

CONTRACEPTIVE TECHNOLOGY

U P D A T E[®]

Interpreting News and Research on Contraceptives and STIs

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Update: Women at high HIV risk can continue hormonal contraceptives

Advise those choosing progestin-only shot on condom use

The World Health Organization (WHO) has reaffirmed its guidance that women living with HIV or at high risk of HIV infection can safely use all hormonal contraceptives without restriction following a recent review of links between the contraceptives and HIV acquisition. However, WHO clarified its previous classification of progestin-only injectable contraception [depot medroxyprogesterone acetate (DMPA)/norethisterone enantate (NET-EN)] for women at high risk of HIV infection: While the method is recommended for use without restriction, women at high risk of HIV who choose this method should be strongly advised to also use condoms and other HIV-preventive measures.¹

The clarification comes after the agency convened a 2012 technical consultation among 75 experts from 18 countries to review findings from all recent epidemiological studies regarding hormonal contraception and HIV risk. The meeting was prompted after the 2011 publication of research that indicated that hormonal contraceptives, such as the pill or injectable contraceptives, might increase a woman's risk of HIV infection.² Those findings suggested that women living with HIV and using hormonal contraception might be more likely to transmit the virus to their partner than women who did not use hormonal contraception.² *(To read more about the research,*

EXECUTIVE SUMMARY

The World Health Organization has reaffirmed its guidance that women living with HIV or at high risk of HIV infection can safely use all methods of hormonal contraception without restriction following a recent review of evidence about links between hormonal contraceptive use and HIV acquisition.

- The agency has added a clarification, however, to its previous classification of progestin-only injectable contraception [depot medroxyprogesterone acetate (DMPA)/norethisterone enantate (NET-EN)] for women at high risk of HIV infection.
- The clarification states that while the method is recommended for use without restriction, women at high risk of HIV who choose this method should be strongly advised to also use condoms and other HIV-preventive measures.

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see the Contraceptive Technology Update article, "Potential link found between hormonal contraception, HIV risk," November 2011, p. 121.)

The expert group concluded that WHO should recommend no restriction on use of any hormonal contraceptive method, including oral contraceptive pills, injectables, patches, rings, and implants, for women living with HIV or at high risk of HIV.

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Editorial Questions

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It also recommended the following clarification be added to the recommendation: "Some studies suggest that women using progestin-only injectable contraception may be at increased risk of HIV acquisition; other studies do not show this association. A WHO expert group reviewed all the available evidence and agreed that the data were not sufficiently conclusive to change current guidance. However, because of the inconclusive nature of the body of evidence on possible increased risk of HIV acquisition, women using progestin-only injectable contraception should be strongly advised to also always use condoms, male or female, and other HIV preventive measures. Expansion of contraceptive method mix and further research on the relationship between hormonal contraception and HIV infection is essential. These recommendations will be continually reviewed in light of new evidence."¹

How about U.S. criteria?

How does the WHO updated guidance impact the U.S. Medical Eligibility for Contraceptive Use (US MEC)? The US MEC provides recommendations for the safe use of contraceptive methods by women with medical conditions or risk factors, including those at high risk for HIV and those living with HIV. This guidance is adapted from WHO's global guidance, explains **Kathryn Curtis, PhD**, an epidemiologist and women's health and fertility branch fellow in the WHO Collaborating Center in Reproductive Health at the Division of Reproductive Health in the Centers for Disease Control and Prevention (CDC).

When the WHO issues updates about the WHO global recommendations, CDC has a process in place to evaluate whether any changes to current US MEC guidance are warranted, says Curtis.

"We have initiated that process and, once it is complete, we will release a statement either confirming existing guidance or announcing any updated recommendations," states Curtis. [To receive e-mail updates on the US MEC, go to the CDC web page, <http://1.usa.gov/y6alkp>. Click on "Sign up to receive U.S. Medical Eligibility Criteria (USMEC) e-mail updates."]

Why add clarification?

