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Teen pregnancy — Time to talk about long-acting reversible contraception

While teen birth rates have fallen, about 1 in 5 births is a repeat

While teen pregnancies are declining in the United States, the nation still leads the world's high-income countries in live teen births, points out a recent Centers for Disease Control and Prevention (CDC) Public Health Grand Rounds session.¹

A closer look at the statistics show that among teens who get pregnant, about half do so due to contraceptive failure.² Of particular concern is repeat births among teens. According to just-released CDC data, about one in five teen births is a repeat birth.³ More than 365,000 teens ages 15-19 gave birth in 2010; almost 67,000 (18.3%) of those were repeat births.³ (See *further statistics in the information box on p. 63.*)

Data from the new report indicate that while nearly 91% of teen mothers who were sexually active used some form of contraception in the postpartum period, only 22% used top-tier contraceptives such as the contraceptive implant and intrauterine contraception.

The CDC is working to improve provider education on long-acting reversible contraception safety and effectiveness and remove logistical barriers to contraceptive use. Long-acting reversible birth control methods such as an implant or intrauterine devices (IUDs) can be a good option for a teen because they do not require action on a regular basis.

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Long-acting reversible contraceptive (LARC) methods are safe and effective in teens, says **Wanda Barfield**, MD, MPH, a pediatrician and director of the CDC's Division of Reproductive Health. "That is really an important message, because I think providers have been led to believe that teens might not be good candidates for those types of contraceptives, but they actually are," notes Barfield. "That is an important opportunity, because for teens, often remembering

to take a pill every day may not be the most effective contraceptive for them."

With the publication of the "U.S. Medical Eligibility Guidelines For Contraceptive Use," providers can make evidence-based decisions in safely using the contraceptive implant or intrauterine devices in teenagers,⁴ says Barfield. The guidelines ranks use of the Copper T-380A and the levonorgestrel IUDs as a "2" (a condition for which the advantages of using the method generally outweigh the theoretical or proven risks) for women under age 20, with the same rating for nulliparous women. The contraceptive implant is rated as a "1" (no restrictions on use) for women of all ages.⁴ The upcoming "Selected Program Recommendations" will offer even more concrete evidence affirming LARC method use in adolescents, Barfield notes. (Contraceptive Technology Update *reported on the guidance. See "The New Year will bring new recommendations," January 2013, p. 5.*)

Too many providers have misconceptions about which contraceptive methods are safe and appropriate for teens, notes Barfield. Education about today's LARCs being different from the infamous Dalkon Shield that caused all other IUDs available at that time to drop out of use is critical. Today's intrauterine contraceptives "are not your mother's IUD," she points out.

CHOICE shows LARCs work

The Contraceptive CHOICE project, which was designed to evaluate reversible birth control methods, found that LARC methods are more effective than pills, patches, or rings in preventing unplanned pregnancy. The CHOICE project found that women using pills, patches, and rings were more than 20 times as likely to become pregnant as women using an IUD or an implant.⁵ (To read more about the research, see the CTU article "The 'Get It and Forget It' methods are here: Remove obstacles to use," April 2012, p. 37.)

The rate of teen births within the CHOICE

EXECUTIVE SUMMARY

While teen pregnancies are declining in the United States, the nation still leads the world's high-income countries in live teen births.

- New data show that about one in five teen births is a repeat birth. More than 365,000 teens ages 15-19 gave birth in 2010; almost 67,000 (18.3%) of those were repeat births.
- Long-acting reversible birth control methods such as an implant or intrauterine device can be safe, effective options for teens because they do not require action to do something on a regular basis.

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Editorial Questions

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cohort was 6.3 per 1,000, compared with the U.S. rate of 34.3 per 1,000,⁶ points out **Robert Hatcher, MD, MPH**, professor emeritus of gynecology and obstetrics at Emory University School of Medicine in Atlanta. “Anyone serious about reducing teen-age births in a community, a state, or in the country as a whole needs to study exactly what those affiliated with the Contraceptive CHOICE project in St. Louis have done,” says Hatcher. “It is carefully documented, and all of us must study the approaches they used to encourage participants to use the LARC methods and all the other steps they followed to provide high-quality contraceptive services to women in St. Louis.”

