Intrauterine contraception safe and effective in teens and adults

For long-term use, teens may benefit from additional counseling

Results from a recent retrospective analysis indicate that similar to adults, intrauterine device (IUD) use in adolescents and nulliparous women is effective and associated with low rates of serious complications. Analysis of findings indicate, however, that teens might benefit from additional counseling regarding symptoms associated with IUD use due to higher rates of discontinuation following the first year of use.

The results come from a multicenter retrospective chart review of adolescents and women in the Baltimore, Washington, DC, and southeastern Virginia area, ages 13-35, who had an IUD inserted for contraception between June 2008 and June 2011. The chart for each study participant was reviewed from the time of IUD insertion through March 31, 2013. Researchers reviewed 2,523 patients’ charts; 2,138 patients were included in the analysis. Thirteen percent of the study population was nulliparous.

After a mean follow-up of 37 months, scientists found the overall rates of IUD expulsion and pregnancy were 6% and 1%, respectively, and were not significantly different by age or parity. Intrauterine device discontinuation rates for all ages were 19% at 12 months and 41% after a mean follow-up of 37 months. At 12 months, discontinuation rates for teens ages 13-19 was 23%, which was not statistically different than IUD discontinuation rates for women ages 20-24 or women ages 25-35, both which were 18%.

Despite similar rates of IUD discontinuation between age groups at 12 months of use, females age 13-19 were more likely to request IUD removal by the end of the total follow-up period. After adjusting for age and parity, the analysis indicates that copper IUD users were more likely to experience expulsion and contraceptive failure compared with levonorgestrel IUD users (hazard ratios 1.62, 95% confidence interval [CI] 1.06-2.50 versus hazard ratios 4.89, 95%, CI 2.02-11.80, respectively).

There continues to be a significant amount of fear regarding IUD use in the public and the medical community, and this concern is even greater regarding the use of IUD in adolescents, says Veronica Gomez-Lobo, MD, director of pediatric and adolescent obstetrics and gynecology at MedStar Washington.
Hospital Center and Children’s National Medical Center, both in Washington, DC. A professor of clinical obstetrics and gynecology at Georgetown University School of Medicine in Washington, DC, and an adjunct associate professor of clinical obstetrics and gynecology at the Uniformed Services University of the Health Sciences in Bethesda, Gomez-Lobo served as a senior author of the paper.

EXECUTIVE SUMMARY

Results from a recent retrospective analysis indicate that similar to adults, intrauterine device (IUD) use in adolescents and nulliparous women is effective and associated with low rates of serious complications. Analysis of findings indicates, however, that teens might benefit from additional counseling regarding symptoms associated with IUD use due to higher discontinuation rates following the first year of use.

• Counseling women of all ages about the expected bleeding changes tied to IUD use before device insertion might enhance tolerance of the method. Teens and young women who participated in the Contraceptive Choice project had high rates of LARC method continuation. In the overall St. Louis cohort, 87.5% continued with the levonorgestrel IUD, and 84.1% continued with the copper-T IUD at 12 months. When stratified by age, at one year 80.6% of teens ages 14-19 continued with the levonorgestrel IUD, with 75.6% continuing with the copper-T IUD. (To review the research on LARC, see the Contraceptive Technology Update articles “Options might begin to emerge with new data out on LARC,” March 2014, p. 25, and “Get practice up to speed on LARC methods,” April 2014, p. 40.)

For the levonorgestrel IUD, CHOICE project counselors used the following information to inform women
about possible bleeding: “Some women have irregular bleeding and cramping after the hormonal IUD is inserted. The irregular bleeding is greatest in the first three to six months, but usually improves. After this period of time, your period is typically much lighter and shorter. Twenty percent of women stop having their periods altogether after the first year.”

For the copper T-380A IUD, the project’s counseling script includes the following wording: “Some women have spotting for the first few months after the copper IUD is inserted. In some women, periods may be heavier or crampier, especially within the first three to six months after insertion, although this may get better over time.” (Download the patient counseling script in English and Spanish at the project’s LARC First website, www.larcfirst.com. Click on “Counseling,” then “The Counseling Session.”)

ACOG backs teen IUD use

As Gomez-Lobo notes, many clinicians might cling to old myths when it comes to IUD use in younger, nulliparous women. Supporters of long-acting reversible contraception (LARC) are working to dispel such myths.