Why was the clarification added? According to information from FHI 360, a Durham, NC-based global development organization, the evidence on whether the use of progestin-only injectable contraception influences contracting HIV is of limited quality and is not conclusive.³

“While recognizing these limitations, members of the WHO expert meeting remain concerned and want to ensure that women receive as much guidance as possible to prevent them from acquiring HIV,” the FHI 360 information states. “Thus, they added a clarification to the current medical eligibility criteria rating of ‘1’ (meaning that the product is approved without restriction), highlighting the importance of enhanced counseling on concurrent condom use and other HIV preventive measures for women at high risk of HIV infection.”

Women at high risk of HIV can continue to use progestin-only injectables for contraception; however, providers must provide enhanced counseling to these women on the importance of correct, consistent condom use and other HIV preventive measures, such as knowing one’s HIV status, knowing one’s sex partner’s status, diagnosis and treatment of other sexually transmitted infections, and reduction in number of sexual partners.

While about 3.2% of U.S. women who use birth control choose the shot, the method is widely used in Africa, where the risks for HIV are much greater.⁴ “In many sub-Saharan African countries, progestin-only injectable contraceptives, principally depot medroxyprogesterone acetate (DMPA), are the most commonly used contraceptive methods,” states information from FHI360. “Injectables are widely used because they are effective, simple to administer, and available by community-based distribution.”³

Better research needed

Much of the existing data on the subject of hormonal contraception and HIV risk is inconclusive, which leaves public health officials without a definitive answer to this important health issue. In its recommendation, the technical consultation states, “In considering the totality of available evidence, the group determined that currently available data neither establish a clear causal association with injectables and HIV acquisition, nor definitively rule out the possibility of an effect.”¹

The experts participating in the WHO consultation used the GRADE (Grading of Recommendations Assessment, Development, and Evaluation) system to look at existing research, explains **Ward Cates, MD, MPH**, distinguished scientist and president emeritus at FHI 360, who chaired a session at the WHO meeting. Better studies with stronger designs are urgently needed, he notes.

“Observational studies are not going to be able to answer the question definitively. We need higher-quality studies, such as randomized controlled

trials,” says Cates. “Also, we need to continue to pursue multipurpose technology methods that can address protection against both unplanned pregnancy and sexually transmitted infections.”

The New York City-based Population Council joins in the call for increased research on the multipurpose technology front. In a statement issued following the release of the WHO consultation, the Population Council said, “Today’s announcement underscores the need for new, multi-purpose products that prevent both HIV and unintended pregnancy, and for new contraceptive methods that better meet the family planning needs of women in developing countries. The Population Council’s Center for Biomedical Research is working on both.”⁵

REFERENCES

1. World Health Organization. Hormonal contraception and HIV. Geneva, Switzerland, 2012. Accessed at <http://bit.ly/x8icBb>.
2. Heffron R, Donnell D, Rees H, et al; Partners in Prevention HSV/HIV Transmission Study Team. Use of hormonal contraceptives and risk of HIV-1 transmission: a prospective cohort study. *Lancet Infect Dis* 2012;12:19-26.
3. FHI 360. Q&A — Hormonal Contraception and HIV. Fact sheet. Durham, NC, 2012. Accessed at <http://bit.ly/z1UjvX>.
4. Guttmacher Institute. Facts on Contraceptive Use in the United States. Fact sheet. New York City, June 2010. Accessed at <http://bit.ly/2Bzdq6>.
5. Population Council. WHO announcement on injectable contraception and HIV a responsible step forward. Press release. Accessed at <http://bit.ly/w3Lswf>. ■

Alert is issued for mislabeled OCs

Another oral contraceptive (OC) packaging alert has been issued. Check your clinic’s stock for norgestimate and ethinyl estradiol birth control pills distributed by Glenmark Generics.

The Mahweh, NJ-based company recently issued a voluntary, nationwide, consumer-level recall of seven lots of the Norgestimate and Ethinyl Estradiol Tablets USP (0.18 mg/0.035 mg, 0.215 mg/0.035 mg, 0.25 mg/0.035 mg) pills because a packaging error could leave women without adequate contraception and at risk for unintended pregnancy.

The packaging defects do not pose any immediate health risks, the company states; however, consumers exposed to affected packaging should

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- Patients with affected product should be instructed by clinicians to return the product to the pharmacy.

