

CONTRACEPTIVE TECHNOLOGY UPDATE®

35TH ANNIVERSARY

MAY 2015

Vol. 36, No. 5; p. 49-60

→ INSIDE

Intrauterine device:
LILETTA new hormonal
option Cover

LARC effectiveness:
Research eyes
effectiveness beyond
the duration on the
label. 52

EC: Research looks
at impact of body
weight, BMI. 53

Condoms: How to get
the message across to
young men. 55

Menopause: Counsel
women on vasomotor
symptoms 57

Young women: Help
bridge the provider
transition 59

Enclosed in this issue:

- Reader Survey

AHC Media

Options expand for women: FDA approves a new intrauterine device

LILETTA joins Mirena and Skyla as hormonal intrauterine options

The Food and Drug Administration (FDA) has announced approval of a new option in intrauterine contraception: the LILETTA intrauterine device (IUD). Medicines360, a San Francisco-based nonprofit pharmaceutical company, and Actavis, a Dublin, Ireland-based pharmaceutical company, have announced that the device will be offered on the commercial market, as well as at reduced cost to public health clinics enrolled in the federal 340B Drug Pricing Program.

The device is expected to be available in the second quarter of 2015. Providers who are interested in receiving information on market availability of the device can sign up for e-mail alerts at the product's provider site, www.lilettahcp.com. [Editor's note: Contraceptive Technology Update posted information on the FDA approval on Feb. 27, 2015, on the ahcmedia.com web site and alerted readers by e-mail. If you didn't receive an e-mail alert, please make sure your current

e-mail is on file. Contact AHC Media Customer Service at customerservice@ahcmedia.com or (800) 688-2421.]

The reduced public sector pricing will help providers offer effective, safe, and affordable medicines to all women, regardless of socioeconomic status, said **Wayne Shields**, chief executive officer of the Association of Reproductive Health Professionals. "The launch of LILETTA marks an important advance in contraceptive access and reproductive agency for women across the United States," said Shields in a press statement.

LILETTA is a flexible, plastic T-shaped system, measuring 32 mm by 32 mm. It releases the progestin levonorgestrel at an initial release rate of 18.6 mcg per day, with an average in vivo release rate of approximately 15.6 mcg per day over three years. The device is labeled for three years of effective use.¹

The device is similar in size to the currently marketed Mirena (Bayer Healthcare Pharmaceuticals, Wayne, NJ), says **Andrew Kaunitz**, MD,

NOW AVAILABLE ONLINE! VISIT www.ahcmedia.com or **CALL** (800) 688-2421

Financial Disclosure: Consulting Editor **Robert A. Hatcher**, MD, MPH, Editor **Rebecca Bowers**, and Executive Editor **Joy Dickinson** report no consultant, stockholder, speaker's bureau, research, or other financial relationships with companies having ties to this field of study. **Melanie Deal**, nurse reviewer, discloses that she formerly was on the speakers bureau for Merck & Co.

Contraceptive Technology Update®

ISSN 0274-726X, is published monthly by AHC Media, LLC
One Atlanta Plaza
950 East Paces Ferry Road NE, Suite 2850
Atlanta, GA 30326.
Periodicals Postage Paid at Atlanta, GA 30304 and at additional mailing offices.

POSTMASTER: Send address changes to:
Contraceptive Technology Update
P.O. Box 550669
Atlanta, GA 30355.

SUBSCRIBER INFORMATION:
Customer Service: (800) 688-2421.
customerservice@ahcmedia.com.
www.ahcmedia.com
Hours of operation: 8:30 a.m. - 6 p.m. Monday-Thursday;
8:30 a.m. - 4:30 p.m. Friday, EST.

EDITORIAL QUESTIONS OR COMMENTS?
Call Joy Daugherty Dickinson (404) 262-5410
or Email: joy.dickinson@ahcmedia.com.

SUBSCRIPTION PRICES:
Print: 1 year with free AMA PRA Category 1 Credits™: \$479.
Add \$19.99 for shipping & handling.
Online only: 1 year (Single user) with free AMA PRA
Category 1 Credits™: \$429

MULTIPLE COPIES: Discounts are available for group subscriptions, multiple copies, site-licenses or electronic distribution. For pricing information, call Tria Kreutzer at 404-262-5482. Canada: \$509 per year plus GST. Elsewhere: \$509 per year.

Back issues: \$75. Missing issues will be fulfilled by customer service free of charge when contacted within one month of the missing issue's date.
GST Registration Number: R128870672.

ACCREDITATION: AHC Media is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center's Commission on Accreditation.

This activity has been approved for 1.25 nursing contact hours using a 60-minute contact hour.
Provider approved by the California Board of Registered Nursing, Provider #14749, for 1.25 Contact Hours.
AHC Media is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

AHC Media designates this enduring material for a maximum of 1.5 AMA PRA Category 1 Credits™.
Physicians should claim only credit commensurate with the extent of their participation in the activity.
This activity is intended for OB/GYNs, nurses, nurse practitioners, and other family planners. It is in effect for 24 months from the date of publication.

Opinions expressed are not necessarily those of this publication. Mention of products or services does not constitute endorsement. Clinical, legal, tax, and other comments are offered for general guidance only; professional counsel should be sought for specific situations.

EDITOR: Rebecca Bowers
EXECUTIVE EDITOR: Joy Daugherty Dickinson (404) 262-5410
CONTINUING EDUCATION & EDITORIAL DIRECTOR: Lee Landenberger

Copyright© 2015 by AHC Media, LLC. Contraceptive Technology Update® and STI Quarterly™ are trademarks of AHC Media. The trademarks are herein used under license. All rights reserved. No part of this newsletter may be reproduced in any form or incorporated into any information-retrieval system without the written permission of the copyright owner.

University of Florida Research Foundation professor and associate chairman of the Department of Obstetrics and Gynecology at the University of Florida College of Medicine — Jacksonville. LILETTA is labeled for three years of effective use; Mirena is labeled for five years of effective use, notes Kaunitz.

