

CLINICAL PROCEEDINGS®

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



April 2003

Choosing When to Menstruate: The Role of Extended Contraception

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This publication is intended for physicians, nurse practitioners, nurse midwives, registered nurses, pharmacists, physician assistants, researchers, public health professionals, and health educators in the field of reproductive health.

ARHP and NPWH are non-profit, 501(c)(3) educational organizations. ARHP's membership includes obstetrician/gynecologists and other physicians, advanced practice clinicians, researchers, educators, and other professionals in reproductive health. NPWH's membership includes nurse practitioners that provide care to women in the primary care setting and in women's health specialty practices.

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Myths and Realities: Menstrual Suppression

Women have been manipulating their menstrual cycles for years—for their honeymoon, for an athletic event, for relief from menstrual cramping—usually by eliminating the hormone-free week in an oral contraceptive (OC) regimen. Health care providers have helped women regulate their cycles to treat endometriosis, migraines, and other medical conditions by prescribing the extended use of contraceptives.

By summer 2003, a dedicated extended OC regimen, Seasonale®, likely will be released. This product will help increase the acceptance and popularity of the extended use of contraceptives to women, health care providers, and third-party payers. Other contraceptive methods for extended use are also being studied. So it is timely for the Association of Reproductive Health Professionals (ARHP) and the National Association of Nurse Practitioners in Women's Health (NPWH) to present *Choosing When to Menstruate: The Role of Extended Contraception*. This issue of *Clinical Proceedings* reviews studies on attitudes and practice of health care providers and women about the extended use of contraceptives as well as research on extended use of various contraceptive methods. It also provides educational tools for health care providers to use in counseling their patients. Counseling is a key element in women's acceptance and proper use of extended regimens.

In addition to reviewing the literature, ARHP and NPWH conducted surveys and held roundtable discussions of experts to gather information for this issue of *Clinical Proceedings*. Through a Harris poll, ARHP interviewed 491 women by telephone about their preferences on the frequency and characteristics of menstrual bleeding. Through online surveys, ARHP's and NPWH's annual meeting registrants provided data on their use of extended regimens. In September 2002, experts analyzed survey results, suggested approaches to counseling, listed obstacles and ways to overcome them, and shared their professional experiences during discussions at ARHP's annual meeting in Denver and at NPWH's annual meeting in Scottsdale. We would like to express our gratitude for their insight and expertise, which so enriched this publication.

Extended regimen contraceptives give 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 contraceptives 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 the impact of menstruation on lifestyle and medical conditions.
2. Name five health advantages of medically regulating menstruation.
3. Name four types of candidates for extended contraceptive regimens.
4. List six hormonal methods for reducing bleeding.
5. Describe obstacles to extended contraceptive regimens.
6. Explain recommended approaches to counseling.

This publication has been made possible by an unrestricted educational grant from Barr Laboratories.



INTRODUCTION

Is monthly menstruation a natural state?

Preagricultural women had about 160 lifetime menstrual cycles, but that number has almost tripled to about 450 cycles for contemporary women who live in industrial, Western nations (see Figure 1). The lower number of menstrual cycles is attributed to late menarche, high parity, extended periods of breastfeeding, and early menopause.¹

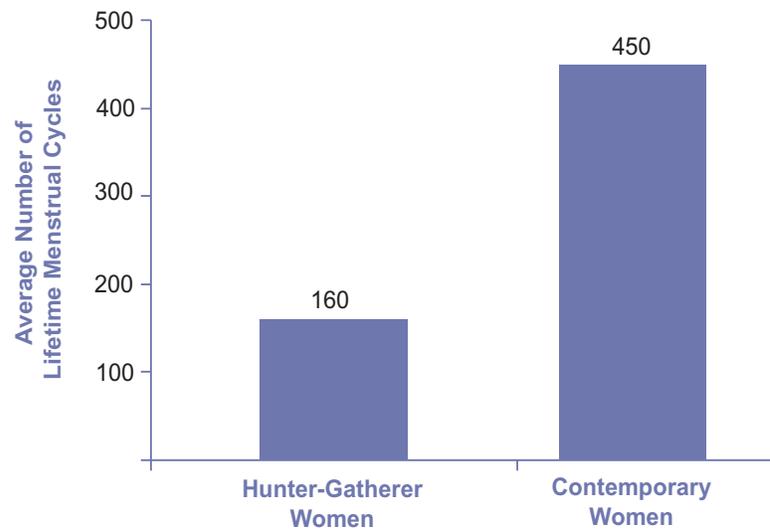
At a minimum, menstruation can be an inconvenience. For many women, however, monthly menstruation causes substantial distress. Of the 2.5 million women in the United States between 18 and 50 years of age who suffer from menstrual disorders, about 65 percent contact their clinician for menstrual symptoms, 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 U.S. women, investigators estimated that women with heavy menstrual flow worked 6.9 percent less, or 3.6 fewer weeks yearly, with estimated lost wages of about \$1,692 per woman annually.⁴ Menstruation can cause anemia from excessive menstrual volume, and pre-existing conditions such as iron deficiency and hereditary anemia can be exacerbated. It can also cause or increase the severity of pelvic pain, endometriosis, and migraine headaches. Menstrual abnormalities, such as dysfunctional uterine bleeding and menorrhagia, add to women's discomfort.