The Contraceptive CHOICE team is planning an upcoming launch of its online Resource Center, confirms **Gina Secura, PhD, MPH**, project director and adjunct assistant professor of epidemiology and senior scientist/epidemiologist in the Department of Obstetrics and Gynecology in the Division of Clinical Research at Washington University in St. Louis. “Our goal is to get it up by July, but we are pushing for it to be sooner than that,” says Secura. “We have received about 80 calls in the last month for our materials, and we are sharing those as best we can.”

Clinicians who are interesting in obtaining CHOICE material prior to the Resource Center web site launch can contact the team by telephoning (314) 747-0800 or e-mailing choice@wudosis.wustl.edu, says Secura. The materials will be posted on the project web site at www.choiceproject.wustl.edu.

Partners work together

The CDC is working with such national organizations as the American Academy of Pediatrics, the American College of Obstetricians and Gynecologists, and the American Academy of Family Practitioners to get the word out on use of LARC methods in teens, says Barfield. (The agency has partnered with the online medical resource site Medscape in presenting an expert commentary on teen pregnancy and reproductive health. Web: <http://bit.ly/XibNcp>.)

There are more than knowledge barriers to overcome with providers when it comes to teens using long-acting methods, notes Barfield. Many providers struggle with reimbursement issues for such devices.

Many repeat births in teens could be prevented through postpartum use of IUDs and implants, notes Barfield. Counseling women during prenatal visits about postpartum contraception, and offering them LARC methods in the hospital after delivery makes it easier for them to avoid unintended pregnancy.

The CDC worked with South Carolina public

What do we know about teen births?

- Nearly 1 in 5 births to teens, ages 15-19, are repeat births.
- Most (86%) are second births.
- Some teens are giving birth to a third (13% of repeat births) or fourth up to sixth child (2% of repeat births).
- American Indian and Alaskan Natives, Hispanics, and black teens are about 1.5 times more likely to have a repeat teen birth, compared to white teens.
- Infants born from a repeat teen birth are more likely to be born too small or too soon, which can lead to more health problems for the baby.

Source: Centers for Disease Control and Prevention (CDC). Vital signs: repeat births among teens — United States, 2007-2010. *MMWR* 2013; 62:249-255. ■

health officials in the Medicaid Health Initiative. The program reimburses for LARC insertion in the hospital before women who have just given birth leave the facility. (*Check it out at <http://1.usa.gov/14XN2H8>. Select “South Carolina’s Medicaid Health Initiative.”*)

Removing barriers so that postpartum contraceptives can be used, particularly postpartum LARC methods, is an important step in combatting repeat teen pregnancies, says Barfield.

“We are really missing opportunities to help teens make good choices after they have had a baby and to really get them into a situation where they are able to plan the next pregnancy,” she notes. “It’s been really important to work with our clinical providers so they can help us to understand the context of their practice.”

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The options expand for extended regimen OCs

With the recent Food and Drug Administration approval of Quartette, a new extended regimen oral contraceptive (OC) from Teva Pharmaceuticals of North Wales, PA, providers have more options to present to women considering this form of birth control.

The new extended oral contraceptive incorporates an ascending-dose approach, with 20, 25 and 30 mcg of ethinyl estradiol, combined with 150 mcg of levonorgestrel over 84 days, followed by seven days of 10 mcg of ethinyl estradiol alone, says **Andrew Kaunitz, MD**, professor and associate chair in the Obstetrics and Gynecology Department at the University of Florida College of Medicine — Jacksonville. Kaunitz served as a principal investigator in Quartette's clinical trial.

“Compared with earlier trials of fixed-dose extended pills, use of this ascending dose formulation appears to be associated with less unscheduled bleeding and spotting, making it an attractive option for women seeking to reduce both the frequency of scheduled bleeding as well as the incidence of unscheduled bleeding and spotting,” Kaunitz states.

Results from the Phase III clinical trial indicate that Quartette is effective at preventing pregnancy. The most common adverse reactions reported in the trial were headaches, heavy/irregular vaginal bleeding, nausea/vomiting, acne, dysmenorrhea, weight increase, mood changes, anxiety/panic attack, breast pain, and migraines.¹ Breakthrough bleeding and unscheduled spotting decreased over successive 91-day cycles, according to results from the drug's primary clinical trial.¹

Why extend regimen?