The American College of Obstetricians and Gynecologists (ACOG) is enthusiastic in its support for expansion of LARC use to women across the reproductive age spectrum and particularly adolescents and nulliparous women, says Eve Espey, MD, MPH, who chairs ACOG’s Long Acting Reversible Contraception Work Group. Espey has just been named chair of the obstetrics and gynecology department the University of New Mexico in Albuquerque.

ACOG is taking steps to help clinicians improve their knowledge regarding appropriate candidates for IUD use, especially adolescents. Espey outlined the following steps:

- publication of a practice bulletin outlining the evidence that LARC methods are safe and effective for women of all ages and more effective for teenagers than short-term methods;6
- publication of a committee opinion supporting adolescent use of LARC methods;5
- publication of a committee opinion highlighting the potential for LARC methods to reduce unintended pregnancy and abortion in the United States;7
- webinar series addressing the spectrum of appropriate candidates;
- talks at numerous ACOG conferences regionally and nationally discussing appropriate candidates;
- development of resources supporting LARC training and practice, including evidence-based slide sets for use in residency training, for grand rounds, etc., and

LARC coding and billing materials to support appropriate reimbursement. (Go to the ACOG LARC webpage, www.acog.org/goto/larc, to find all appropriate materials);

- routine distribution and promotion to the full ACOG membership of all of the above listed publications, resources, and events through the LARC Program webpage, the LARC Program e-newsletter, and ACOG social media channels.

REFERENCES


Research stirs debate on mammography

The role of screenings in the early detection of breast cancer is in the media spotlight again as results of a new study indicate that annual mammography in women ages 40-59 does not reduce mortality from breast cancer beyond that of physical examination or usual care when adjuvant therapy for breast cancer is freely available.1

In 1980, the Canadian National Breast Screening Study was initiated by researchers as a randomized controlled trial of screening mammography and physi-
clinical examination of breasts in 89,835 women, ages 40 to 59. The new report updates findings based on up to 25 years (mean 22 years) follow-up. All women participating in the study underwent an initial clinical breast examination at the screening center by nurses or physicians. Women ages 40-49 were randomized to baseline and four additional annual mammograms, or no mammography (usual care with their family physician). Women ages 50-59 were randomized to annual breast examinations at the study center with or without baseline and four additional annual mammograms.

The analysis shows 1,190 breast cancers were diagnosed; 666 occurred in women who had mammograms, and 524 occurred in the control group. However, after 25 years, nearly the same amount of women in each group had died from the disease. The analysis also indicates that 22% of invasive breast cancers detected in the arm of the study in which women received mammography were overdiagnosed, which caused women to undergo unnecessary procedures for cancers that were slow-growing or did not require treatment.1

**Guidance to change?**

In November 2009, the U.S. Preventive Services Task Force (USPSTF) recommended against routine screening mammography for women ages 40-49 and advised biennial rather than annual screening for women ages 50-74.2 The group updated its guidance in December 2009 to state, “The decision to start regular, biennial screening mammography before the age of 50 years should be an individual one and take patient context into account, including the patient’s values regarding specific benefits and harms.” (See the Contraceptive Technology Update article, “Check the new screening guidance for cervical cancer and breast cancer,” January 2010, p. 1.)

The American College of Obstetricians and Gynecologists (ACOG) issued guidelines in 2011 that call for mammography screening be offered annually to women beginning at age 40.3 (See “New guidance issued for breast screening, CTU, October 2011, p.116.) ACOG continues to stand by its 2011 guidance in light of the new evidence, as does the American Cancer Society, which has issued similar recommendations.

**What’s your stance?**

When the USPSTF issued its 2009 recommendations, its rationale was based on that for women ages 40-49 years who are at relatively low risk for breast cancer, annual mammograms might lead to false positive results that result in psychological harms, unnecessary imaging tests, and biopsies in women without cancer. As for women ages 50 to 74 years, too-frequent screening could lead to overdiagnosis.4

An important point made by the current research was the harm done to women by mammographic screening, notes Anita Nelson, MD, professor in the Obstetrics and Gynecology Department at the David Geffen School of Medicine at the University of California in Los Angeles. In the current study, 22% (106/484) of mammography-detected invasive breast cancers were over-diagnosed, which represented one over-diagnosed breast cancer for every 424 women who received mammography screening in the trial.1

The current study’s findings regarding lack of efficacy of screening mammograms and overdiagnosis are comparable to other recent studies assessing breast cancer screening,5,6 notes Andrew Kaunitz, MD, professor and associate chair in the Obstetrics and Gynecology Department at the University of Florida College of Medicine — Jacksonville. Annual mammography screens have become an easy recommendation for clinicians to make, while for patients, the reassurance that accompanies a normal mammogram is comforting, observes Kaunitz. While many patients will be perplexed by information from the new study, others might view it with suspicion, he notes.

