reproductive Health Professionals' Menstrual Suppression Survey, many women who are interested in extended regimen contraception are concerned that:
 - a. there could be long-term health risks to suppressing menstruation
 - b. menstrual suppression will affect their future fertility
 - c. they will have side effects while using extended regimen contraception
 - d. all of the above
3. A Gallup survey of female obstetrician/gynecologists conducted for the American College of Obstetricians and Gynecologists in 2003 found that what percentage had tried menstrual suppression themselves?
 - a. 8 percent
 - b. 19 percent
 - c. 37 percent
 - d. 53 percent
4. In the largest trial of extended regimen contraception to date comparing Seasonale® with Nordette®, investigators found that the frequency of unscheduled bleeding episodes was:
 - a. initially higher with Seasonale and declined with each successive cycle
 - b. initially lower with Seasonale and increased with each successive cycle
 - c. higher throughout the study with Seasonale
 - d. lower throughout the study with Seasonale
5. The large randomized trial of Seasonale versus Nordette found:
 - a. mild endometrial hyperplasia associated with use of extended regimen contraception
 - b. moderate endometrial hyperplasia associated with use of extended regimen contraception
 - c. no endometrial pathology associated with use of extended regimen contraception
 - d. severe endometrial hyperplasia associated with use of extended regimen contraception
6. In the German trial of Yasmin®, researchers found that women on the extended regimen had:
 - a. better sexual satisfaction
 - b. enhanced fertility
 - c. fewer vaginal infections
 - d. less dysmenorrhea
7. In the continuous trial by Marni Kwiecien and colleagues conducted in Oregon, subjects in the continuous regimen group had significantly less:
 - a. acne than those in the standard group
 - b. bloating and menstrual pain than those in the standard group
 - c. dyspareunia than those in the standard group
 - d. both a and c
8. Which of the following contraceptives are being investigated for extended use?
 - a. The contraceptive patch (Ortho Evra®)
 - b. The contraceptive vaginal ring (NuvaRing®)
 - c. Both a and b
 - d. Neither a nor b
9. Which of the following statements is correct in regard to the intrauterine system Mirena®?
 - a. 0 percent of users become amenorrheic by 1 year
 - b. ~20 percent of users become amenorrheic by 1 year
 - c. ~50 percent of users become amenorrheic by 1 year
 - d. ~70 percent of users become amenorrheic by 1 year
10. Which of the following is NOT an obstacle to the use of extended or continuous regimen contraception?
 - a. concerns about discreetness of method
 - b. long-term safety concerns
 - c. third-party coverage
 - d. women's beliefs



PROGRAM EVALUATION

On a scale of 1 to 5, with 5 being the best, please rate this *Clinical Proceedings*[®] in terms of the following:

1. Extent to which stated program objectives are met.
 - a. Describe three examples of the impact of menstruation on lifestyle, productivity, and medical conditions.
5 4 3 2 1
 - b. Name four approaches to prescribing extended hormonal contraception.
5 4 3 2 1
 - c. Name five noncontraceptive health advantages of medically suppressing menstruation.
5 4 3 2 1
 - d. Cite two clinical trials that provide data on endometrial safety of extended regimens of oral contraception.
5 4 3 2 1
 - e. List three obstacles to extended contraceptive regimens and state two recommended approaches to patient counseling.
5 4 3 2 1
2. Relevance to clinical practice
5 4 3 2 1
3. Increased understanding of the topic
5 4 3 2 1
4. Relevance of content to objectives
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5 4 3 2 1

7. Please comment on the scientific rigor, fairness, and balance of the material: _____

8. What topics would you suggest for future programs?

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How a Woman's Reproductive System Works

Women's ovaries make three hormones: estrogen, progesterone, and some testosterone.