Women and providers are familiar with traditional OC regimens that include 21 days of hormones, followed by a seven-day hormone-free interval. This interval, however, can result in hormone withdrawal symptoms in women who are sensitive to fluctuating hormone levels.²

With extended-cycle regimens, the hormone-free interval is shortened or eliminated to manage common menstrual symptoms such as headaches, tiredness, bloating, excessive bleeding, and menstrual pain.

A 2005 systematic review of extended-cycle versus traditional 28-day cycle OCs found similar efficacy and safety between the two types of regimens.³ It remains unknown whether the additional weeks of hormone exposure increase the risk of venous thromboembolism in extended-cycle users.⁴

Results of a 2011 survey of providers at six national medical conferences show that of the 799 providers surveyed, 92% had recommended extended-cycle regimens, with obstetrics and gynecology practitioners most likely to recommend their use.⁵ However, 73.5% of providers indicated they continue to prescribe OCs that induce monthly withdrawal bleeds as their most common regimen.⁵

For extended regimen pills, there are four 30 mcg ethinyl estradiol/150 mcg levonorgestrel pills, packaged as 84 active pills and seven placebo pills: Seasonale and Jolessa (Teva Pharmaceuticals, North Wales, PA), Quasense (Watson Pharmaceuticals, Morristown, NJ), and Introvale (Sandoz, Princeton, NJ). There are three 30 mcg ethinyl estradiol/150 mcg levonorgestrel and 10 mcg ethinyl estradiol pills, packaged as 84 active pills and seven low-dose estrogen pills: Seasonique and Camrese (Teva Pharmaceuticals) and Amethia (Watson Pharmaceuticals). There are three 20 mcg ethinyl estradiol/100 mcg levonorgestrel pills and 10 mcg pills, packaged as 84 active pills and seven low-dose estrogen pills: LoSeasonique and CamreseLo (Teva Pharmaceuticals) and Amethia Lo (Watson Pharmaceuticals).

There are two continuous regimen pills, containing 20 mcg ethinyl estradiol/90 mcg levonorgestrel, packed as 28-day packs with no hormone-free interval: Lybrel (Wyeth Pharmaceuticals, Philadelphia) and Amethyst (Watson Pharmaceuticals).⁶

EXECUTIVE SUMMARY

With the recent Food and Drug Administration approval of Quartette, a new extended regimen oral contraceptive from Teva Pharmaceuticals, providers have more options to present to women considering this form of birth control.

- With extended-cycle regimens, the hormone-free interval is shortened or eliminated to manage common menstrual symptoms such as headaches, tiredness, bloating, excessive bleeding, and menstrual pain.
- Because routine use of extended-cycle and continuous OCs is relatively new and differs from what women have been told about the importance of monthly bleeding, clinicians need to be ready to answer questions about the absence of a monthly bleed.

Which women might be best candidates for extended regimen OCs? Women who are not interested in using an intrauterine device, contraceptive implant, contraceptive injection, or contraceptive vaginal ring in lieu of a daily pill, says **Eleanor Bimla Schwarz, MD, MS**, director of the Women's Health Services Research Unit and associate professor of medicine, epidemiology, and obstetrics, gynecology, and reproductive sciences at the University of Pittsburgh (PA).

Tips for counseling patients

What are some important counseling tips to help women achieve success with this form of birth control?

Schwarz suggests that if spotting becomes problematic, women may take a three-day break and then restart pills for at least three weeks before the next break.

Because routine use of extended-cycle and continuous OCs is relatively new and differs from what women have been told about the importance of monthly bleeding, clinicians need to be ready to answer questions about the absence of a monthly bleed.⁷

Explain that there is no medical or health reason to bleed while on hormonal contraceptives.⁸ Assure women that menstrual blood does not build up when women are using hormonal birth control. Return to fertility after discontinuation is expected to be the same as for conventional pills.⁸ [On April 2, 2013, Contraceptive Technology Update issued an e-bulletin on the drug's approval. To receive breaking news as it occurs, provide your email address to AHC Media customer service at customerservice@ahcmedia.com or (800) 688-2421.]