“While we await updated guidance from professional societies, my approach is to encourage patients to follow the 2009 US Preventive Service Task Force guidelines: Start at age 50 in average risk women, and screen every two years,” states Kaunitz.

**REFERENCES**

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New treatment eyed for pain of vulvodynia

Your next patient tells you she has been experiencing sharp pain near the opening of the vagina that ranges from slightly uncomfortable to knife-like in severity. She is reluctant to use tampons and has been abstaining from intercourse due to the pain. What is your diagnosis?

Consider vulvodynia, a chronic condition characterized by pain and burning in the vulva in the absence of infection or other known disease. The pain can vary from mild to excruciating and might be provoked, spontaneous, or both.¹ Results of a new study indicate that vulvodynia incidence varies by age, ethnicity, and marital status, with a potential higher risk for women with pre-existing depression, sleep, or pain disorders.¹

“We had a good idea of what the prevalence of vulvodynia was, but this data gives us a better understanding of how often new cases develop and the potential risk factors that may be involved,” said lead author Barbara Reed, MD, MSPH, professor of family medicine at the University of Michigan Medical School in Ann Arbor in a statement accompanying the publication of results. “We found the most striking and unexplainable differences between ethnic and racial groups; other predictors included younger age, sleep dysfunction, comorbid pain conditions, genital symptoms not yet meeting diagnostic criteria, and psychological distress.”

Researchers conducted the longitudinal population-based study in southeast Michigan women ages 18 and older using a validated survey-based vulvodynia screening test, repeated at six-month intervals over 30 months. Average age was 50, with 42% of women ages 40-59. The overall incidence rate was 4.2 cases per 100 person-years, and rates per 100 person-years were greater in women who were younger (7.6 cases per 100 person-years at age 20, compared with 3.3 cases per 100 person-years at age 60), Hispanic (9.5 cases per 100 person-years), married, or living as married (4.9 cases per 100 person-years); had reported symptoms of vulvar pain but did not meet vulvodynia criteria on the initial survey (11.5 cases per 100 person-years); or had reported past symptoms suggesting a history of vulvodynia (7.5 cases per 100 person-years).

“One of the major problems with vulvodynia is physicians tend not to recognize it, diagnose it, or treat it, so many women suffer without knowing their symptoms have a name and that treatment is possible,” said Reed. “The more physicians become aware of how often this happens and who the condition affects, the more likely they are to teach patients about vulvodynia and treat them or refer them for care.”

Focus on gabapentin

The first national, multicenter study of a treatment to reduce vulvar pain in women is being led by Candace Brown, MSN, PharmD, a professor in the department of pharmacy, obstetrics and gynecology, and psychiatry at the University of Tennessee Health Science Center in Memphis. The study is examining use of gabapentin, an anticonvulsant treatment, that has appeared to be effective in previous, localized trials.² The aim of the multicenter study is to prove the effectiveness of gabapentin as a treatment for provoked vestibulodynia and to determine what causes

EXECUTIVE SUMMARY

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• Vulvodynia is a chronic condition characterized by pain and burning in the vulva in the absence of infection or other known disease. The pain can vary from mild to excruciating and might be provoked, spontaneous, or both.

• The first national, multicenter study of a treatment to reduce vulvar pain in women is underway. Scientists are examining use of gabapentin, an anticonvulsant treatment that has appeared to be effective in previous, localized trials.
the condition. While clinicians have used gabapentin off label for vulvodynia treatment, there is no treatment approved by the Food and Drug Administration for the condition, says Brown.

The $2.6 million grant was awarded to the Memphis institution in 2012 by the Eunice Kennedy Shriver National Institute of Child Health and Human Development, a division of the National Institutes of Health. Collaborators include the University of Medicine and Dentistry of New Jersey in New Brunswick and the University of Rochester (NY).

There will be two components to the study, explains Brown. One component, which comprises the clinical trial, will measure how effective gabapentin is compared to placebo. The other component will determine what causes the disorder, and which women will respond to the study drug.