Even though many women and clinicians believe that menstruation is necessary to their health, no evidence exists that it improves women's health or prevents uterine infections or cancer.

So, *should women's menstruation cycles be altered?*

Figure 1: Frequent Menstruation Is a Relatively New Biological State



Source: see reference 1

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3. Dalton K, Holton W. *Once a Month: Understanding and Treating PMS*, 6th ed. Alameda, CA: Hunter House, 1999.
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CHOICES ABOUT MENSTRUATION

Advances in contraception are allowing women more choices: the type of hormonal contraceptive to use to alter the menstrual cycle, how often or whether to have a menstrual period, and the number of days to menstruate. Some women may want to stop their periods for a few months; others, for years. They can also decide to alter their cycle during particular times in their lives, such as for a honeymoon or athletic event, for medical 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. Groups of women who could benefit from hormonal methods to regulate menstruation include:⁴⁻⁸

- ◆ Women with menstrual-related medical gynecological problems
- ◆ Adolescents
- ◆ Perimenopausal women
- ◆ Athletes
- ◆ Females in the military
- ◆ Mentally handicapped women
- ◆ Any women who choose to menstruate less frequently

Table 1: Conditions That Can Benefit From Amenorrhea

- ◆ Iron deficiency anemia
- ◆ Catamenial conditions
 - Menstrual-related migraine headaches
 - Menstrual-related seizures
- ◆ Dysmenorrhea
- ◆ Premenstrual dysphoric disorder
- ◆ Menorrhagia
 - Idiopathic menorrhagia
 - Uterine fibroids
 - Adenomyosis
 - Coagulation/hematologic problems

“In 1977, I started to extend the use of active OCs because I had periods every 21-23 days for 7 days. My pattern was to use OCs 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 OC 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 and also great for overseas travel.”

—Sybil, family practice resident, age 27

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CONSUMER AND CLINICIAN ACCEPTANCE

CONSUMER ACCEPTABILITY

According to recent surveys, many women—regardless of age—would prefer to eliminate menses completely or reduce the frequency to less than once a month if they had the choice.

Dutch Study

In 1996, researchers conducted telephone interviews with 325 Dutch women to determine their preferred changes in their current bleeding pattern and their attitudes towards changes in bleeding patterns when using oral contraceptives (OCs) and hormone therapy (HT).¹ They also studied the extent to which women use OCs and HT to change their menstrual bleeding pattern. Data were collected in each of four age groups: 15-19, 25-34, 45-49, and 52-57. The results were:

Preferred changes in bleeding patterns. 71.5 percent of menstruating women preferred changes in bleeding patterns, such as less painful periods, shorter periods, less heavy periods, and 9 percent preferred a total absence of menstrual bleeding.

Preferred frequency of menstruation. Most women in the youngest three age groups preferred bleeding once a month or never. More than half of menstruating women ages 45-49 preferred menstruating less than once per month. (see Figure 2)

Preferred frequency of menstrual bleeding, if manipulated by OCs or HT. The percentage of women desiring to stop menstruation completely increased with age. (see Figure 2) Most women preferred to menstruate less than once a month or never (71 percent for 15-19-year-olds, 60.2 percent for 25-34-year-olds, and 58.6 percent for 45-49-year-olds).

Women's attitudes towards their menstrual bleeding patterns when using OCs and HT. Negative attitudes toward changes in menstrual bleeding pattern, if caused by OC use, were most prevalent for unexpected bleeding and heavier flow.

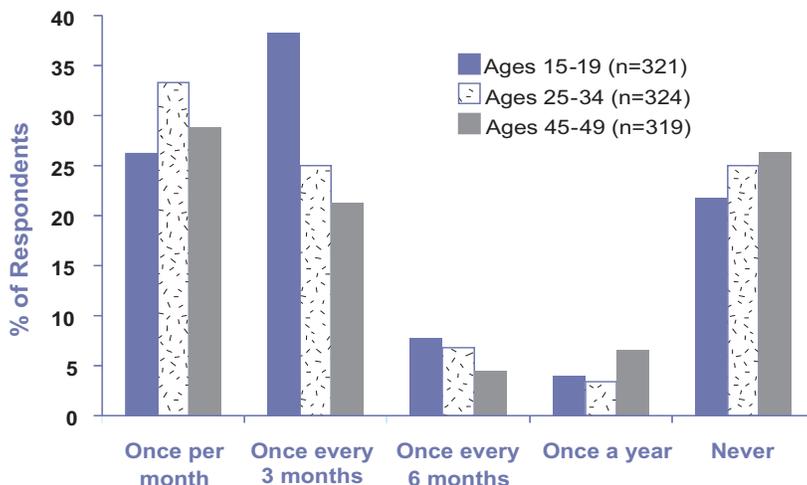
Use of OCs for menstrual problems, to delay menstrual bleeding, or both. Adolescent girls and perimenopausal women used OCs for menstrual problems significantly more often than women in the 25-34 year age group.