At a time when women can buy combined pills for \$4 to \$10 per cycle at national "big box" retail stores, **Robert Hatcher, MD, MPH**, professor emeritus of gynecology and obstetrics at Emory University School of Medicine in Atlanta, says he is "underwhelmed" by this new approach to hormonal contraception. When Quartette hits market shelves later this year, it well could be introduced as the most expensive oral contraceptive ever marketed in the United States, predicts Hatcher.

"My other concern is that the changing dosages of hormones will be confusing to both clinicians and women using this new preparation," Hatcher states.

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Women 40+ still need effective contraception

Women over age 40 might underestimate their need for effective birth control; however, despite declining fertility, such women can be at risk for unintended pregnancy.

This population has special attributes that influence contraceptive choice, notes a new review that outlines birth control options for older women, as well as their benefits and disadvantages.¹ Women of older reproductive age might be experiencing perimenopausal symptoms that could be managed with contraceptives. However, they also might have medical conditions that make estrogenic methods inappropriate, the review notes.

Older women are more likely than younger women to have adverse consequences should they become pregnant. The risk of spontaneous abortion and chromosomal abnormalities rises for those older than age 40.² Older age also is associated with higher risk of obstetric complications, including gestational diabetes, hypertension, placenta previa, cesarean delivery, perinatal death, and maternal death.³

Review authors present data from an extensive

review of the literature, and they provide evidence on risks and benefits, as well as practical pointers on how to best use contraception in the over-40 population, notes review co-author **Carrie Cwiak, MD, MPH**, associate professor of obstetrics and gynecology at Emory University in Atlanta. The review can serve as a tool to complement a clinician in-service training or a resident lecture on how to address the contraceptive needs of women over 40, she notes.

Contraception remains an important concern for older reproductive age women, says co-author **Andrew Kaunitz, MD**, professor and associate chair in the Obstetrics and Gynecology Department at the University of Florida College of Medicine — Jacksonville. “This new review provides evidence-based guidance that will help clinicians counsel older reproductive age women regarding sound contraceptive choices,” notes Kaunitz.

Offer effective options

Women older than age 40 need to talk with their clinicians about which choice of contraception is best for them given their health, says lead author **Rebecca Allen, MD, MPH**, assistant professor of obstetrics and gynecology at the Warren Alpert Medical School of Brown University in Providence, RI. Even if they have used a specific method in the past, it might be less appropriate now because of other medical conditions, she notes.

Current evidence supports the safety of combination methods, such as birth control pills, the contraceptive patch, and the contraceptive vaginal ring, in those older reproductive age women who are lean, healthy nonsmokers, notes Kaunitz.

For women who medically are not appropriate candidates for combination hormonal methods, progestin-only and nonhormonal methods such as intrauterine devices (IUDs), the contraceptive implant,

EXECUTIVE SUMMARY

Women over age 40 might underestimate their need for effective birth control; however, despite declining fertility, women over 40 can still be at risk for unintended pregnancy.

- Older women are more likely than younger women to have adverse consequences should they become pregnant. The risk of spontaneous abortion and chromosomal abnormalities rises for those older than age 40.
- Women of older reproductive age might be experiencing perimenopausal symptoms that could be managed with contraceptives. However, they also might have medical conditions that make some contraceptive methods inappropriate.

contraceptive injections, and minipills represent safe contraceptive choices, states Kaunitz. Tubal sterilization for women and vasectomy for male partners are also options for women over 40 years of age who have completed their families, the reviewers note. Older women are less likely to regret permanent sterilization.⁴

Susan Wysocki, WHNP-BC, FAANP, president & chief executive officer of iWomansHealth in Washington, DC, which focuses on information on women’s health issues for clinicians and consumers, says, “It is important not to assume that the woman over 40 knows what all her options for contraception might be. Even if she has successfully used a method for a number of years, she may be happier with another option.”

Also, remember to provide information about emergency contraception and provide an advance prescription as one would for a younger woman, Wysocki advises.