Women participating in the research will be examined over a 16-week period. For the first eight weeks, they will be randomly selected to receive gabapentin or a placebo. During the following eight weeks, participants will alternate and take the study drug or a placebo that was not taken initially. Researchers will use a pain questionnaire to measure changes in qualitative pain using a pain rating index, and they will analyze responses to determine gabapentin’s effectiveness.


**Give patients options**

What can clinicians advise women to do to relieve chronic vulvar pain? Offer the following suggestions from the American College of Obstetricians and Gynecologists:

- Wear 100% cotton underwear, with no underwear at night.
- Avoid tight-fitting undergarments and pantyhose.
- Avoid douching.
- Use mild soaps for bathing and clean the vulva with water only.
- Do not use vaginal wipes or deodorants or bubble bath.
- Do not use pads or tampons with deodorants.
- Use lubrication for intercourse.
- Avoid exercises that put pressure directly on the vulva, such as bicycling.

**REFERENCES**


**Endometriosis is the focus of new scientific research**

Scientific efforts are being aimed at understanding and treating endometriosis, one of the most common health problems for women. Research has just provided a first step toward providing a more informed way of classifying endometriosis based on the underlying biological cause of the disease.¹

Endometriosis is a condition in which the type of tissue that forms the endometrium is found outside the uterus. It occurs in about one in 10 women of reproductive age and is most often diagnosed in women in their 30s and 40s.² Because pain associated with the condition might be mistaken for normal menstrual cramping, younger women have particularly high rates of misdiagnosis.³ Thirty percent to 50% of women with endometriosis might experience infertility.⁴

With endometriosis, endometrial tissue most often is found in such areas as the peritoneum, ovaries, Fallopian tubes, outer surfaces of the uterus, bladder, ureters, intestines, rectum, and cul-de-sac. In endometriosis, the tissue (known as implants) responds to changes in estrogen and might grow and bleed such as the uterine lining does during the menstrual cycle. Surrounding tissue can become irritated, inflamed, and swollen. The breakdown and bleeding of implants each month also can cause formation of adhesions, which can cause organs to stick together. The bleeding, inflammation, and scarring of implants often result in pain, especially before and during menstruation.

Scientists at the Massachusetts Institute of Technology (MIT) in Cambridge, MA, and Newton-Wellesley Hospital Center for Minimally Invasive Gynecologic Surgery in Newton, MA, have identified a pattern of immune system signaling molecules that correlates with certain symptoms of endometriosis. They also have been able to determine the underlying cellular activity that produces this signature. By using this signature, scientists might be able to develop a patient stratification system similar to that used for breast cancer patients, whose treatments are tailored
to the molecular profile of their tumors. In the future, such a signature also might provide a mechanistic endpoint for assessing efficacy of new agents aimed at curtailing inflammatory mechanisms that drive disease progression, researchers note.

“Endometriosis patients report symptoms of infertility and pain, and beyond that, it’s just kind of a guessing game,” said Linda Griffith, PhD, MIT School of Engineering Professor of Teaching Innovation in the biological engineering and mechanical engineering departments in a release accompanying the study’s publication. “There are few molecular mechanisms known.”

Check treatment options

The contraceptive injection subcutaneous depot medroxyprogesterone acetate (DMPA-SC, DepoSubQ Provera 104, Pfizer, New York City) was given Food and Drug Administration approval in 2005 for treatment of pain related to endometriosis after research indicated it was as effective as leuprolide acetate, a gonadotropin-releasing hormone (GnRH) analog, for such use.5

According to Contraceptive Technology, combined oral contraceptives also decrease the menstrual pain suffered by women with endometriosis. This benefit is enhanced by use extended-cycle pills, which reduce the number of painful episodes women have.6 The contraceptive implant (Nexplanon, Merck, Whitehouse Station, NJ) also might be effective in reducing pelvic pain associated with endometriosis.7

In 2012 Abbott (now Abbvie, North Chicago, IL), in cooperation with Neurocrine Biosciences in San Diego, announced the initiation of a pivotal Phase 3 clinical trial designed to evaluate the safety and efficacy of elagolix in female patients with endometriosis. Early studies indicate that elagolix, an oral GnRH antagonist, might be effective in treating pain associated with endometriosis.8 Scientists expect to have initial data from the first of two Phase 3 clinical trials of elagolix in endometriosis treatment in the second half of 2014, says Abbvie spokesperson David Freundel. The compound also is being evaluated in a Phase 2b clinical trial as a potential treatment option for women with uterine fibroids, he notes.