2002 ARHP Harris Poll

In 2002, ARHP commissioned Harris Interactive Inc. to interview 491 women by telephone about their preferences on the frequency and characteristics of menstrual bleeding. The interviews were conducted during the weeks of June 14-17 and July 18-22, 2002, with women between the ages of 18 and 49.²

- ◆ Only 30 percent relied on the occurrence of their menstrual period to tell them if they were healthy; 31 percent to tell them if they were able to have children; 38 percent to tell them if they were pregnant.
- ◆ Overall, 44 percent would prefer never to menstruate, increasing to 59 percent for women ages 40-49; 29 percent preferred to menstruate once a month.
- ◆ More than one in four women have missed professional, social, athletic, or family-oriented events because of her period, menstrual cramps, or other menstrual effects.
- ◆ 70 percent use or have used OCs; 15 percent have used OCs to delay or stop their period.

Figure 2: Preferred Frequency of Menstruation



Comparison of Dutch and Harris Polls

The Dutch and ARHP/Harris surveys can be compared according to how often women would prefer to menstruate. The majority of women in both studies preferred to have a period less than once a month or never; however, in the Dutch study, the percentages of such women were higher in the lower age groups. In the two surveys, women desiring a complete absence of menstruation increased with age. A significantly higher percentage (73.7 percent) of women in the Dutch study than in the ARHP study (28 percent) preferred to have periods every three months.

Descriptive/Exploratory Study

In 2002, Linda Andrist, PhD, WHNP, associate professor at MGH Institute of Health Profes-



sions, and her colleagues conducted a study to explore women's attitudes and beliefs about menstruation in general, and menstrual suppression.³ Self-administered questionnaires were given to a convenience sample of 221 females, between 12 and 30 years old, who were highly educated and most of whom were Caucasian. Forty-eight percent were not using a hormonal birth control method, and 50 percent were using OCs.

Interest in changing menstrual pattern. More than two-thirds of respondents were interested in reducing menstrual pain and the amount of bleeding, particularly those who were not using OCs.

Importance of monthly menstruation. When asked if it was necessary to have a period every month, of those not on a hormonal method, 52 percent said "yes," 32 percent said "no," and 15 percent were "unsure." Of those on OCs, 37 percent said "yes," 45 percent said "no," and 18 percent were "unsure."

Interest in menstrual suppression. 57 percent strongly agreed or agreed they were interested, 12 percent neither agreed nor disagreed, and 31 percent disagreed or strongly disagreed. Women currently using OCs were more interested in using a contraceptive for menstrual suppression than women who were not 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 not be normal. A significant finding was that women's attitudes toward menstruation (negative vs. neutral or positive) were more predictive of their interest in menstrual suppression than were their perimenstrual symptoms.

"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. Unfortunately, physicians are uncomfortable with off-label use: they feel like they are bending the rules, so it needs to be made more acceptable."

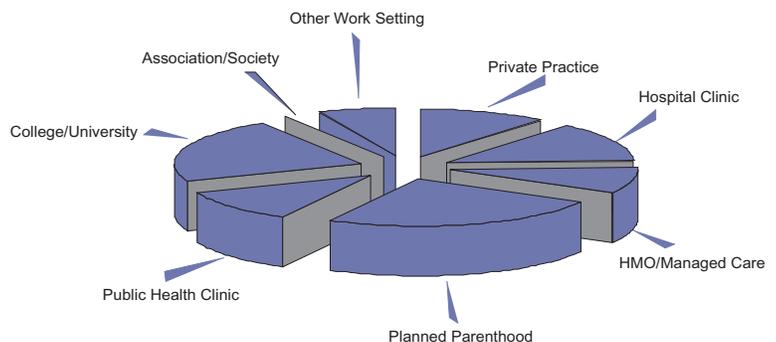
—Maria, ob-gyn physician, age 31

PROVIDER ACCEPTABILITY

ARHP and NPWH Annual Meeting Registrant Clinician Survey

The Association of Reproductive Health Professionals (ARHP) and the National Association of Nurse Practitioners in Women's Health (NPWH) surveyed their annual meeting registrants, totaling 117, August-September 2002, to determine their prescription practices of extended OCs.⁴ The majority of respondents specialized in obstetrics/gynecology (78 percent) with the remainder in pediatrics/adolescent health, internal medicine, family practice, pharmacy, and education. The largest segments of respondents were nurse practitioners (48 percent), followed by physicians (16 percent) and were in private practice (33 percent). Figure 3 provides further information on respondents' affiliation.

Figure 3: ARHP and NPWH Annual Meeting Registrant Survey Participant Affiliations



Source: see reference 2

Survey Results

Patient interest in extended OC regimen. 65 percent of their patients ask about the regimen.