More than birth control

There are many potential noncontraceptive benefits of birth control methods in this age group, says Allen. For example, the oral contraceptive pill can treat perimenopausal hot flashes and perimenopausal anovulatory uterine bleeding, she notes.

The levonorgestrel IUD alleviates heavy menstrual bleeding caused by conditions such as adenomyosis and uterine fibroids, which become more common in women over age 40, states Allen. Since 2009, the U.S. labeling of the device carries a specific indication for treatment of heavy menstrual bleeding in women who desire contraception. (*Contraceptive Technology Update reported on the approval; see “Options for treatment of heavy bleeding in focus,” December 2009, p. 137.*) Its use leads to a 97% reduction in menstrual blood loss by 12 months, and the method offers high satisfaction rates.⁵

Evidence indicates many of the available contraceptive methods, including oral contraceptives, intrauterine devices, and the contraceptive injection, reduce a woman’s risk of endometrial and ovarian cancer, notes Allen.

When to stop?

When should women stop using contraception? Most women will be able to use contraception safely until they are assured of menopause, the review authors note.

“Determining when to stop a contraceptive method should include an evaluation of the benefits of the

method, the health risks resulting from its use as age increases, the diminishing risk of pregnancy, and the availability of alternative methods,” the authors state.

The median age of menopause is approximately 52 years, meaning 50% of women age 52 will continue to have ovulatory function, says Kaunitz. Because FSH (follicle stimulating hormone) testing is unreliable in women using combination estrogen-progestin contraceptives, the authors point out that one approach is to arbitrarily continue contraception until age 55, when the likelihood of ovulation/conception becomes remote.¹

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See nonsurgical options for abnormal bleeding

A new Agency for Healthcare Research and Quality (AHRQ) review of available evidence reveals that women who have problematic irregular or heavy cyclic menstrual bleeding have several safe and effective nonsurgical treatment options.¹ The variety of effective options suggests that many women can address symptom relief and contraceptive or fertility desires. (See the full report at <http://1.usa.gov/12BbERZ>.)

“We were really pleasantly surprised that there was a body of literature of good and fair quality that affirmed a lot of the clinical care that we do,” says **Katherine Hartmann, MD, PhD**, professor of obstetrics and gynecology and director of women’s health research at Vanderbilt University in Nashville. “There are good choices based on women’s childbearing desires, their metabolic circumstances, and their preferences, as well as what they are comfortable with using.”

Clinicians are familiar with abnormal uterine bleeding. It is among the most common gynecologic com-

plaints of reproductive-age women in ambulatory care settings. It is estimated to affect 11-13% of reproductive-age women at any given time.¹

Prevalence increases with age. About one-quarter of women ages 36-40 experience such bleeding.^{2,3} Women usually consult a clinician when the amount, timing, or other characteristics of their bleeding have changed from their individual norm. Population norms for menstrual bleeding, as established by fifth and 95th percentiles, include:

- frequency of menses within a 24- to 38-day window;
- regularity (cycle-to-cycle variation) within 2-20 days;
- duration of flow from four to eight days;
- blood loss volume from 5 to 80 ml.⁴⁻⁸

What works?

The new review takes a look at nonsurgical options to treat abnormal bleeding, with an emphasis on interventions that are accessible to and within the scope of usual practice for primary care practitioners in any clinical care setting. Contraceptive and noncontraceptive effective treatment options are available for women who have problematic, irregular, or heavy cyclic menstrual bleeding.

The review team found a high strength of evidence that combined oral contraceptives can improve menstrual regularity for women with irregular bleeding patterns. The use of metformin, a drug commonly used to treat diabetes, is supported by moderate strength of evidence for improving cycle regularity especially among women with polycystic ovary syndrome, reviewers note.

Multiple interventions for heavy cyclic bleeding are supported by evidence that they reduce menstrual blood loss, the research team states. Strong evidence

EXECUTIVE SUMMARY

A new Agency for Healthcare Research and Quality (AHRQ) review of available evidence reveals that women who have problematic irregular or heavy cyclic menstrual bleeding have several safe and effective nonsurgical treatment options.