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The tablets were manufactured and packaged by Glenmark Generics of Mumbai, India, and are distributed by the company's U.S. division. The product was distributed to wholesalers and retail pharmacies nationwide between Sept. 21, 2011 and Dec. 30, 2011.

Look for lot numbers

The packaging error occurred when select blisters were rotated 180 degrees within the card, reversing the weekly tablet orientation and making the lot number and expiry date visible only on the outer pouch. Any blister for which the lot number and expiry date is not visible is subject to recall. The packaging error is limited to the following seven lots listed of Norgestimate and Ethinyl

Ethinyl Estradiol Tablets USP, 0.18 mg/0.035 mg, 0.215 mg/0.035 mg, 0.25 mg/0.035 mg (listed by lot number, expiration date): 04110101, 07/31/2013; 04110106, 07/31/2013; 04110107, 07/31/2013; 04110114, 08/31/2013; 04110124, 08/31/2013; 04110129, 08/31/2013; and 04110134, 09/30/2013.

According to the company, the packaging related issue was discovered when a consumer complaint was received regarding a blister pack with pills packaged in reverse order. The correct packaging configuration calls for three pouch packs packaged in a carton, with each pouch pack having one blister containing 28 tablets (seven tablets each of a different strength and inactive tablets) in which the sequence is white to off-white tablets on the top row and inactive light green tablets in the bottom row.

Any adverse events that might be related to the

use of the recalled product should be reported to Glenmark Generics at (888) 721-7115 from 8 a.m. to 5 p.m. Monday to Friday. Adverse events also may be reported to the Food and Drug Administration's (FDA) MedWatch Program. Go to www.fda.gov/Safety/MedWatch/default.htm, and click on "Report A Serious Medical Product Problem Online" to access Form FDA 3500. Events may be entered online; the form may be printed and mailed to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787; or it may be faxed to (800) 332-0178.

Are OCs in your stock?

The recall marks the third OC packaging recall since October 2011. (*See the Contraceptive Technology Update articles "Pfizer issues recalls for Akrimax OCs," April 2012, p. 42, and "Qualitest pulls suspect OCs, December 2011, p. 137.*) However, there is a reasonably high likelihood that the Glenmark recall has not made an impact in your practice, as the company recently entered the U.S. generic contraceptive market.

The company received its first FDA approval in April 2010 for Heather, the generic equivalent of Nor-QD (Watson Pharmaceuticals), followed by the July 2010 approval of norethindrone 0.35 mg, the generic version of Micronor (Janssen Pharmaceuticals). Since then, it has received approval for Briellyn, the generic version of Ovcon 35 (Warner Chilcott); Alyacen 1/35, the generic version of Ortho-Novum 1/35 (Janssen Pharmaceuticals); Alyacen 7/7/7, the generic version of Ortho-Novum 7/7/7 (Janssen Pharmaceuticals); and Marlissa, the generic version of Nordette (Duramed Pharmaceuticals). The FDA approval for the norgestimate and ethinyl estradiol tablets USP (0.18 mg/0.035 mg, 0.215 mg/0.035 mg, 0.25 mg/0.035 mg) pills, the generic version of Ortho Tri-Cyclen, came in June 2011. ■

Progestin-only pill eyed as OTC OC candidate

With relatively few contraindications to use, progestin-only pills might be a possible candidate for over-the-counter (OTC) use in the United States. But what will it take to move progestin-only pills to the drugstore shelves?

New research underscores the low prevalence of contraindications to progestin-only pills.¹

Researchers looked at data from two studies, the Self-Screening Study (a sample of reproductive-aged women in the general population in El Paso, TX) and the Prospective Study of OC Users (a sample of current oral contraceptive [OC] users who obtain pills in El Paso clinics or over the counter in Mexican pharmacies). Researchers found just 1.6% of women from the general population and 0.6% of current users in El Paso had at least one contraindication to progestin-only pills. This finding contrasts with the prevalence of contraindications to combined oral contraceptives, which has been reported to be as high as 39%.²

If progestin-only pills were available over the counter, they could improve women's access to contraception and better enable women to prevent unwanted pregnancies, says **Kari White, PhD**, assistant professor in the University of Alabama at Birmingham School of Public Health. In addition, this move would provide women with an OTC contraceptive option that is more effective than methods currently available, such as condoms and spermicides, says White, who served as lead author of the current research.