Extended OC regimen prescription practices. 77 percent prescribe extended OC regimen contraception: 5–20 percent of OC prescriptions are extended regimen (27 percent of respondents); 20–35 percent of the prescriptions are extended regimen (7 percent of respondents).

The prescription patterns include more than 21 active pills per cycle and shortened pill-free interval (15 percent); 42 active pills followed by 7-day pill-free interval (29 percent); 63 active pills followed by 7-day pill-free interval (72 percent); active pill with instructions for patient to take a 7-day pill-free interval if spotting occurs with continuous use (35 percent); other (12 percent)—continuous active pills; 6 months; 2–7 pill-free days if any breakthrough bleeding; 84 days.



Reasons for prescribing extended OC regimen.

Reasons include patient request (79 percent); lifestyle (78 percent); endometriosis (83 percent); dysmenorrhea (73 percent); menorrhagia (73 percent).

Reasons for not prescribing extended OC regimen.

Twenty-eight percent do not prescribe extended OC regimen contraception because patients do not request it (43 percent); not licensed to prescribe (26 percent); not providing direct patient care (17 percent); extended regimen not part of approved class labeling for oral contraceptives; insurance coverage; requires extra counseling with patients; limited data on use of extended regimen (each indicated by 4 percent).

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4. Association of Reproductive Health Professionals and National Association of Nurse Practitioners in Women's Health. Annual meeting registrant survey. August-September 2002.

USING ORAL CONTRACEPTIVES TO REDUCE MENSTRUAL BLEEDING

The most common method used to regulate menstruation is to alter the way in which a monophasic oral contraception (OC) is taken. With this method, the placebo week from the standard 21/7-day cycle is eliminated. The length of extended use varies, but in the 2002 ARHP and NPWH surveys of annual meeting registrants, 72 percent of the registrants who prescribe extended OC regimens indicated they prescribe 63 active pills followed by a 7-day pill-free interval.¹ Sulak and colleagues found that the typical pattern for women on the extended regimen was 12 weeks (84 days) of active pills followed by 6 pill-free days.²

For most women, the risks of using today's lower-dose pills are very small, and there are substantial health benefits. Women who take OCs are less likely to develop osteoporosis, ovarian or endometrial cancer, benign breast disease, and pelvic inflammatory disease.³ A recent major study confirms that using the pill does not affect the risk of breast cancer among women 35 to 64 years of age.⁴ OCs can also help ease menstrual-related disorders such as dysmenorrhea and menorrhagia, premenstrual syndrome, and perimenopausal symptoms, such as hot flashes, night sweats, and irregular monthly periods.⁵

However, some women should not take OCs. For a complete list of contraindications, please visit the World Health International Web site at: www.who.int/reproductive-health/family_planning/.

STUDIES ON EXTENDED USE OF ORAL CONTRACEPTIVES

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

Extending Cycle from 28 Days to 49 Days with Conventional OCs

A study comparing a traditional 28-day cycle to an extended 49-day cycle of the 30 mg ethinyl estradiol (EE)/300 mg norgestrel monophasic birth control regimen was conducted from April 1998 to April 2000.⁶ The objective was to compare the two regimens in terms of differences in bleeding pattern, symptoms, need for sanitary protection (pads or tampons), and overall satisfaction. Patients were randomly assigned to either 21/7 or 42/7 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 women (54.5 percent) on the 28-day cycle and 29 (63 percent) on the 49-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, or prolonged menses. In the first trimester, the number of bleeding days was significantly reduced with



the extended OC cycle: (21/7 = 10.9, 42/7 = 6.4 mean days of bleeding, $P = .005$). In the first and fourth trimesters the number of spotting days was similar between both schedules (28-day = 4.8, 49-day = 3.7 mean days, $P = .24$).

Hygiene product use. Women using the extended regimen spent significantly less on hygiene products (28-day = \$41.45, 49-day = \$17.54, $P < .001$). Over the entire study, women on the extended regimen used hygiene products for significantly fewer days (28-day cycle = 53.5 days, 49-day cycle = 27.3 days, $P < .001$).

Satisfaction. The level of women's satisfaction with their pill schedule was reported using a five-point scale (1 = not satisfied to 5 = better than other methods and would recommend to other women). The OC satisfaction scores were similar for the two regimens (21/7 = 4.0, 42/7 = 5.0, $P = .13$).

Continued contraceptive use. At the study exit, of the women who planned to continue with hormonal contraception, 52.4 percent who used the extended regimen wished to continue with it; 16.7 percent who used the 28-day regimen wished to switch to the extended regimen.