The menstrual cycle is the days between the start of one menstrual period and the start of the next menstrual period

Each month:

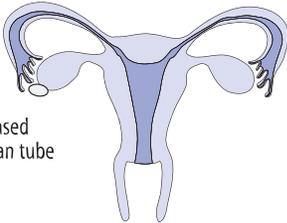
Normal Cycle

Estrogen

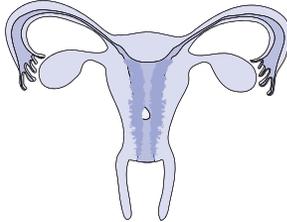


The estrogen tells the ovary to develop an egg to release.

The egg is released into the fallopian tube



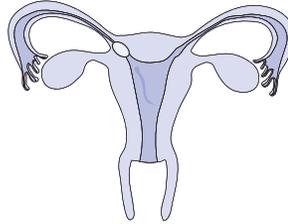
Once the egg has been released, progesterone signals the uterus to make a soft, thick lining, just in case the egg is fertilized. The progesterone also stops the ovary from developing and releasing new eggs



When an egg does not become fertilized, the body stops making the progesterone and the lining of the uterus stops thickening. Within about 14 days after the release of the egg, the thickened lining of the uterus sheds. This is called menstruation or a period.

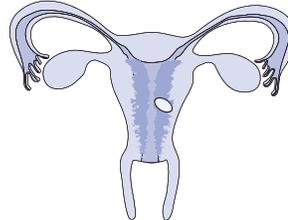
Fertilization

If a woman is having sex during the time the egg is traveling down the fallopian tube and not using birth control, the egg may, together with a sperm, form a fertilized egg.

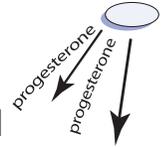


The egg then travels to the uterus.

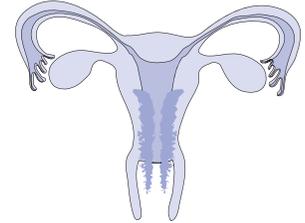
Once the egg has been released, progesterone signals the uterus to make a soft thick, lining, for the egg to grow.



Birth Control Pill



Most birth control pills contain both estrogen and progesterone. Progesterone in the pill signals the body not to develop an egg so pregnancy does not occur.



Because an egg is not released, pregnancy does not occur. The lining of the uterus does not thicken as it would to prepare for a fertilized egg. The estrogen in the pill keeps the normal lining of the uterus from breaking down. During the pill-free week, the lining of the uterus dissolves, causing a period.

What Happens if I Take Active Pills for More Than 21 Days in a Row?

Whether you take an active pill for 21 days and then the placebo pill for seven days or take an active pill for 60 or even 90 days straight, the effect of the pill on your reproductive system is the same. Except with the 21-day pill, you bleed more often (during the placebo-pill week). The birth control pill was designed to mimic a woman's menstrual cycle. However, there is no health reason for women on the pill to bleed every month.

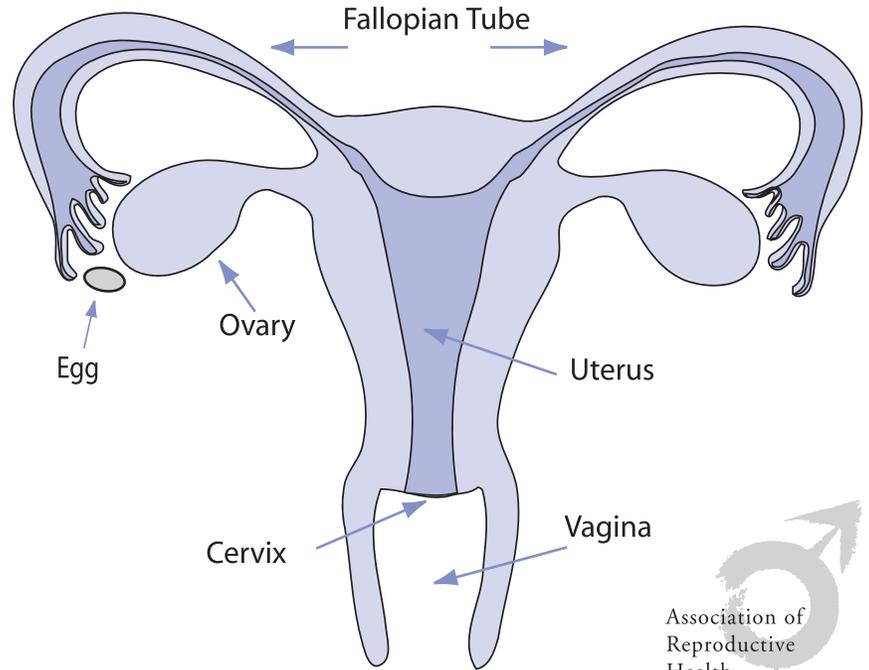
Women who take more than 21 pills in a row can expect to have fewer periods over the course of a year. For example, a woman taking pills three months in a row followed by a week off will have only four periods a year. There are no known medical or health risks for taking the pill this way.