- The variety of effective options suggests that many women can address symptom relief and contraceptive or fertility desires.
- Abnormal uterine bleeding is among the most common gynecologic complaints of reproductive-age women in ambulatory care settings. It is estimated to affect 11-13% of reproductive-age women at any given time
- Prevalence increases with age; about one-quarter of women ages 36-40 experience such bleeding.

suggests that combined oral contraceptives are effective, while moderate strength of evidence indicates that the levonorgestrel intrauterine device (IUD), nonsteroidal anti-inflammatory drugs (NSAIDs), and tranexamic acid reduce bleeding relative to baseline, decrease total volume of bleeding when comparisons are made across treatment groups, and decrease days of bleeding per cycle, the team notes.

In direct comparisons, research indicates the levonorgestrel IUD is superior to NSAIDs, tranexamic acid is superior to NSAIDs, and tranexamic acid combined with an NSAID was superior to tranexamic acid alone. Results from combined oral contraceptives and NSAID comparisons suggest comparable effectiveness, the research team notes.

“Not all women will benefit from these interventions,” the researchers state. “Across agents data are sparse to evaluate long-term improvements and risk of harms.”

New data in

Clinicians will want to add a just-published study to the new body of evidence on effective abnormal bleeding options, says **Robert Hatcher**, MD, MPH, professor emeritus of gynecology and obstetrics at Emory University School of Medicine in Atlanta. In a randomized study of women who presented to primary care providers in the United Kingdom with excessive menstrual bleeding, the levonorgestrel intrauterine system was more effective than other medical treatments, such as tranexamic acid, NSAID, combined oral contraceptives, progestin-only pill, and the contraceptive injection, in reducing the effect of heavy menstrual bleeding on quality of life.⁹

Researchers randomized 571 women with menorrhagia to treatment with levonorgestrel IUD or usual medical treatment, which includes tranexamic acid, mefenamic acid, combined oral contraceptives, mini-pills, or the contraceptive injection. Researchers identified the primary outcome as the patient-reported score on the Menorrhagia Multi-Attribute Scale (MMAS). The scale used scores from 0 to 100, with lower scores indicating greater severity) and was assessed over two years. Secondary outcomes included general quality-of-life and sexual-activity scores and surgical intervention.

Researchers report scores improved from baseline to six months in the levonorgestrel-IUD group and the usual-treatment group (mean increase, 32.7 and 21.4 points, respectively; $P < 0.001$ for both comparisons). The improvements were maintained over a two-year period but were significantly greater in the levonorgestrel-IUD group than in the usual-treatment group

(mean between-group difference, 13.4 points; 95% confidence interval, 9.9 to 16.9; P less than 0.001).⁹

Improvements in all MMAS domains (practical difficulties, social life, family life, work and daily routine, psychological well-being, and physical health) were significantly greater in the levonorgestrel-IUD group than in the usual-treatment group, and these improvements also were true for seven of the eight quality-of-life domains, researchers note. At two years, more of the women still were using the levonorgestrel-IUD than were undergoing the usual medical treatment (64% vs. 38%, P less than 0.001).⁹

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New model may pinpoint last menstrual period

Results of a just-published study indicate a possible method to predict when a woman will have her final menstrual period.¹ Such findings might be helpful

in aiding women and providers in combatting potential bone loss and cardiovascular risk associated with onset of menopause.

Clinicians monitor bleeding patterns to determine when a woman is entering the menopause transition stage. However, this transition stage is an imprecise predictor of when the final menstrual period will take place. It is estimated that more than 60% of women who are classified as being in early menopause (when periods are less predictable, but there are no big gaps in cycles) become postmenopausal without any additional clinical bleeding signal.¹

Many women going through the transition ask their clinicians when they will reach menopause and stop menstruating, says **Arun Karlamangla**, MD, assistant professor in the David Geffen School of Medicine at the University of California in Los Angeles (UCLA). Providers as yet have a good way of telling women how close they are to having their last menstrual cycle, says Karlamangla, a co-author of the current study. Even women who already have had their last cycle will not know for sure if it was the last one until 12 months have passed, he notes.

“This study was designed to test if such information could be gleaned from measurements of their hormones and comparing them to previous measurements of the same hormones when menstrual cycling was regular,” Karlamangla says.