Although there tend to be a perception that progestin-only pills are less effective than combined pills, there are formulations registered in Europe that contain desogestrel that have been found to be quite effective at preventing ovulation and pregnancy and are very popular, says White. With Cerazette, a 75 mcg desogestrel pill marketed internationally by Merck, ovulation inhibition is maintained after 12-hour delays in tablet intake, with return of ovulation taking at least seven days.³ While the pill is available in several international countries, it is not available in the United States. (*To read more about Cerazette, see the Contraceptive Technology Update article, "Progestin-only pills: Where do they fit in?"*)

EXECUTIVE SUMMARY

With relatively few contraindications to use, progestin-only pills might be a possible candidate for over-the-counter (OTC) use in the United States. New research now underscores the low prevalence of contraindications to progestin-only pills, which opens the door to further research of a potential pill candidate.

- One-fifth of (20.25%) of Contraceptive Technology Update readers who participated in the 2011 Contraception Survey say they support over-the-counter availability of progestin-only contraceptives.
- About 23% said they support pharmacy access to oral contraceptives when a pharmacist can screen for contraindications.
- About 25% said they did not support OTC access.

January 2006, p. 9.)

One-fifth of (20.25%) of CTU readers who participated in the 2011 Contraception Survey say they support over-the-counter availability of progestin-only contraceptives. About 23% said they support pharmacy access to oral contraceptives when a pharmacist can screen for contraindications. About 25% said they did not support OTC access.

More research needed

What are the next research steps in bringing a potential OTC product to the U.S. market? With support from the Society of Family Planning, the Oral Contraceptives Over-the-Counter Working Group recently completed a nationally representative survey of women of reproductive age on their opinions about OTC access to OCs and their interest in using the pill if it were available OTC, says **Dan Grossman, MD**, a member of the Working Group and senior associate at Ibis Reproductive Health in Oakland, CA. The Working Group is a coalition of reproductive health rights and justice organizations, nonprofit research and advocacy groups, university-based researchers, and clinicians who are advocating for a safe, effective OTC pill. (*CTU reported on the Working Group. See "Is it time to bring OCs over the counter?" July 2010, p. 77.*)

"We are completing the analysis of that now, and we hope to submit for publication in the next month," says Grossman. "Other research that will be needed is a label comprehension study and an actual use study of a potential OTC product."

Move past hurdles

Reproductive health advocates have been on the move since the recent December 2011 rejection of full OTC status for the emergency contraceptive Plan B One Step by Health and Human Services Secretary Kathleen Sibelius. How did the rejection impact plans, if any, for possible development of an OTC OC? (*Read more about the move; see "OTC access to EC blocked — What's next?" February 2012, p. 15.*)

"Secretary Sibelius' decision to overrule the recommendation of the Food and Drug Administration (FDA) is certainly outrageous and very disappointing," says Grossman. "Until this has been resolved, it seems unlikely that an OTC application for an OC product would be approved without a similar age restriction."

The New York City-based Center for Reproductive Rights in February 2012 asked the

federal court to reopen the center's 2005 lawsuit against the FDA for imposing unnecessary age restrictions on emergency contraception. The center also requested the addition of Sebelius as a defendant in the reopened case for her role in overruling the FDA's decision to approve Plan B One-Step for over-the-counter status in December 2011.

"We remain hopeful that the evidence-based recommendation of the FDA regarding Plan B One-Step will eventually prevail," says Grossman. "But in the meantime, we are continuing with our efforts."

REFERENCES

1. White K, Potter JE, Hopkins K, et al. Contraindications to progestin-only oral contraceptive pills among reproductive-aged women. *Contraception* 2012. Doi:10.1016/j.contraception.2012.01.008.
2. Grossman D, Fernandez L, Hopkins K, et al. Accuracy of self-screening for contraindications to combined oral contraceptive use. *Obstet Gynecol* 2008; 112:572-578.
3. Korver T, Klipping C, Heger-Mahn D, et al. Maintenance of ovulation inhibition with the 75-microg desogestrel-only contraceptive pill (Cerazette) after scheduled 12-h delays in tablet intake. *Contraception* 2005; 71:8-13. ■

Threat up for gonorrhea that is multi-drug resistant

Public health officials are sounding the alarm on the growing threat of multi-drug resistant gonorrhea. What will it take to turn the tide against gonorrhea, the second most commonly reported communicable disease in the United States?