The two levonorgestrel IUDs, Mirena and LILETTA, appear to be identical in terms of size and elaboration of the progestin levonorgestrel, says **Robert Hatcher**, MD, MPH, professor emeritus of gynecology and obstetrics at Emory University School of Medicine in Atlanta. Hatcher points to *A Clinical Guide for Contraception*, which states, “The levonorgestrel intrauterine system can be used for at least seven years, and probably for 10 years.”² This statement would suggest that the new LILETTA IUD ultimately will be shown to be effective for more than the three years for which it is approved, he notes.

“This means that when we communicate with patients about the LILETTA IUD, we should not say, “This IUD must be removed in three years,” says Hatcher. “What we should say is that this IUD is effective for at least three years.”

When the copper T380A IUD,

now marketed as ParaGard, arrived on the scene, it was approved for just four years, states Hatcher. The appropriate counsel for a woman receiving the Copper T IUD at that time was “this IUD is effective for at least four years,” not “this IUD must be removed after four years,” Hatcher observes.

Six to eight years ago, one could refer to “the levonorgestrel IUD” and know it referred to Mirena. This is no longer the case, says Hatcher. Mirena, LILETTA, and Skyla (Bayer Healthcare Pharmaceuticals, Wayne, NJ) are all levonorgestrel IUDs, notes Hatcher.

How effective is it?

In a multicenter open-label clinical trial that included 1,751 women ages 16-45, LILETTA was found to be 99.45% effective in preventing pregnancy in women regardless of age, parity, or body mass index (BMI). The study is ongoing to evaluate the use of the device for up to four, five, and seven years.

The IUD was studied in women with a mean BMI of 26.9 kg/m³. The clinical trial included overweight (24%), obese (24%), and morbidly obese (5%) women. Researchers note that while levonorgestrel systemic exposure decreased with increasing

EXECUTIVE SUMMARY

A new option in intrauterine contraception has been approved: the LILETTA intrauterine device.

- Pharmaceutical companies Medicines360 and Actavis have partnered to offer the device on the commercial market, as well as at reduced cost to public health clinics enrolled in the federal 340B Drug Pricing Program. LILETTA is expected to be available in the second quarter of 2015.
- A flexible, plastic T-shaped system, the device measures 32 mm by 32 mm in size. It releases the progestin levonorgestrel at an initial release rate of 18.6 mcg per day, with an average in vivo release rate of approximately 15.6 mcg per day over three years. LILETTA is labeled for three years of effective use.

body weight, there was no apparent effect of BMI or body weight on contraceptive efficacy.¹

About 60% of trial participants were nulliparous. The following women were excluded: women with a history of ectopic pregnancy, pelvic inflammatory disease, trophoblastic disease without a subsequent intrauterine pregnancy, who were less than four weeks post-pregnancy, had HIV, or were not in a mutually monogamous relationship at study entry.

The pregnancy rate calculated as the Pearl Index (PI) in women ages 16 to 35 years, inclusive, was the primary efficacy endpoint used to assess contraceptive reliability, researchers note.¹ The index was calculated based on 28-day equivalent exposure cycles. Evaluable cycles excluded those in which back-up contraception was used unless a pregnancy occurred in that cycle. The Year One PI was based on two pregnancies, and the cumulative three-year pregnancy rate was calculated by the life table method, based on a total of six pregnancies that occurred after the onset of treatment and within seven days after LILETTA removal or expulsion.

The cumulative pregnancy rate (95% confidence interval [CI]) in the Year One PI was calculated at 0.15 (0.02, 0.55) based on 17,125 28-day cycles of exposure. Cumulative pregnancy rate (95% CI) for the cumulative three-year life table was calculated at 0.55 (0.24, 1.23), based on 34,711 28-day cycles of exposure.¹

What can users expect?

Approximately 19% of women treated with LILETTA experienced amenorrhea within one year of treatment, and more than one-third experienced amenorrhea by the third year of treatment. In an analysis of

women who discontinued the study early, 97% returned to menses within three months after the device was removed.

The incidence of ectopic pregnancy in the clinical trial, which excluded women with a history of ectopic pregnancy who did not have a subsequent intrauterine pregnancy, was approximately 0.12% per 100 woman years.

In the clinical trial, an overall expulsion rate of 3.5% was reported, with a rate of 2.0% in nulliparous women and 5.6% in parous women. Expulsion might be associated with symptoms of bleeding or pain, or it might be asymptomatic and go unnoticed. LILETTA typically decreases menstrual bleeding over time; therefore, an increase in menstrual bleeding might be indicative of an expulsion, researchers note.¹

In the contraceptive trial, 12.3% of LILETTA users discontinued prematurely due to an adverse reaction. The most common adverse reactions leading to discontinuation were expulsion (3.5%) and bleeding complaints (1.5%). The next most common adverse reactions causing discontinuation were acne (1.3%), mood swings (1.3%), dysmenorrhea (0.6%), and uterine spasm (0.6%). Two women discontinued the clinical study due to PID, and one discontinued due to endometritis.

Check insertion times

If a woman is not using a form of hormonal contraception or an IUD, LILETTA can be inserted any time there is reasonable certainty the woman is not pregnant. If the device is not inserted during the first seven days of the menstrual cycle, a barrier method of contraception, such as condoms and spermicide, should be used or the patient should abstain

from vaginal intercourse for seven days to prevent pregnancy.

If women are switching from oral, transdermal, or vaginal hormonal contraceptives, LILETTA may be inserted at any time. It may be inserted during the hormone-free interval of the previous method. If it is inserted during active use of the previous method, the prescribing information indicates to continue the previous method after device insertion for seven days or until the end of the current cycle. If a woman is using continuous hormonal contraception, the method should be discontinued seven days after device insertion.¹

Women using the contraceptive injection who wish to switch to LILETTA can have the device inserted at any time. A barrier method of contraception, such as condoms and spermicide, also should be used for seven days if the device is inserted as instructed more than three months (13 weeks) after the last injection.