Extending Conventional 21/7 Regimen to Individualized Schedules

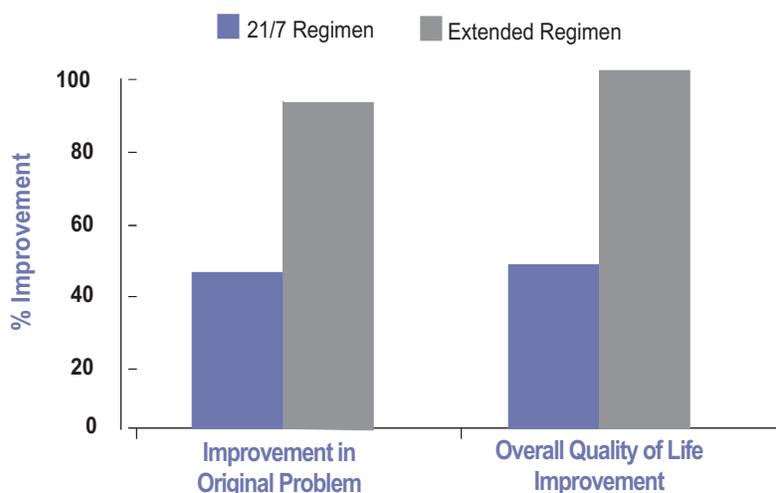
Sulak and colleagues conducted a retrospective survey to assess how women accepted altering the 21/7-day oral contraceptive regimen to delay menses and reduce hormone withdrawal symptoms.² Records of 318 patients who were counseled about extended OC use from December 1993 through October 2000 were reviewed. Of these, 292 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 less than 7 days. All women used a monophasic OC formulation with 30 to 35 mg EE and at baseline reported having pelvic pain, bleeding, headaches, analgesic use, nausea or vomiting, bloating or swelling, and/or breast tenderness during the hormone-free week. Women reported similar side effects from OCs, which were significantly worse during the 7-day hormone-free interval than during the 21-day hormone interval, in a 2000 study by Sulak et al.⁷

Reasons for using extended regimen. Reasons included decrease of 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.

Women who chose the extended regimen. 59 percent chose to continue on an extended regimen, with an average cycle of 12 weeks of active pills followed by 6 pill-free days. No unintended pregnancies occurred during the study.

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

Figure 4: Symptomatic Improvement With Extended OCs vs 21/7 Regimen



Source: see reference 2

Extended 84/7-Day Oral Contraceptive (Seasonale®)

Seasonale is an extended 84/7-day monophasic, oral contraceptive regimen consisting of 150 mg levonorgestrel (L) and 30 mg EE.⁸ Its application has been accepted by the US Food and Drug Administration, and it is expected to be on the market by summer 2003. A large, multicenter, randomized study examined its safety and



efficacy. In this study, a total of 1,394 healthy women, ages 18-40, who desired oral contraception, were randomly assigned to Seasonale (150 mg L/30 mg EE), Seasonale (100 mg L/20 mg EE), or a comparable-dose, conventional 28-day OC regimen (Nordette® or Levlite®). The safety and efficacy of Seasonale were compared with conventional 21/7 OC use in this 1-year, 47-site study. Through electronic diaries, researchers measured daily compliance, bleeding and spotting, and menstrual-related symptoms. Endometrial biopsies were performed on a subset of patients at initiation and completion of therapy. The results of the study were:

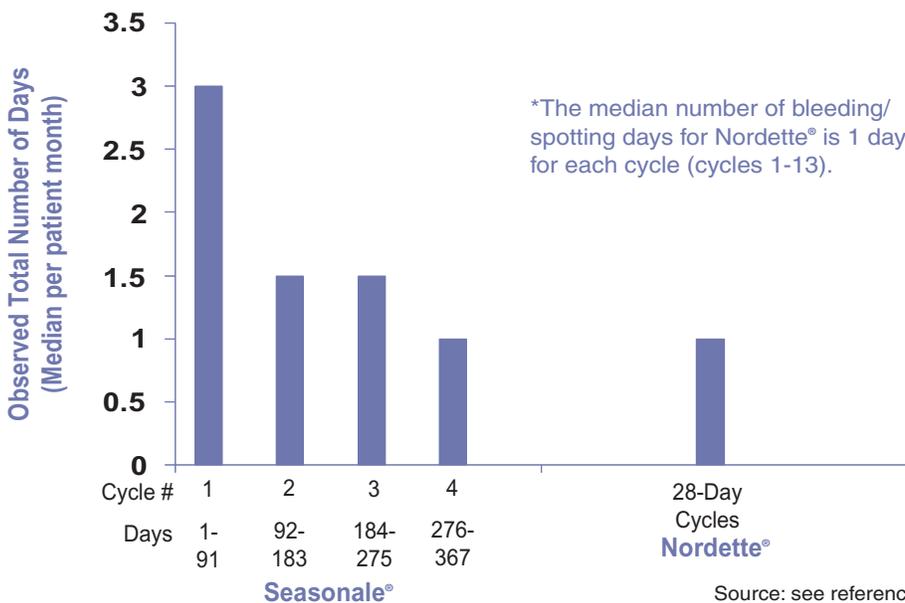
- ◆ Seasonale is as effective in preventing pregnancy as conventional 21/7-day combination OC use.
- ◆ Duration of withdrawal bleeding is comparable between Seasonale and conventional OCs. Frequency of unscheduled bleeding episodes were initially higher with Seasonale, but declined over time (see Figure 5).
- ◆ No endometrial pathology was noted in participants randomly assigned to Seasonale.
- ◆ Nonmenstrual side effects with Seasonale were comparable to those with the conventional 21/7.