"Though there is no evidence yet of treatment failures in the United States, trends in decreased susceptibility coupled with a history of emerging

EXECUTIVE SUMMARY

Public health officials are sounding the alarm on the growing threat of multi-drug resistant gonorrhea. Though there is no evidence yet of treatment failures in the United States, trends in decreased susceptibility, coupled with a history of emerging resistance and reported treatment failures in other countries, point to a likelihood of failures on the horizon and a need for urgent action.

- Clinicians should treat all cases of gonorrhea with the most effective regimen: a 250-mg intramuscular dose of ceftriaxone.
- One gram of azithromycin also should be given orally to cover other copathogens and to provide another antimicrobial with activity against *N. gonorrhoeae* at a different molecular target.

resistance and reported treatment failures in other countries point to a likelihood of failures on the horizon and a need for urgent action," says **Judith Wasserheit, MD, MPH**, professor and vice chair of the Department of Global Health at the University of Washington in Seattle and co-author of a new analysis of the emerging threat.¹

Gonorrhea is the second most commonly reported communicable disease in the United States. The Centers for Disease Control and Prevention (CDC) estimates that more than 700,000 persons in the United States get new gonorrheal infections each year.² *Neisseria gonorrhoeae*, the bacteria that causes the sexually transmitted infection (STI), is wily in its resistance to antimicrobial agents. It developed resistant to sulfanilamide in the 1940s, penicillins and tetracyclines in the 1980s, and fluoroquinolones by 2007. Third-generation cephalosporins are the first-line treatment options now recommended by the CDC.³

Drugs losing ground

The effectiveness of cephalosporins for treating gonorrhea is decreasing rapidly, warns the CDC.⁴ (To read more about the decline, see the September 2011 STI Quarterly supplement article, "Options running out for gonorrhea treatment, p. 3.)

Researchers with the CDC's Gonococcal Isolate Surveillance Project have reported a 17-fold increase in elevated minimum inhibitory concentrations, which serve as a measure of drug susceptibility. In the past, national treatment recommendations have been changed to focus on other effective drugs when resistance to drugs has increased; however, there are no other drugs available to successfully treat the infection.

"The bottom line is that gonorrhea is a very complex bacteria, and we've seen it evolve and become resistant to every antibiotic recommended for treatment over the years," says **Gail Bolan, MD**, director of the CDC's Division of STD Prevention. "In the past, CDC has kept pace with this evolving organism, monitoring for trends in susceptibility and changing treatment guidelines as needed because we had alternative antibiotics to use.

However, public health officials are at an impasse, since there are no new drugs in development, and new options are urgently needed, says Bolan, who serves as lead author of the current analysis. "CDC is working with the National Institutes of Health on a randomized controlled trial to see how effective different combinations of existing drugs are at treating gonorrhea," says Bolan. "We hope to have find-

ings of the trial by next year.”

Resistance testing key

Action must take place at all levels of government, as well as public and private research and development entities, to prevent untreatable gonorrhea, says Bolan. One important piece of that response is the need for state health departments and other public and private labs to maintain or re-build the ability to culture and test for resistance, she states. If testing cannot be performed locally, departments should partner with labs that can perform resistance testing, notes Bolan.

The CDC is working with states to build culture capacity through a multi-step process, report Bolan. The first step involves identification of which states have capacity to perform gonorrhea culture. The CDC has worked with the Association of Public Health Laboratories in conducting a survey to identify those sites. Survey findings indicate that only about 5% of the gonorrhea tests performed by surveyed public health labs were culture tests, she notes.

“We also are planning further investigations to find out which states have labs with culture capacity,” says Bolan. “We are currently providing technical assistance to labs in areas where gonorrhea prevalence is high to help them re-establish culture capacity.”

The CDC also is reaching out to clinicians via state sexually transmitted infection (STI) directors to make sure clinicians are aware of local and nearby labs that offer culture tests, says Bolan. The federal agency is working with local and state STI control programs to develop local response plans in case cephalosporin resistance emerges in their area.