The use of LILETTA is contraindicated in women with the following:

- known or suspected pregnancy;
- congenital or acquired uterine anomaly, including fibroids if they distort the uterine cavity;
- known or suspected breast cancer or other progestin-sensitive cancer, now or in the past;
- known or suspected uterine or cervical neoplasia;
- liver disease, including tumors;
- untreated acute cervicitis or vaginitis, including lower genital tract infections, until infection is controlled;
- postpartum endometritis or infected abortion in the past three months;
- unexplained uterine bleeding;
- current IUD;

- acute pelvic inflammatory disease (PID) or history of PID (except with later intrauterine pregnancy);
- conditions increasing susceptibility to pelvic infection;
- hypersensitivity to any

component of the device.

REFERENCES

1. LILETTA (levonorgestrel-releasing intrauterine system) prescribing

information. Accessed at <http://bit.ly/1CdbHt0>.

2. Speroff L, Darney PD. *A Clinical Guide for Contraception*. Philadelphia: Lippincott Williams & Wilkins; 2011. ■

Intrauterine device and implant are effective beyond use approved by the FDA

An initial analysis of data conducted by Washington University School of Medicine in St. Louis indicates that hormonal intrauterine devices (IUDs) and contraceptive implants remain highly effective one year beyond their approved duration of use.¹

The etonogestrel subdermal implant (Nexplanon, Merck, Whitehouse Station, NJ) and the 52-mg levonorgestrel IUD (Mirena, Bayer Healthcare Pharmaceuticals, Wayne, NJ) represent two of the most effective forms of reversible contraception available with a failure rate of less than 1% over the respective three-year and five-year durations approved by the Food and Drug Administration. Data indicate both devices provide effective use past their approved durations. Three studies in which a total of 275 women used the etonogestrel implant Implanon for longer than three years found no pregnancies during the fourth year of use. A 2014 systematic review concluded that the 52-mg levonorgestrel IUD could be used safely for up to seven years.^{2,3}

The Contraceptive CHOICE Project had an “amazing” uptake and continuation of long-acting reversible contraception (LARC) among its participants, says **Colleen McNicholas**, DO, MSCI, assistant professor in the Washington University School of Medicine’s Obstetrics and Gynecology Department. This level of

participation has given researchers a unique opportunity to study a cohort of women using these methods for a longer time, McNicholas observes. The Contraceptive CHOICE Project was a prospective cohort study of reproductive-aged women in St. Louis designed to promote the use of LARC by eliminating cost, access, and knowledge barriers.

The present study, known as the Effectiveness of Prolonged use of the IUD and Implant for Contraception (EPIC) study, is seeking to fill gaps in the literature regarding extended use of the etonogestrel implant and 52-mg levonorgestrel IUD. It aims to enroll a total of 800 women. The currently published initial analysis included 237 women who used implants and 263 women who used hormonal IUDs.

“This study gives us an

opportunity to show the devices are still effective, in different populations of users,” says McNicholas, who served as lead author of the current paper. “This improves the cost-effectiveness of the device and helps women avoid unnecessary removals/re-insertions.”

Review the research

Women participating in the EPIC analysis were ages 18 to 45, and their contraceptives had to be within six months of expiring when they enrolled. The women were informed of a possible risk of pregnancy if the devices were used beyond the duration of use approved by the Food and Drug Administration.

Unintended pregnancy rate per 100 women-years was calculated. To check serum etonogestrel levels, implant users were offered periodic

EXECUTIVE SUMMARY

An initial analysis of data conducted by Washington University School of Medicine in St. Louis indicates that hormonal intrauterine devices (IUDs) and contraceptive implants remain highly effective one year beyond their approved duration of use.

- The etonogestrel subdermal implant and the 52-mg levonorgestrel IUD represent two of the most effective forms of reversible contraception available with a failure rate of less than 1% over the respective three-year and five-year durations approved by the Food and Drug Administration.
- Study findings indicate the devices still are effective in different populations of users past their approved duration of use. This duration improves the cost-effectiveness of such devices and helps women avoid unnecessary removals/re-insertions, researchers state.

venipuncture. The Kruskal-Wallis test, a form of statistical analysis, was used to compare the etonogestrel levels across body mass index (BMI) groups.

The researchers documented no pregnancies in the implant group and one pregnancy in the IUD group. This failure rate is similar to that of IUDs used within the recommended five-year window, researchers note.

Scientists will continue to follow the women and others who enroll in the study. The final results will determine if the 52-mg levonorgestrel IUD and the contraceptive implant are effective for up to three years beyond their approved duration of use.

It will be important to study the mechanism of action for the implant during its fourth year of use, says **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. Many turn to the implant because it so reliably suppresses ovulation, she says.

LARC is catching on

The use of LARC methods is catching on. Use of IUDs and

implants jumped five-fold between 2002 and 2011, according to a new U.S. government report.⁴ Among women ages 15 to 44, the use of such long-term reversible contraceptives rose from 1.5% in 2002 to 7.2% in 2011-2013, according to the Centers for Disease Control and Prevention report. (*For more on contraceptive use, see “Statistics show more use of LARC — How can you maintain momentum?” Contraceptive Technology Update, March 2015, p. 25.*)

With more women moving to LARC methods, the continued follow-up of the EPIC study participants will provide data that might change the provision of contraceptive services. The potential to further improve the cost-effectiveness by extending the life of these devices could provide “tremendous” economic benefit to insurers and to society, researchers state.

“The longer a contraceptive method is effective, the bigger the impact it can have,” said co-author **Jeffrey Peipert**, MD, PhD, the Robert J. Terry Professor of Obstetrics and Gynecology at Washington

University School of Medicine in St. Louis. “In the long term, this work has the potential to change how we provide contraceptive methods around the world and can enable women to control their reproductive health and family size.”