Being able to estimate when the final menstrual period will take place has taken on importance beyond just helping women gauge when they will stop having periods, said the study’s lead author, **Gail Greendale**, MD, professor of medicine in the division of geriatrics at the David Geffen School of Medicine at UCLA. “We know that potentially deleterious physiological developments, such as the onset of bone loss and an increase in cardiovascular risk factors, precede the final menses by at least a year,” said Greendale in a release accompanying the study’s publication.

Follow the research

To conduct the study, the researchers analyzed longitudinal data collected annually for up to 11 years from 554 women taking part in the National Institutes of Health’s Study of Women’s Health Across the Nation.

At enrollment, the women were between the ages of 42 to 53, had an intact uterus and at least one ovary, were not using medications affecting ovarian function, and had experienced at least one menstrual period in the prior three months. Scientists then looked at levels of estradiol and follicle stimulating hormone (FSH). Why? The level of FSH starts increasing and estradiol

starts decreasing about two years prior to the final menstrual period, or about a year before the rise of bone loss and cardiovascular risk factors.^{2,3}

Results of the analysis indicate the levels of the two hormones could be used to estimate whether women were within two years of beginning their final menstrual period, within one year, or beyond their final period.

Researchers note the study had some limitations, including its modest sample size. Also, hormone levels were sampled once a year. More frequent sampling might have allowed a more precise estimate of a woman’s place on the timeline.

What’s the next step?

Being able to predict a woman’s final menstrual period could have broader implications for women’s health, said Greendale. In the year leading up to the final menstrual period, women face accelerated bone loss and increased cardiovascular risk, she noted.

“For example, some researchers have proposed that an intervention begun one or two years before the final menstrual period would greatly decrease future fracture risk by preventing the very rapid bone loss that occurs in the few years before and few years after the final menses,” Greendale said. “But before ideas such as this can be tested, we need to accurately predict where a woman is in her timeline to menopause.”

What is the next step in research? Karlamangla says researchers will need to validate the method in another cohort of women.

“Once it has been validated, web-based calculators can be made available for doctors and their patients to use to determine where a woman is on the timeline to menopause,” he states.

EXECUTIVE SUMMARY

Results of a just-published study indicate a possible method to predict when a woman will have her final menstrual period. Such findings might be helpful in aiding women and providers in combatting potential bone loss and cardiovascular risk associated with onset of menopause.

- Clinicians monitor bleeding patterns to determine when a woman is entering the menopause transition stage. However, this transition stage is an imprecise predictor of when the final menstrual period will take place.
- It is estimated that more than 60% of women who are classified as in early menopause (when periods are less predictable, but there are no big gaps in cycles) become postmenopausal without any additional clinical bleeding signal.

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Judge drops restrictions on EC age — finally!

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In a decision more than 10 years in the making, a U.S. Federal District judge ruled April 5, 2013, that the Food and Drug Administration (FDA) must lift age and point-of-sale restrictions on Plan B One-Step emergency contraception (EC) within 30 days.

Plan B, a levonorgestrel EC product, was first approved as a prescription-only medication in 1999. Since that time, medical, legal, and advocacy groups have struggled to bring this safe medication over-the-counter to enhance timely access, while being blocked by delays and political interference along the way.

Before the court's most recent ruling, this method was available over the counter (OTC) in pharmacies, but only to women age 17 or older and only when government-issued identification could be provided. Younger women and those without identification were

required to have a prescription to access Plan B.

This dual-label structure also forced the drug to be “behind-the-counter” in order for pharmacists to check age and identification requirements, cutting off access to the drug during hours when pharmacy desks were closed or unstaffed. In practice, even individuals 17 years of age or older faced barriers in trying to access the medication. Such barriers are especially problematic considering this method of EC is much more effective the sooner it is taken after unprotected sex.

The most recent hurdle in the path to EC access came in December 2011 when Kathleen Sebelius, secretary of the Department of Health and Human Services, overrode an FDA decision that would have removed age restrictions and allowed sale of the medication on open shelves in any store where OTC medications are sold. This intervention sparked the renewal of an earlier lawsuit on the matter and resulting eventually in the April 5 decision.