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-µg EE /100-mg levonorgestrel formulation for 12 study cycles (336) days. They found that women on continuous OC use had significantly fewer bleeding days than women following the 28-day cycle.⁹

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Figure 5: Unscheduled Bleeding/Spotting with Extended Regimen by the 4th Cycle





OTHER HORMONAL METHODS FOR REGULATING MENSTRUATION

In addition to oral contraceptives (OCs), other hormonal contraceptives can be used to reduce bleeding. Some of these approaches cyclically reduce frequency of bleeding (extended OC regimens), whereas others are continuous and reduce or eliminate bleeding. See Table 2 for a list of these methods.

NEWER, LONGER-ACTING METHODS

Two newer, longer-acting, combination hormonal contraceptives are also potential methods for regulating menstruation.¹ Further studies need to be done on extended use of these therapies.

Contraceptive vaginal ring (NuvaRing®).² Extended use of this combination estrogen-progestin method, approved for contraceptive use in October 2001, 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), it was determined that ovulation continued to be inhibited, and there were no unfavorable safety observations.³ These results may not be found in a larger population of women of different body weights, ages, etc; therefore, use beyond 3 weeks cannot be recommended. Further studies are under way.

"I started using an extended OC regimen in my residency so I would have one less thing to deal with. Initially, after 2-3 months of continuous OCs, 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

Transdermal combination contraceptive patch (Ortho Evra®).⁴ Extended use of this method (conventionally worn 3 out of 4 weeks), approved for contraceptive use in November 2001, also presents an appealing concept.

Clinical trials on extended use of NuvaRing and Ortho Evra are being conducted.

Table 2: Therapeutic Options for Suppressing Menses

Methods	Injectable progestin-only contraceptives (Depo-Provera) ¹	Levonorgestrel Intrauterine System (Mirena)	Norethindrone acetate (oral ² progestins)	Danazol (Danocrine) ₃	Gonadotropin-releasing hormone (GnRH)	Seasonale ^{4E} (Indication for contraception pending)
Description and Dosage	Injectable progestin-only contraceptives: 150 mg every 3 months	Progestin-releasing IUD: releases 20 µg levonorgestrel daily; effective for 5 years	Oral progestins: 5 mg, 1-3 times daily	Danazol: 100-200 mg twice daily (optional titration to lowest dose sufficient to maintain amenorrhea) Gonadotropin inhibitor with progestational and androgenic properties	Leuprolide acetate (Lupron Depot): delivery methods and dosages vary	Extended 84/7-day monophasic, oral contraceptive regimen consisting of levonorgestrel + ethinyl estradiol
Contraception provided	Yes	Yes	Yes	No	No	Yes
Medical Uses	Menorrhagia, dysmenorrhea, endometriosis, anemia, PMS, menstrual migraines	Menorrhagia	Menorrhagia, dysmenorrhea, endometriosis, anemia, premenstrual syndrome, menstrual migraines	Endometriosis, fibrocystic breast disease, menorrhagia	Menorrhagia, dysmenorrhea, endometriosis, anemia, premenstrual syndrome, menstrual migraines	Menorrhagia, dysmenorrhea, endometriosis, anemia, premenstrual syndrome, menstrual migraines
Adverse Effects	Irregular bleeding or spotting, possible weight gain, 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 may be counteracted with add-back progestin and/or estrogen/progestin	Breakthrough bleeding/spotting
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	Slightly more costly than conventional OCs

1. None of the medical noncontraceptive uses listed are FDA-approved indications, except as noted.
 2. Approved for the treatment of endometriosis.
 3. 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.
 4. Source: See references 5 and 6

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OBSTACLES TO USING EXTENDED CONTRACEPTIVE REGIMENS

Obstacles to health care providers prescribing and women using extended contraceptive regimens 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 will be 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 providers think that it builds up the endometrium.”

—Rosa, nurse practitioner, age 44

Third-party coverage. Coverage of oral contraceptives 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.

Medicaid coverage for oral contraceptives varies from state to state. For example, in Delaware, both public and private providers of hormone contraceptives can issue up to three cycles of pills at a time but can bill for only one cycle per month. But Medicaid pays by the tablet, so if an OC prescription is written “daily for 63 days” and indicated as a medical necessity, Medicaid will more likely approve it.

According to an expert at the American Association of Health Plans, when a provider writes a prescription for more than one packet 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. Earlier studies of women taking an extended OC regimen have not shown adverse health consequences. Seasonale has also been proven safe.² Additional studies on long-term use of extended OCs as well as other extended contraceptive methods are needed.