REFERENCES

1. McNicholas C, Maddipati R, Zhao Q, et al. Use of the etonogestrel implant and levonorgestrel intrauterine device beyond the U.S. Food and Drug Administration-approved duration. *Obstet Gynecol* 2015; 125(3):599-604.
2. Raymond EG. Contraceptive implants. In: Hatcher RA, Trussell J, Nelson AL, et al. *Contraceptive Technology*: 20th revised edition. New York: Ardent Media; 2011.
3. Wu JP, Pickle S. Extended use of the intrauterine device: A literature review and recommendations for clinical practice. *Contraception* 2014; 89:495-503.
4. Daniels K, Daugherty J, Jones J. Current contraceptive status among women aged 15-44: United States, 2011-2013. *NCHS data brief, no 173*. Hyattsville, MD: National Center for Health Statistics. 2014. ■

Research eyes effect of body weight and BMI impact on emergency contraception

Results of a new statistical analysis of clinical data suggest a significant drop in the efficacy of levonorgestrel emergency contraception (EC) with increasing body weight.¹

Questions of whether body mass index (BMI) or weight might influence the efficacy of EC first were raised when findings from a 2011 analysis indicated that levonorgestrel, when taken for emergency contraception among overweight

or obese women, had decreased efficacy in preventing pregnancy.² (*Contraceptive Technology Update reported on the data in the article, “Hope vs. reality — Access to EC pills doesn’t work,” January 2013, p. 8.*)

To further evaluate the effect of weight and BMI on the efficacy of levonorgestrel emergency contraception, researchers pooled data from two large, multicenter, randomized controlled trials designed to assess emergency contraceptive

efficacy to evaluate the effect of weight and BMI on pregnancy rates among women who received levonorgestrel.^{3,4}

The researchers used descriptive methods, such as comparing means and distributions according to pregnancy status and pregnancy rates across weight and BMI categories, as well as cubic spline modeling, to describe the relationship between pregnancy risk and weight/BMI. Cubic spline modeling utilizes five

predictions of the pregnancy rates corresponding to five percentiles (the first, third, fifth, seventh, and ninth deciles) of the distribution of the data.

A total of 1,731 women were in the analysis population, and 38 pregnancies were reported. Women for whom levonorgestrel was not effective in preventing pregnancy had a significantly higher mean body weight and BMI than women who did not become pregnant (76.7 versus 66.4 kg, p less than .0001; 28.1 versus 24.6 kg/m², p less than .0001).

The estimated pregnancy rate increased significantly from 1.4% (95% confidence interval [CI]: 0.5%-3.0%) among the group of women weighing 65-75 kg to 6.4% (95% CI: 3.1%-11.5%) and 5.7% (95% CI: 2.9%-10.0%) in the 75-85 kg and above-85 kg groups, respectively, findings indicate. Statistical modeling demonstrated a steep increase in pregnancy risk starting from a weight near 70-75 kg to reach a risk of pregnancy of 6% or greater around 80 kg. Similar results were obtained for statistical modeling of BMI, as well as when the two studies were analyzed individually, researchers report.³

How to proceed?

Clinicians need to take into consideration such data when talking with women about emergency contraception. Why? The average U.S. woman now weighs 75 kg (165 pounds).⁵

Levonorgestrel emergency contraceptive pills are approved for unrestricted sales on store shelves. They include Plan B One-Step (Teva Women's Health, North Wales, PA); Take Action (Teva), Next Choice One Dose (Actavis, Parsippany, PA), My Way (Gavis Pharmaceuticals, Somerset, NJ), Levonorgestrel 0.75

EXECUTIVE SUMMARY

Results of a new statistical analysis of clinical data suggest a significant drop in the efficacy of levonorgestrel emergency contraceptive pills (ECPs) with increasing body weight.

- Questions of whether body mass index (BMI) or weight might influence the efficacy of ECPs first were raised when findings from a 2011 analysis indicated that levonorgestrel, when taken for emergency contraception among overweight or obese women, had decreased efficacy in preventing pregnancy.
- Researchers pooled data from two large, multicenter, randomized controlled trials designed to assess emergency contraceptive efficacy to evaluate the effect of weight and BMI on pregnancy rates among women who received such pills. For women weighing more than 75 kg (165 pounds), levonorgestrel ECPs were minimally effective.

mg tablets (Perrigo, Allegan, MI), and AfterPill (Syzygy Healthcare Solutions, Westport, CT).

Publication of the new analysis will spread enthusiasm for ulipristal acetate, because most clinics are not able to provide copper IUDs for emergency contraception, says **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.

Study findings suggest that ulipristal acetate (ella, Afaxys, Charleston, SC) also is impacted by weight. It appears to lose effectiveness at a higher BMI threshold of 35.^{2,6} Ulipristal acetate is available by prescription only in the United States; it was approved in January 2015 for pharmacy over-the-counter sales by the European Commission.

Robert Hatcher, MD, MPH, professor emeritus of gynecology and obstetrics at Emory University School of Medicine in Atlanta, points to the book *Managing Contraception 2015-2016*, which summarizes the loss of effectiveness of emergency contraceptive pills in overweight women with two concise statements:

- “Emergency contraception with

progestin-only pills (e.g. Plan B) is virtually useless with women with a BMI of 36 or greater.”