Most women who start the pill for the very first time will have spotting or bleeding in between the time from one period to the next as their body adjusts. The same thing is true for women who begin taking pills for more than 21 days in a row. Wearing a panty liner might be advisable during these first few months.

The spotting is NOT a sign that there is something wrong. Eventually a woman's body gets used to the pills, and the spotting stops. The longer a woman takes the continuous pills, the less frequently spotting will happen.

Your health care professional can help you with questions about what you might expect from taking active pills for more than 21 days in a row.

A Woman's Reproductive System



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MAIL this form to 2401 Pennsylvania Avenue, NW, Suite 350, Washington, DC 20037

First Name _____

Last Name _____

Degree _____

Address _____

City _____ State/Province _____

Country _____ Zip/Postal Code _____

Work Phone _____

Home Phone _____

E-mail _____

Select the option that best describes you:

Physicians \$175

MD, DO

Advance Practice Clinicians, Researchers, Educators \$110

RN, NP, BSN, RHP, PhD, MPH, MSN, CNM

Joint Membership (with other organizations) \$100

Visit www.arhp.org/membership for a current list of partners.

Students/Residents, Retired \$40

Proof of status required for student/resident members. You may fax your student ID or other verification to (202) 466-3826.

International (Applies to individuals in developing countries only) \$0

Applies to individuals in developing countries. International members in developed countries should adhere to regular membership categories; physician, advanced practice clinician/researcher educator, joint, or student/retired.

Degree(s)

MD

PA

DO

RN

NP

CNM

MPH

PhD

MA/MS/MBA

MSW

BA/BS/BSW

Other: _____

Work Setting (Choose primary one)

private practice

hospital

HMO/managed care

laboratory

public health clinic

military

retail pharmacy

industry/corporation

college/university

association/society

other: _____

Specialty

ob/gyn

endocrinology

family practice

internal medicine

mental health

urology

public health

oncology

pediatrics/adolescent medicine

education

infertility

social work

pharmacy

other: _____

Payment Info

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Mastercard

American Express

Card Number _____ Exp _____

Name on Card _____

Check Purchase Order _____

The Association of Reproductive Health Professionals (ARHP) is a professional medical association composed of physicians, advanced practice clinicians, researchers, educators, and other professionals who share an interest and an expertise in reproductive health. Reproductive Health means that all people have a right to be comfortable with their sexual relations; that they have the information available to them to make intelligent choices about sexual relations; that they have the ability to reproduce and regulate their fertility; that women are able to go through pregnancy and childbirth safely; that people are able to have sexual relations free from the fear of contracting disease; and that all people have reproductive options available to them. The membership subscribes to the principles of individual autonomy in the area of fertility regulation, including the right of a woman to determine whether and when to sustain or terminate her pregnancy.

I AFFIRM MY SUPPORT OF THE ASSOCIATION OF REPRODUCTIVE HEALTH PROFESSIONALS AND ITS PURPOSES.

Signature (all members must sign): _____ Date: _____