Swiss-based pharmaceutical company Gedeon Richter PregLem is looking at an oral, once-a-week steroid sulfatase inhibitor for the management of endometriosis. Steroid sulfatases are enzymes expressed in tissues whose growth is estrogen-dependent; in these tissues, these enzymes convert inactive estrogens and androgens into their corresponding biologically active forms. Scientists are studying the drug, PGL5001, in hopes to reduce endometriotic lesions by targeting the inflammatory pathway of the disease and restoring progesterone sensitivity. If the drug proves successful in its current proof of concept testing, it has the potential to cause regression of the disease rather than simply alleviating symptoms.9

REFERENCES

Use guidance to cut stroke risks in women

Clinicians now have in hand, for the first time, guidelines that have been developed for preventing stroke in women. These guidelines include the following recommendations:

- Women with a history of high blood pressure before pregnancy should be considered for low-dose aspirin and/or calcium supplement therapy to lower preeclampsia risks.
- Women who have preeclampsia have twice the risk of stroke and a four-fold risk of high blood pressure later in life. Therefore, preeclampsia should be recognized as a risk factor well after pregnancy, and other risk factors such as smoking, high cholesterol, and obesity in these women should be treated early.
- Pregnant women with moderately high blood pressure (150-159 mmHg/100-109 mmHg) may be considered for blood pressure medication, whereas expectant mothers with severe high blood pressure (160/110 mmHg or above) should be treated.
- Women should be screened for high blood pressure before taking birth control pills because the combination raises stroke risks.
- Women who have migraine headaches with aura should stop smoking to avoid higher stroke risks. (To review the guidelines, go to the American Heart Association website, http://bit.ly/1gDifEg. Click on “Current Year,” then under “February 2014,” select “Guidelines for the Prevention of Stroke in Women.”)

Stroke awareness is important, as one in five women will have a stroke in her lifetime. Stroke is the number three cause of death in women; about 55,000 more women than men die of stroke each year.

“If you are a woman, you share many of the same risk factors for stroke with men, but your risk is also influenced by hormones, reproductive health, pregnancy, childbirth, and other sex-related factors,” said Cheryl Bushnell, MD, MHS, director of the Wake Forest Baptist Stroke Center and education associate professor of neurology at Wake Forest School of Medicine, both in Winston-Salem, NC. Bushnell is lead author of the new guidelines published in “Stroke,” the journal of the American Heart Association.

Authors of the new guidelines say it is important to improve stroke awareness and provide more rigorous education to women at younger ages, including those of childbearing age, because of women’s increased risk of stroke with age, as well the risks of stroke associated with pregnancy, gestational hypertension, and hormonal contraception. The onset of stroke risk factors such as obesity, hypertension, and diabetes mellitus also occur at younger ages. Future research focused on risk profile development is needed to appropriately tailor prevention strategies for women, the authors state.

“Until sex-specific risk is better understood, prevention and management of stroke and cardiovascular risk factors remains essentially the same for men and women,” the authors note.

Check blood pressure

The new guidance recommends blood pressure measurement prior to initiation of hormonal contraception, which falls in line with the “U.S. Selected Practice Recommendations for Contraceptive Use, 2013.” The relative increase in stroke risk with low-dose oral contraceptives (OCs) is small, and the risk of stroke with OC use is lower than the risk associated with pregnancy. However, certain subgroups of women, particularly those who are older, smoke cigarettes, or have hypertension, diabetes mellitus, obesity, hypercholesterolemia, or prothrombotic mutations, might be at higher risk for stroke, the guidance authors note.

Who is not a candidate for combined hormonal contraception? Severe hypertension (systolic pressure equal or greater than 160 mm Hg or diastolic pressure equal or greater than 100 mm Hg) or vascular disease is ranked as Category 4, a condition that represents an unacceptable health risk if the contraceptive method is used. Less severe hypertension (systolic pressure of 140-159 mm Hg or diastolic pressure of 90-99 mm Hg) or adequately controlled hypertension are ranked as Category 3 conditions, where the theoretical or proven risks usually outweigh the advantages of using the method. Use of Category 3 methods is not generally