- “Emergency contraception with ella is useless (ineffective) in women with a BMI of 35 or greater.”⁷

The copper intrauterine device (IUD) is the most effective form of emergency contraception. It can be inserted up to five days after unprotected intercourse, which reduces the risk of pregnancy by 99%. It retains full efficacy over time and with obesity, and it provides ongoing contraception for up to 12 years.⁸

Clinicians also might want to consider a recently published commentary that calls for changes in patient counseling for emergency contraception, because typical counseling doesn't take into account the relative effectiveness of available methods or patient characteristics such as BMI.⁹ (*For more information on tiered counseling, see “It's time for a tiered approach to counseling on emergency contraception,” CTU, March 2015, p. 29.*)

REFERENCES

1. Kapp N, Abitbol JL, Mathé H, et al. Effect of body weight and BMI

- on the efficacy of levonorgestrel emergency contraception. *Contraception* 2015; 91(2):97-104.
2. Glasier A, Cameron ST, Blithe D, et al. Can we identify women at risk of pregnancy despite using emergency contraception? Data from randomized trials of ulipristal acetate and levonorgestrel. *Contraception* 2011; 84(4):363-367.
 3. Creinin MD, Schlaff W, Archer DF, et al. Progesterone receptor modulator for emergency contraception. A randomized controlled trial. *Obstet Gynecol* 2006; 108(5):1089-1097.
 4. Glasier AF, Cameron ST, Fine PM, et al. Ulipristal acetate versus levonorgestrel for emergency contraception: A randomised non-inferiority trial and meta-analysis. *Lancet* 2010; 375:555-562.
 5. McDowell MA, Fryar CD, Ogden CL, et al. *Anthropometric reference data for children and adults: United States, 2003–2006*. Hyattsville, MD: National Center for Health Statistics. Accessed at <http://1.usa.gov/XnlZ7o>.
 6. Moreau C, Trussell J. Results from pooled Phase III studies of ulipristal acetate for emergency contraception. *Contraception* 2012; 86:673-680.
 7. Ziemann M, Hatcher RA, Allen AZ. *Managing Contraception 2015-2016*. Atlanta: Bridging the Gap Communications; 2015.
 8. Reproductive Health Access Project. *Emergency contraception: Timing, weight, and efficacy*. November 2013. Accessed at <http://bit.ly/18GsqnV>.
 9. Thompson K, Belden P. Counseling for emergency contraception: Time for a tiered approach. *Contraception* 2014; 90(6):559-561. ■

How to get the message across to young men about using condoms consistently and correctly

When used consistently and correctly, latex condoms are effective at preventing sexually transmitted infections (STIs), including HIV. But are young men getting the information they need to use condoms correctly?

Young men especially need to hear the condom message. The most recent national surveillance data from the Centers for Disease Control and Prevention indicate that sexually active adolescents and young adults are at increased risk for STIs when compared to older adults.¹ Consider these statistics:

- In 2013, as in previous years, men ages 20-24 had the highest rate of chlamydia (1,325.6 cases per 100,000 males) among all male age groups.
- Men ages 20-24 had the highest rate of gonorrhea (459.4 cases per 100,000 males) in 2013 among all male age groups. During 2012–2013, the gonorrhea rate for men in this age group increased 1.3% over the previous year.
- In 2013, the rate of primary and secondary syphilis among men

ages 15-19 was the highest reported since 1995: 6.4 cases per 100,000. Men ages 20-24 in 2013 had the highest rate since 1992: 27.7 cases per 100,000.¹

Multiple types of condom-use errors and problems are prevalent among men at high risk of infection, including “fit-and-feel” problems, breakage, lost erection, and slippage.² What are key points for providers to mention when it comes to correct application and proper lubrication?

First, emphasize that men and their partners — whoever the partner may be, male or female

— must decide the right fit and feel of condom, says **Richard Crosby**, PhD, endowed professor and chair of the College of Public Health at the University of Kentucky in Lexington. There are too many types of condoms on the market today for men not to experiment with them, says Crosby, a member of the Bloomington, Indiana-based Kinsey Institute Condom Use Research Team, an international research group.

Much like trying on shoes, men should find the one type of condom that they like the best, the one that makes them feel confident, secure,

EXECUTIVE SUMMARY

When used consistently and correctly, latex condoms are effective at preventing sexually transmitted infections (STIs), including HIV.

- The most recent national surveillance data indicate that sexually active adolescents and young adults are at increased risk for STIs when compared to older adults.
- Multiple types of condom-use errors and problems are prevalent among men at high risk of infection, including “fit-and-feel” problems, breakage, lost erection, and slippage.
- Proper counseling and provision of high-quality condoms and lubricants can help men and their partners have “better sex with latex.”

and at the same time, comfortable knowing that they are protected, Crosby notes. “It shouldn’t feel like they are wearing something that is awkward,” states Crosby. “It would be like wearing the wrong size shoe.”

Remember that condoms come in different materials, says **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. Polyisoprene condoms (Durex RealFeel, RB plc, Slough, Berkshire, England and LifeStyles Skyn, Ansell Healthcare Products, Iselin, NJ) can help transmit body heat while protecting against STIs, especially for latex-allergic couples, she notes.

Include partners in choice

Equally important is that the selected condom be compatible with the fit and feel preferences of the sex partner, Crosby says. One style or make of condom might work well with one partner, but the same condom might not be as good for another partner, he notes. This search for the right fit and feel gives couples a chance to talk about condom use, which in essence also leads to more condom use, says Crosby.

“If they talk about condoms before they have sex, they’re more likely to actually use condoms during sex,” says Crosby. “It creates sort of a built-in mechanism for the couple to dialogue about safer sex, way before they have it.”

Be sure to offer ample supplies of high-quality lubricants to men and women. There are now silicone lubricants that last longer and feel better than traditional water-based lubricants, says Crosby. Lubricants come in different sensations, viscosities, and scents, and they are attractively packaged, says Crosby.

“Single-use lubrication vials should always be standard. Like a hamburger and fries at McDonald’s, you wouldn’t order one without the other,” notes Crosby. “When you’re giving people condoms, allow them to choose from an equal and high-end supply of lubricants.”

Recent studies have identified a number of potential safety issues with personal lubricants; data suggest that lubricants with high osmolality might cause vaginal and anal

“IT SHOULDN’T
FEEL LIKE THEY
ARE WEARING
SOMETHING
THAT IS
AWKWARD. IT
WOULD BE LIKE
WEARING THE
WRONG SIZE
SHOE.”

epithelial damage.³ Until definitive answers are reached, refer to an international technical advisory listing on commercial lubricants (<http://bit.ly/1AdGZtB>) to check osmolality of current options.