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 them feel connected to the cycle of life. Some use menstruation as a way to determine if they’re pregnant, as a reason to avoid sex, to ascertain fertility, or because of pressure from family and friends. Other women avoid contraceptives because of religious beliefs.³

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.”⁴ 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.”⁴

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.⁵ Suha Kridli, PhD, RN, reviewed studies of Arab women’s beliefs about menstruation and family planning.⁶ 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 the 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 provider awareness/beliefs. Some health 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.^{7,8}



“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 an extended contraceptive regimen. 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 done correctly 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. It’s hard for many people to remember to take a pill every day. With the patch, each new patch should be applied on the same day of each week.

Side effects. In a recent study of 1,675 women, the most common reason cited for discontinuing OCs was bleeding irregularities.⁹ Breakthrough bleeding tends to be higher initially with an extended OC regimen than with a conventional OC regimen. However, after three or four cycles, the number of days of unscheduled bleeding/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 they 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. Noteworthy, however, is that most clinicians prescribe OCs for women with heavy periods and dysmenorrhea, even though OCs are not approved for this use. And as mentioned previously, third-party payers are reluctant to cover extended contraceptives because of this “off-label” use.

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PATIENT COUNSELING

One of the most common reasons for women stopping 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 patient fears and concerns.

To tailor your counseling on extended contraceptive regimens to each woman, it's helpful to know your patients' frame of reference, such as their cultural and religious beliefs, family members' views, and expectations of how the regimen would benefit them.

To help answer some commonly asked questions such as "Is it safe to use contraceptives continuously?" refer to *Frequently Asked Questions*, on page 14.

When Introducing Concept

Overall concept:

- ◆ There is no medical reason to bleed while on hormonal contraceptives.
- ◆ Periods on the pill are "false periods" that were designed to make bleeding with the pill seem more like a natural cycle.
- ◆ Menstrual blood does not build up when women are on hormonal methods.

Safety: No serious side effects from nine studies involving 1,950 patients.

Advantages:

- ◆ Can help alleviate conditions such as painful periods, excessive bleeding, premenstrual syndrome, and menstrual-related migraine headaches.
- ◆ With conventional OCs, more side effects, such as bloating, headaches, and breast tenderness, occur during the pill-free interval than during the active pill phase. Eliminating this pill-free interval may reduce these side effects.
- ◆ More convenient in general and during particular occasions, such as vacations and athletic activities.
- ◆ Don't need to purchase and carry as many hygiene products.

Disadvantages:

- ◆ Can have unpredictable breakthrough bleeding as with conventional OCs. It will lessen as body adjusts to new hormone balance.
- ◆ Need to remember schedule, such as when to take pill or change patch.
- ◆ May be more difficult to tell if pregnant. Look for other signs of pregnancy, such as breast tenderness, nausea, fatigue, etc. If necessary, pregnancy tests can be performed.
- ◆ Cost.

Female reproduction anatomy and menstrual physiology (see Patient Pull-Out):

- ◆ Role of estrogen and progesterone and how they relate to menstrual cycle.
- ◆ How standard birth control method works (see Patient Pull-out for OCs).
- ◆ How extended 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 at all.
- ◆ Schedule of method, such as taking OCs at the same time every day.

What to expect:

- ◆ Spotting.
- ◆ Blood is dark brown (oxidized due to remaining in vagina longer) rather than red (blood noted with active bleeding).
- ◆ Blood has different texture.

When to call provider:

- ◆ For side effects, such as heavy bleeding, nausea, vomiting, bloating, mood changes, headaches.

Pregnancy's signs and symptoms, other than a missed period:

- ◆ Breast tenderness.
- ◆ Fatigue.
- ◆ Nausea.
- ◆ Frequent urination.



FREQUENTLY ASKED QUESTIONS ON EXTENDED CONTRACEPTION

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 three 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

More women are becoming interested in reducing or eliminating their periods.¹ For example, the majority of the women in the 1996 Dutch study and the women interviewed through the Harris poll in 2002 preferred to menstruate less than once a month or never.^{2,3} Also, according to recent research by Sulak et al. and Miller et al., the majority of women who try an extended regimen choose to continue with it.^{4,5}

Providers are also recognizing the benefit of extended contraception. Of the 117 ARHP and NPWH's meeting registrants who were surveyed, 77 percent said they prescribed extended contraceptives.⁶

Yet, numerous barriers to regulating menstruation still exist. With the release of Seasonale—a dedicated product for extended contraceptive use—some of these barriers, such as acceptability, awareness, insurance coverage, and safety, will be lessened. However, increasing the awareness and knowledge of health care providers and women about extended contraceptives and creating counseling tools for providers are also essential. Recommendations include:

Educate providers about regulating menstruation:

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

Improve patient counseling:

- ◆ Explaining the female reproductive system and the effect of extended contraception on the system
- ◆ Addressing myths about the need to menstruate
- ◆ 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 contraception, through provider counseling and media venues:

- ◆ Need to menstruate while on contraceptives
- ◆ Ways to alter menstruation
- ◆ Health and lifestyle advantages to regulating menstruation
- ◆ Research findings on health effects of extended contraceptive methods

Conduct further research to answer questions:

Extended Regimen Method

- ◆ What patterns of bleeding can women expect with extended use over time?
- ◆ Is an extended regimen appropriate for new oral contraceptive (OC) users?
- ◆ What are the health effects, if any, of the long-term use of extended contraceptives?