EXECUTIVE SUMMARY

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- It is important to improve stroke awareness and provide more rigorous education to women at younger ages, including those of childbearing age, due to women’s increased risk of stroke with age, as well the risks of stroke associated with pregnancy, gestational hypertension, and hormonal contraception.
- The onset of stroke risk factors such as obesity, hypertension, and diabetes mellitus also occur at younger ages.
recommended unless other methods are unavailable or unacceptable to the patient.3

Women with a history of high blood pressure before pregnancy should be considered for low-dose aspirin and/or calcium supplement therapy to lower pre-eclampsia risks, the new guidance states. Women who have preeclampsia have twice the risk of stroke and a four-fold risk of high blood pressure later in life; therefore, the condition should be recognized as a risk factor well after pregnancy, and other risk factors such as smoking, high cholesterol, and obesity in these women should be treated early.1

**Stroke hits women hard**

Women need to protect themselves against stroke; findings from a new study indicate that women who survive stroke have a worse quality of life than men.6 The study findings showed that at three months, women were more likely than men to report problems with mobility, pain/discomfort, and anxiety and depression.

What can women do to cut their risk of disease? Tell patients they don’t need to run marathons or do intense aerobics to reduce their risks; moderate intensity exercise, such as brisk walking or playing tennis, might do the trick, according to research presented at the 2014 International Stroke Conference in San Diego.7

Researchers analyzed information from 133,479 women in the California Teachers Study to see how many suffered a stroke between 1996 and 2010. The California Teacher Study encompasses a wide range of ages, from those in their 20s to those in their 90s. Those who reported doing moderate physical activity in the three years before enrolling in the study were 20% less likely than women who reported no activity to suffer a stroke.

“You don’t have to do an extreme boot camp,” said Sophia Wang, PhD, the study’s lead author and professor in the Department of Population Sciences within the Beckman Research Institute at the City of Hope in Duarte, CA. “The types of activities we’re talking about are accessible to most of the population.”

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**Generic EC — One step closer to OTC status**

The Food and Drug Administration (FDA) is looking to generic versions of the levonorgestrel-based emergency contraception (EC) pill Plan B One-Step (Teva Pharmaceuticals, North Wales, PA) to submit applications for new labeling after the agency ruled the generic version can be sold on store shelves without restriction. Labels for the generic drug must indicate the product is intended for use only by women ages 17 and older, but women will not need to show proof of age to purchase it.

Jessica Arons, president and chief executive officer of the Washington, DC-based Reproductive Health Technologies Project, praised the FDA’s action toward obtaining full over-the-counter status for emergency contraception. “EC can be used safely and effectively by people of all ages, and it should be available without unnecessary and arbitrary barriers,” said Arons in a press statement accompanying the FDA action.

Cecile Richards, president of the New York City-based Planned Parenthood Federation of America, termed the FDA move as “a significant step forward for women’s health.” “When a woman fears she might become pregnant after her contraceptive has failed or she has had unprotected sex, she needs fast
access to emergency contraception, not delays at the pharmacy counter,” said Richards in a prepared statement. “Having more than one kind of emergency contraception stocked on store shelves will make EC more accessible to everyone, and that means more women than ever will be able to prevent unintended pregnancy.”

**Dollars add up**

Emergency contraceptive pills can be costly for women who pay out of pocket for them. Results of a July 2013 survey of some 400 pharmacies nationwide indicate the average price for Plan B One-Step at nearly $48, with generic EC product pricing at $41.

Generic products include My Way, launched in February 2013 by Gavis Pharmaceuticals of Somerset, NJ, and Next Choice One Dose, sold by Actavis of Parsippany, NJ. Next Choice One Dose received FDA approval in July 2012.

Generic EC products will be able to drop the age limit in their labeling entirely when Teva loses its market exclusivity labeling for ages 16 and under on April 30, 2016. Age restrictions for Plan B One-Step were lifted in June 2013 when the United States dropped its appeal against an April 2013 court order to remove such restrictions. *(To review the legal history, see the Contraceptive Technology Update articles “Appeal filed to delay unrestricted EC sales,” July 2013, p. 79, and “U.S. drops age limits for Plan B One-Step,” August 2013, p. 88.)*

**Will prices drop?**

Moving generic products to the shelf might result in market competition that will drive down the price of EC overall, said Arons.

“We hope and expect that all manufacturers of generic EC products will submit applications with the suggested labeling to the FDA immediately,” she said. “The sooner generic EC becomes available without point-of-sale restrictions, the sooner people will be able to purchase a more affordable, time-sensitive, back-up birth control option without delay.”