There is no reason to spare the expense when it comes to buying quality condoms and lubricants for clinic distribution, states Crosby. The argument of “we can’t afford them” does not hold up, he advocates. A 2011 estimate of costs for diagnosis and treatment of chlamydia offered figures of cost per case at \$20 in males and \$244 in females.⁴ Given those figures, providing high-quality condoms and lubricants is cost-

effective, says Crosby.

Crosby suggests using the phrase “better sex with latex” to remind patients that protected sex is sex that is free of worries about giving or getting an STI. Without those anxiety feelings, patients can magnify the overall experience so it is more satisfying, focused, and less of a guilt experience afterward.

Ask the patient, “Do you want better sex?” says Crosby. This question leads into a discussion about the positive aspects of condom/lubricant use. By offering the patient a variety of quality condoms and lubricants for take-home use, it develops an ongoing relationship with the patient. This action turns the dynamic from “we don’t want to see you with another STI” to “we want to see you come back for refills on condoms and lubricants,” Crosby notes.

REFERENCES

1. Centers for Disease Control and Prevention. *Sexually Transmitted Disease Surveillance 2013*. Atlanta: U.S. Department of Health and Human Services; 2014.
2. Crosby R, Yarber WL, Sanders SA, et al. Slips, breaks and “falls”: Condom errors and problems reported by men attending an STD clinic. *Int J STD AIDS* 2008; 19(2):90-93.
3. World Health Organization, Department of Reproductive Health and Research, United Nations Population Fund, Family Health International. *Use and procurement of additional lubricants for male and female condoms: WHO/UNFPA/FHI360*. Accessed at <http://bit.ly/1AdGZtB>.
4. Minnesota Chlamydia Partnership. *The Minnesota chlamydia strategy: Action plan to reduce and prevent chlamydia in Minnesota*. Accessed at <http://bit.ly/1b0dKVd>. ■

Counsel women on how to cope with menopause's vasomotor symptoms

New research indicates that frequent vasomotor symptoms (VMSs) associated with menopause could last more than seven years for many women.¹

The duration of vasomotor symptoms is an important question for women in general and the clinicians who treat them, says **Nancy Avis**, PhD, professor of public health sciences/social sciences at Wake Forest Baptist Medical Center in Winston-Salem, NC.

“Women want to know how long they can expect their hot flashes to last and whether it is unusual for them to last a long time,” remarks Avis, who served as lead author of the current paper. “Up to now, we have lacked good longitudinal data on this issue because it requires a long period of follow-up of women going through the menopausal transition; thus, clinicians have not been able to provide women with very good information.”

The Study of Women's Health Across the Nation (SWAN), a multiracial/multiethnic observational study of women entering menopause, has been following women since 1996 and provides an ideal study in which to address this question, says Avis. She and her coauthors analyzed data from 1,449 women with frequent vasomotor symptoms (defined as six or more affected days in the previous two weeks). The research team is continuing to follow women in the SWAN study and might have even more information in a few years, Avis notes.

To conduct the current analysis, researchers evaluated women at a median of 13 visits during the study. Two primary outcomes were

established: total VMS duration, which measured the years elapsed between the first and last report of frequent vasomotor symptoms, and post-final menstrual period, the number of years that frequent symptoms persisted after the final period. Cessation of vasomotor symptoms was defined as two consecutive visits without hormone replacement therapy or experiencing symptoms. Researchers also sought to identify risk factors for the two measures.

Analysis indicates the median total duration of vasomotor symptoms at 7.4 years. Among 881 women who were aware of their final menstrual period, the median post-final menstrual period persistence was 4.5 years.¹

Timing of menopause emerged as an important factor in the duration of vasomotor symptoms, researchers report. The longest total vasomotor duration (median, more than 11.8 years) and post-final menstrual period persistence (median, 9.4 years) occurred among women who were premenopausal or early perimenopausal when they first experienced frequent vasomotor symptoms. Women who were

postmenopausal when symptoms began had the shortest total symptom duration (median, 3.4 years). Black women experienced the longest total symptom duration (median, 10.1 years); Japanese and Chinese women reported the shortest symptom duration (median, 4.8 years and 5.4 years, respectively). The median total symptom durations were 6.5 years for non-Hispanic white women and 8.9 years for Hispanic women.¹

Longer symptom duration was associated with younger age, lower educational level, history of smoking, greater perceived stress, greater sensitivity to symptoms, and depression and anxiety at the time of the first report of symptoms, researchers report. Shorter symptom duration was observed among women with partners, higher educational level, less financial pressure, and greater social support.¹

If women are at the beginning of menopause, they might still be fertile, notes a commentary that accompanies the current paper.² If these women experience frequent vasomotor symptoms, low-dose combined oral contraceptives might protect them from pregnancy while tempering hot flashes and night sweats, authors note.

EXECUTIVE SUMMARY

New research indicates that frequent vasomotor symptoms associated with menopause could last more than seven years for many women.

- If women are at the beginning of menopause, they might still be fertile. Low-dose combined oral contraceptives might offer pregnancy protection while tempering hot flashes and night sweats.
- Nonhormonal prescription treatments for managing vasomotor symptoms include use of selective serotonin-reuptake inhibitors and serotonin-norepinephrine reuptake inhibitors. Nonprescription remedies include soy, isoflavone supplements, black cohosh, vitamin E, and yoga.