The judge heavily criticized the secretary, saying her “directive ... forced the agency to ride roughshod over the policies and practices that it has consistently applied in considering applications for switches in drug status to over-the-counter availability” and calling her actions “arbitrary, capricious, and unreasonable.”¹

What will happen?

Removing point of sale and age restrictions will broaden access to EC in a variety of ways. Women under 17 soon should be able to purchase the medication without delays caused by visiting providers to obtain prescriptions. For older teens and adults, Plan B should soon be available on open shelves in pharmacies, as well as in grocery stores, convenience stores, and anywhere that OTC medications are stocked. Availability of EC at places such as gas stations could provide access at critical moments when unprotected sex has occurred and pharmacies are closed for the night.

Opponents have expressed concern that increased access to EC will put young adolescents in danger and increase risk-taking behavior. Fortunately, research clearly disputes both of these claims. Recent data published by the journal, *Pediatrics*, discusses the very small percentage of sexually active 10-, 11-, and 12-year-old girls (.6%, 1.1%, and 2.4% respectively); incidence of pregnancy among this group is miniscule.² Therefore, the likelihood of this group to need emergency contraception is extremely low.

There is no evidence of levonorgestrel EC being harmful to patients, regardless of age. Furthermore, several studies have established that increased access to EC does not increase episodes of unprotected sex or

decrease use of ongoing contraception. Increased access to EC simply increases the likelihood of patients to use the method when they need it and to take it in a timely way.³⁻⁶

What is your role?

Despite OTC access for levonorgestrel EC methods, clinicians will still have an important role in counseling and dispensing emergency contraceptives. The ulipristal acetate EC pill, ella, is still prescription-only regardless of age. Ella has an advantage in that it does not lose efficacy over a five-day period,⁷ and therefore might be preferable for young women who seek EC four or more days after unprotected sex. It is also more effective in women with higher body mass index, compared to Plan B or generic equivalents.⁸ The most effective form of EC remains the copper intrauterine device, which has the added benefit of ongoing long-term contraception but requires a clinician for insertion.⁹

Finally, educating patients about emergency contraception is still essential if they are to know how, when, and in what circumstances to seek it out, whether OTC or by prescription. Also, some patients still might seek prescriptions for Plan B in order to use insurance coverage. The cost of LNG EC ranges from about \$35 to \$60,¹⁰ which remains a significant barrier, especially to teens.

As this column goes to press, we are still awaiting action on this ruling by the FDA and remain hopeful that increased access will be in place for teens and adults in the coming days. [Editor's note: On April 5, 2103, Contraceptive Technology Update issued an e-bulletin on the judge's ruling. To receive breaking news as it occurs, provide your email address to AHC Media customer service at customerservice@ahcmedia.com or (800) 688-2421.]

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COMING IN FUTURE MONTHS

- New flexible extended dosing regimen pill eyed
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- HIV vaccine research — Where is it headed?
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After reading *Contraceptive Technology Update*, the participant will be able to:

- identify clinical, legal, or scientific issues related to development and provisions of contraceptive technology or other reproductive services;
- describe how those issues affect services and patient care;
- integrate practical solutions to problems and information into daily practices, according to advice from nationally recognized family planning experts;
- provide practical information that is evidence-based to help clinicians deliver contraceptives sensitively and effectively.

CNE/CME QUESTIONS

1. According to Centers for Disease Control and Prevention (CDC) (*Morb Mortal Wkly Rep* 2013; 62:249-255), how many teen births are repeat births?
 - A. About one in five
 - B. About one in 10
 - C. About one in 20
 - D. About one in 35
2. What is the name of the extended regimen oral contraceptive approved in March 2013?
 - A. Skyla
 - B. Quartette
 - C. Quasense
 - D. Camrese
3. What contraceptive option carries a specific label indication for treatment of heavy menstrual bleeding in women who desire contraception?
 - A. The contraceptive implant
 - B. The levonorgestrel intrauterine device
 - C. The Copper T-380A intrauterine device
 - D. The contraceptive injection
4. What drug is supported by moderate strength of evidence for improving cycle regularity, especially among women with polycystic ovary syndrome?
 - A. Clomid
 - B. Orlistat
 - C. Finasteride
 - D. Metformin

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