With changes with the Affordable Care Act (ACA), particularly related to coverage of medications and supplements that became effective in 2014, remember that certain over-the-counter medications are covered at no cost when written as a prescription. For family planning patients who are enrolled in ACA-compliant plans, clinicians should write EC prescriptions so patients can obtain the drug at no cost, said Jeanne Conry, MD, PhD, president of the American College of Obstetricians and Gynecologists.

Keep in mind that the copper-T 380A intrauterine device (IUD) represents a safe, effective form of emergency contraception that provides long-acting reversible contraception. Compared to EC users who choose oral levonorgestrel, those who select the copper IUD have lower rates of pregnancy in the next year, results of 2013 study indicate. The prospective study followed women for one year after choosing the copper T380 IUD or oral levonorgestrel for EC. The study was powered to detect a 6% difference in pregnancy rates within the year after presenting for emergency contraception.

Of the 542 women who presented for EC, agreed to participate in the trial and met the inclusion criteria, 215 (40%) chose the copper IUD and 327 (60%) chose oral LNG. In the IUD group, 127 (59%) were nulligravid. IUD insertion failed in 42 women (19%). The one-year follow-up rate was 443/542 (82%); 64% of IUD users contacted at one year still had their IUDs in place.

The one-year cumulative pregnancy rate in women choosing the IUD was 6.5% vs. 12.2% in those choosing oral LNG [hazard ratio (HR) 0.53, 95% confidence interval (CI): 0.29-0.97, p=.041]. By type of EC method actually received, corresponding values were 5.2% for copper IUD users vs. 12.3% for EC pill users (HR 0.42, 95% CI: 0.20-0.85, p=.017). A multivariable logistic regression model controlling for demographic variables indicates that women who chose the IUD for EC had fewer pregnancies in the following year than those who chose oral LNG (HR 0.50, 95% CI: 0.26-0.96, p=.037). Greater use of the copper IUD for EC might lower rates of unintended pregnancy in high-risk women, researchers conclude.

**REFERENCES**

Check new web site for Contraceptive Technology

Add another bookmark to your Internet surfing sites. The authors of Contraceptive Technology have just debuted a new website: www.contraceptivetechnology.com. Clinicians can access resources for practical information and education on family planning methods. Each month includes new additions to the latebreakers and clinical pearl sections, which update information inspired from the annual Contraceptive Technology and Quest for Excellence conferences.

CDC issues guidance for lab detection of STIs

The Centers for Disease Control and Prevention (CDC) has released 2014 recommendations for the laboratory-based detection of Chlamydia trachomatis and Neisseria gonorrhoeae in its Morbidity and Mortality Weekly Report. The report updates CDC’s 2002 recommendations for screening tests to detect C. trachomatis and N. gonorrhoeae infections, and it provides new recommendations regarding optimal specimen types, the use of tests to detect rectal and oropharyngeal C. trachomatis and N. gonorrhoeae infections, and circumstances when supplemental testing is indicated.

The new recommendations intended for use by clinical laboratory directors, laboratory staff, clinicians, and disease control personnel who must choose among available tests, establish standard operating procedures for collecting and processing specimens, interpret test results for laboratory reporting, and

(Continued on p. 60)
counsel and treat patients.

The full recommendations can be found on CDC’s laboratory information page, http://1.usa.gov/1nqwiSY.

CNE/CME QUESTIONS

1. When is irregular bleeding the most common in women who use the levonorgestrel intrauterine device?
   A. Immediately after insertion
   B. The first 30 days of use
   C. The first 3-6 months
   D. The first 12 months of use

2. What is the drug now under research for use in treatment of pain associated with vulvodynia?
   A. Valproic acid
   B. Topiramate
   C. Zonisamide
   D. Gabapentin

3. What is the drug now under research for use in treatment of pain associated with endometriosis?
   A. Elagolix
   B. Cetrorelix
   C. Degarelix
   D. Abarelix

4. According to the U.S. Selected Practice Recommendations for Contraceptive Use, 2013, who is absolutely NOT a candidate for combined hormonal contraception?
   A. Women with hypertension (systolic pressure of 140-159 mm Hg or diastolic pressure of 90-99 mm Hg)
   B. Women with hypertension (systolic pressure equal or greater than 160 mm Hg or diastolic pressure equal or greater than 100 mm Hg)
   C. Women with controlled hypertension
   D. Obese women

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