With a longer timeframe for menopause, some women might look to nonhormonal treatments for managing vasomotor symptoms. The selective serotonin-reuptake inhibitors (SSRIs) and serotonin-norepinephrine reuptake inhibitors paroxetine, escitalopram, venlafaxine, and desvenlafaxine have been shown to be more effective than placebo for hot flashes.³ Paroxetine 7.5 mg (Brisdelle, Noven Therapeutics, Miami) is the only SSRI approved by the Food and Drug Administration for this indication.³

Nonprescription remedies such as soy, isoflavone supplements, black cohosh, vitamin E, and omega-3 fatty acids are generally low risk but with efficacy generally similar to placebo, notes a 2014 clinical guidance issued by the North American Menopause Society (NAMS).³

Menopausal hormone therapy is the most effective treatment for vasomotor symptoms, notes the Society's guidance. Options include systemic estrogen, estrogen-progestogen, estrogen-bazedoxifene, progestogen alone, or combined oral contraceptives in women requiring contraception.³ Duavee, marketed by Wyeth Pharmaceuticals, Philadelphia, a combination of the selective estrogen receptor modulator bazedoxifene and conjugated estrogen, is Food and Drug Administration-approved for the treatment of hot flashes.

According to the Society guidance, custom-compounded bioidentical hormones aren't recommended because of lack of regulation, rigorous safety and efficacy testing, batch standardization, and purity measures.³ Many women use compounded bioidentical hormones, according to a recent analysis.⁴ Of the 57 to 75 million prescriptions for menopausal hormone therapies filled

each year, 36 million prescriptions are written for Food and Drug Administration-approved hormone therapy. The remaining 28 to 39 million prescriptions are likely for compounded hormones, the analysis indicates.⁴

If you think hot flashes taper off as a woman reaches age 52, the year generally considered as the time of natural menopause, think again. Some 40% of women ages 60 to 65 still have hot flashes, according to a just-published study.⁵

While these hot flashes are occasional and mild for many women, for some such symptoms remain troublesome, data indicate. Women bothered by these symptoms often are not getting treatment, even though treatments are available, researchers report.⁵

Most guidelines recommend against using systemic hormones for women more than 10 years after menopause or after age 60 and to use them only for a limited time—ideally 3-5 years in the case of combined estrogen/progestogen therapy. This recommendation is a change from the prescribing habits of the 1990s, when there was widespread use of hormone therapy for women in all phases of menopause, says **Margery Gass, MD**, NAMS executive director. Findings from the Women's Health Initiative study changed such prescribing habits, with clinicians advised to prescribe only for symptoms and for a limited time.

Estrogen therapy alone has fewer

risks than the combined therapy, but only women who have had a hysterectomy should use estrogen alone. It appears that estrogen alone can be used safely for a longer time, says Gass. Because later analyses of data indicated that older women had more side effects from hormonal therapy, the conclusion was that women should use hormone therapy in their early post-menopausal years when they are most symptomatic, then discontinue as soon as symptom relief is reached, notes Gass.

"Women need to know that they do still have options to treat their hot flashes and sexual symptoms, even if they are older or cannot or do not wish to use hormone therapy," says Gass. "NAMS encourages all women bothered by their menopause symptoms to seek the help they need and not to give up."

REFERENCES

1. Avis NE, Crawford SL, Greendale G, et al. Duration of menopausal vasomotor symptoms over the menopause transition. *JAMA Intern Med* 2015; doi: 10.1001/jamainternmed.2014.8063.
2. Richard-Davis G, Manson JE. Vasomotor symptom duration in midlife women — Research overturns dogma. *JAMA Intern Med* 2015; doi: 10.1001/jamainternmed.2014.8099.
3. Shifren JL, Gass ML; NAMS Recommendations for Clinical Care of Midlife Women Working Group. The North American Menopause

COMING IN FUTURE MONTHS

- Smartphone app aids condom distribution
- Research progresses on potential herpes vaccine
- Review options for treating heavy menstrual bleeding
- Vaginal microbicide update — What's the forecast?

Society recommendations for clinical care of midlife women. *Menopause* 2014; 21(10):1038-1062.

4. Pinkerton JV, Santoro N.

Compounded bioidentical hormone

therapy: Identifying use trends and knowledge gaps among US women.

Menopause 2015; doi:10.1097/

GME.0000000000000420.

5. Gartoulla P, Worsley R, Bell RJ, et al.

Moderate to severe vasomotor and sexual symptoms remain problematic for women aged 60 to 65 years.

Menopause 2015; doi:10.1097/

GME.0000000000000383. ■

Help young women transition to adult healthcare

Young women ages 18 to 25 represent a heterogeneous population transitioning from adolescence into adulthood who might present with unique issues and challenges, including a potential gap in healthcare after pediatric healthcare. The American College of Obstetrics and Gynecology (ACOG) has just released a committee opinion to help providers structure preventive healthcare visits to screen for health issues and counsel patients about a variety of health topics, including reproductive health.¹

In 2011, the U.S. population was more than 311 million.² Women ages 18-24 comprised 9.6% of the 158 million U.S. females. This age group might need assistance in transitioning from a pediatrician to a provider of adult healthcare, notes **Julie Strickland**, MD, chair of ACOG's Adolescent Health Care Committee, which issued the opinion.

Young women in this age group often have some gaps in medical care, Strickland observes. Often, they are newly on their own and don't really know what provider to use to assess their needs. Also, young women might feel well, so they don't go for sick visits, but yet have a lot of screening needs, Strickland states.

Many young women come to view their obstetrician-gynecologist as their primary health provider.³ In a preventive healthcare visit, providers should screen for health issues and counsel patients about a variety of health topics, some of which are particularly relevant to their age

group.¹

During the visit, ask about the young woman's living situation, including with whom she lives, how well she gets along with others at home, and whether she feels safe and secure. Questions about friends' high-risk behaviors such as alcohol consumption and drug use can make the patient more receptive to answering questions about her own personal habits.

Assess a patient's social support, says **Melanie Gold**, DO, MQT, DABMA, FAAP, FACOP, medical director of New York — Presbyterian Hospital's School Based Health Centers and adolescent medicine faculty at Columbia University Medical Center in New York City. Identify who might be an advocate for a young woman's care, whether it might be her mother, an aunt, or a trusted friend, Gold says.