Counseling

- ◆ How can health providers counsel women on taking OCs consistently?
- ◆ What are the cultural differences in how women and families view menstruation?
- ◆ How do women feel about spotting with the extended regimen?

Facilitating an Extended Regimen

- ◆ How can providers best integrate the extended use of contraceptive regimens 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 regulate their menstrual cycles. To choose, they and their providers need to be knowledgeable about the benefits and risks of various extended 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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Choosing When to Menstruate: The Role of Extended Contraception POST-TEST, PROGRAM EVALUATION, AND CREDIT REQUEST FORM

POST-TEST

Please circle the best answer for each question.

1. Which one of the following represents health benefits of extended contraception?
 - a. Reduction of heavy bleeding in women with uterine fibroids
 - b. Prevention of endometrial cancer
 - c. Improvement in iron deficiency anemia
 - d. All of the above
2. Which one of the following conditions is not a contraindication to oral contraception (OC)?
 - a. Migraine headaches with visual disturbances
 - b. Benign breast disease
 - c. Benign liver tumors
 - d. B and C
3. Which one of the following is not an obstacle to prescribing extended contraceptives?
 - a. Compromised future fertility
 - b. Inadequate health insurance coverage of regimen
 - c. Lack of provider acceptance of regimen
 - d. Perception that extra provider counseling time is needed
 - e. Lack of extensive long-term studies on extended contraceptive regimens
4. Which one of the following statements about potential medical options for reducing menstruation is true?
 - a. Mirena is effective birth control for 7 years
 - b. Danocrine is indicated for contraception
 - c. Oral progestins are not indicated for treatment of endometriosis
 - d. Depo-Provera may cause prolonged irregular bleeding or spotting
5. In counseling your patients about extended OCs, which one of the following issues should be addressed?
 - a. Need for frequent pill-free periods
 - b. Likelihood of breakthrough bleeding
 - c. Necessity of bleeding at least every 3 months.
 - d. A and B
6. Which one of the following statements about extended OCs is true?
 - a. Women on extended OCs rarely have breakthrough bleeding
 - b. Extended OCs and hormone therapy have similar health effects
 - c. Bleeding/spotting with extended OCs is predictable
 - d. Extended OCs do not delay pregnancy once they are stopped
7. Which one of the following statements about menstruation has been proven to be true?
 - a. Menstruation improves women's health overall
 - b. Women need to menstruate every 2-3 months to get rid of the buildup in the uterine lining
 - c. Menstruation prevents uterine infections and cancer
 - d. Menstruation is necessary to retain fertility
 - e. None of the above is true
8. Researchers who conducted telephone interviews with Dutch women in 1996 found which one of the following statements to be true?
 - a. The percentage of women desiring to stop menstruation did not vary with age
 - b. The majority of women preferred to menstruate less frequently than monthly
 - c. A significantly lower percentage of adolescent girls than women in the 25-34 year age group preferred to menstruate less
 - d. About 40 percent of menstruating women expressed no preference for a change in their bleeding pattern
9. Which one of the following statements is correct concerning the findings from the recent randomized control trial on Seasonale®?
 - a. Seasonale is as effective in preventing pregnancy as conventional 21/7 combination OCs.
 - b. More nonmenstrual side effects occurred with Seasonale than with conventional 21/7 OCs
 - c. Frequency of unscheduled bleeding episodes were the same with Seasonale as with conventional OCs initially
 - d. More endometrial pathology was noted with Seasonale than with continuous 21/7 OC use
10. For which one of the following time periods is it safe for women to use OCs continuously?
 - a. Three months
 - b. Six months
 - c. Nine months
 - d. Indefinite period of time



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 the impact of menstruation on lifestyle and medical conditions

5	4	3	2	1
---	---	---	---	---
 - b. Name five health advantages of medically regulating menstruation

5	4	3	2	1
---	---	---	---	---
 - c. Name four types of candidates for extended contraceptive regimens

5	4	3	2	1
---	---	---	---	---
 - d. List six hormonal methods for reducing bleeding

5	4	3	2	1
---	---	---	---	---
 - e. Describe obstacles to extended contraceptive regimens

5	4	3	2	1
---	---	---	---	---
 - f. Explain recommended approaches to 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. Extent to which stated program objectives are met

5	4	3	2	1
---	---	---	---	---
5. Effectiveness of teaching/learning methods

5	4	3	2	1
---	---	---	---	---
6. Usefulness of materials such as this that are supported by educational grants from industry

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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*A Special Joint Publication of ARHP and
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