Talk with your patient about whether she has any concerns or questions about the shape or size of her body or the way she looks, the guidance advises. Ask whether she wants to gain or lose weight, and if she has ever tried to lose weight or control her weight by vomiting, using diet pills or laxatives, or not eating for a day. Questions about intake of fruits and vegetables, calcium, multivitamin with folic acid, iron, and dietary restrictions can help you understand dietary behaviors. Be sure to check use of herbal and natural supplements, because some supplements can interfere with certain prescription medications; for example, St. John's

wort interferes with the efficacy of oral contraceptive pills.

Because injuries are the most common preventable cause of morbidity and mortality among young women, safety questions are important facets of the preventive visit. All patients should be asked about abuse, neglect, physical or sexual violence, and reproductive coercion, such as sabotage of contraceptive methods.¹

Gold says she sees sleep disorders in this age group, as young women are juggling multiple responsibilities such as school, job, and family. Lack of sleep can lead to increased risk of diabetes, weight gain, heart disease, depression, driving accidents, and mistakes at school or work.¹ (*Use resources from the federal National Institutes of Health's National Heart, Lung, and Blood Institute for additional information and resources on sleep. Visit <http://1.usa.gov/1Evgg1W>.)*

REFERENCES

1. Committee opinion no. 626: The transition from pediatric to adult health care: Preventive care for young women aged 18-26 years. *Obstet Gynecol* 2015; 125(3):752-754.
2. Department of Health and Human Services, Health Resources and Services Administration, Maternal and Child Health Bureau. *Women's Health USA 2011*. Rockville, MD: U.S. Department of Health and Human Services, 2011.
3. Callahan ST, Cooper WO. Changes in ambulatory health care use during the transition to young adulthood. *J Adolesc Health* 2010; 46:407-413. ■

EDITORIAL ADVISORY BOARD

CHAIRMAN Robert A. Hatcher, MD, MPH
Senior Author, Contraceptive Technology
Professor Emeritus of Gynecology and
Obstetrics, Emory University School of
Medicine, Atlanta

David F. Archer, MD, Professor of OB/
GYN, The Jones Institute for Reproductive
Medicine, The Eastern Virginia Medical
School, Norfolk

Kay Ball, RN, PhD, CNOR, FAAN
Perioperative Consultant/Educator
K&D Medical, Lewis Center, OH

Melanie Deal, MS, WHNP-BC, FNP,
Nurse Practitioner, University Health Ser-
vices, University of California, Berkeley

Linda Dominguez, RNC, WHNP, Clinical
Consultant, Southwest Women's Health
Albuquerque, NM

Andrew M. Kaunitz, MD, Professor &
Associate Chairman, University of Florida
Research Foundation Department of
Obstetrics and Gynecology, University of
Florida College of Medicine — Jacksonville

Anita L. Nelson, MD, Professor, OB-GYN
David Geffen School of Medicine
University of California, Los Angeles

Wayne Shields, President & CEO, Associa-
tion of Reproductive Health Professionals
Washington, DC

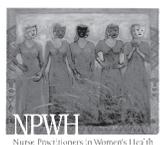
James Trussell, PhD, Professor of Eco-
nomics and Public Affairs Director, Office
of Population Research, Princeton (NJ)
University

David Turok, MD, MPH, Associate Profes-
sor, Department of Obstetrics and Gyne-
cology, University of Utah, Salt Lake City

Susan Wysocki, WHNP-BC, FAANP,
President & CEO, iWomansHealth
Washington, DC

**To reproduce any part of this newslet-
ter for promotional purposes, please
contact: Stephen Vance.** Phone: (800)
688-2421, ext. 5511. Email: stephen.vance@ahcmedia.com.
**To obtain information
and pricing on group discounts, multiple
copies, site-licenses, or electronic dis-
tribution please contact: Tria Kreutzer.**
Phone: (800) 688-2421, ext. 5482. Email:
tria.kreutzer@ahcmedia.com. **To reproduce
any part of AHC newsletters for edu-
cational purposes, please contact The
Copyright Clearance Center for permis-
sion:** Email: info@copyright.com. Website:
www.copyright.com. Phone: (978) 750-8400

Contraceptive Technology Update is
endorsed by the National Association of
Nurse Practitioners in Women's Health and
the Association of Reproductive Health
Professionals as a vital information source
for healthcare professionals.



CNE/CME INSTRUCTIONS

To earn credit for this activity, please follow these instructions:

1. Read and study the activity, using the provided references for further research.
2. Scan the QR code to the right or log on to the AHCMedia.com site to take a post-test. Go to "MyAHC" and then "My Courses" to view your available CE activities. Tests are taken after each issue. First-time users will have to register on the site using the 8-digit subscriber number on their mailing label, invoice, or renewal notice.
3. Pass the online tests with a score of 100%; you will be allowed to answer the questions as many times as needed to achieve a score of 100%.
4. After successfully completing the test, your browser will be automatically directed to the activity evaluation form, which you will submit online.
5. Once the completed evaluation is received, a credit letter will be e-mailed to you instantly.



CNE/CME QUESTIONS

1. What is the labeled duration of use for the LILETTA intrauterine device?
 - A. Three years
 - B. Five years
 - C. Seven years
 - D. 12 years
2. What is the labeled duration of use for the Nexplanon subdermal contraceptive?
 - A. Three years
 - B. Five years
 - C. Seven years
 - D. 12 years
3. Study findings by Kapp N, et al [*Contraception* 2015; 91(2):97-104] indicate that for women weighing more than 75 kg, levonorgestrel emergency contraceptives were minimally effective. What is the average weight of the American woman?
 - A. 50 kg
 - B. 60 kg
 - C. 75 kg
 - D. 80 kg
4. What is the selective serotonin-reuptake inhibitor that is approved for treatment of hot flashes?
 - A. Escitalopram
 - B. Venlafaxine
 - C. Desvenlafaxine
 - D. Paroxetine

CNE/CME OBJECTIVES

After reading *Contraceptive Technology Update*, the participant will be able to:

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