In the meantime, the first priority for clinicians is to treat all cases of gonorrhea with the most effective regimen.¹ A 250-mg intramuscular dose of ceftriaxone is considered the most effective treatment in curing gonococcal infections at genital and extragenital sites. One gram of azithromycin also should be given orally to cover other copathogens and to provide another antimicrobial with activity against *N. gonorrhoeae* at a different molecular target, the current analysis states.

REFERENCES

1. Bolan GA, Sparling PF, Wasserheit JN. The emerging threat of untreatable gonococcal infection. *NEJM* 2012; 366:485-487.
2. Centers for Disease Control and Prevention. Gonorrhea — CDC Fact Sheet. Atlanta, 2011. Accessed at <http://www.cdc.gov/std/Gonorrhea/STDFact-gonorrhea.htm>.

3. Centers for Disease Control and Prevention. Sexually transmitted diseases treatment guidelines, 2010. *MMWR* 2010; 59(RR 12): 1-110.
4. Centers for Disease Control and Prevention (CDC). Cephalosporin susceptibility among *Neisseria gonorrhoeae* isolates — United States, 2000-2010. *MMWR* 2011; 60:873-877. ■

New criteria clarify menopause stages

Clinicians and researchers now have more comprehensive parameters to assess the stages of menopause with updated criteria known as the Stages of Reproductive Aging Workshop +10 (STRAW +10). The new guidance, which updates information originally issued in 2001, will help clinicians predict when a woman will enter menopause and aid in selection of treatment options for menopausal symptoms and other related conditions.¹ (*To access a copy of the guidance, go to <http://bit.ly/xziuTc>.*)

The new report is the result of findings gathered during a fall 2011 symposium co-sponsored by the National Institute on Aging, Office of Research on Women's Health, North American Menopause Society, American Society for Reproductive Medicine, International Menopause Society, and the Endocrine Society.

“The North American Menopause Society convened a group of experts from key medical societies around the world to update our understanding of the stages women go through from adolescence to menopause and beyond,” stated Margery Gass, MD, executive director of the North American Menopause Society, in a statement accompanying the report. “This new

EXECUTIVE SUMMARY

Clinicians and researchers now have more comprehensive parameters to assess the stages of menopause with updated criteria known as the Stages of Reproductive Aging Workshop +10 (STRAW +10).

- The new guidance, which updates information originally issued in 2001, will help clinicians predict when a woman will enter menopause and aid in selection of treatment options for menopausal symptoms and other related conditions.
- The new guidance offers simplified bleeding criteria for the early and late menopausal transition, recommends modifications to criteria for the late reproductive and the early postmenopausal stages, provides information on the duration of the late transition and early postmenopause, and recommends application regardless of women's age, ethnicity, body size, or lifestyle characteristics.

update has broader application to more women and provides additional details for determining where a woman is in these reproductive stages.”

Check new guidance

The new guidance offers simplified bleeding criteria for the early and late menopausal transition; recommends modifications to criteria for the late reproductive and the early postmenopausal stages; provides information on the duration of the late transition and early postmenopause; and recommends application regardless of women’s age, ethnicity, body size, or lifestyle characteristics.

Family planning clinicians might want to look at the late reproductive stage, labeled as Stage -3. This stage marks the time when fecundability begins to decline and a woman might begin to notice changes in her menstrual cycles. Endocrine parameters, which are important to fertility assessments, begin to shift prior to overt changes in menstrual cycles; therefore, the late reproductive stage now has been subdivided into two substages: -3b and -3a. In -3b, menstrual cycles remain regular without change in length or early follicular phase levels of follicle-stimulating hormone (FSH); however, antimüllerian hormone (AMH) and antral follicle counts are low. In Stage -3a, subtle changes in menstrual cycle characteristics, specifically shorter cycles, begin. In early follicular phase (cycle days 2-5), FSH increases and becomes more variable, with the other three markers of ovarian aging being low.¹

Another important point of reference is early menopause. New data on the trajectories of change in mean levels of FSH and estradiol now indicate that FSH continues to increase and estradiol continues to decrease until about two years after the final menstrual period, after which the levels of each of these hormones stabilize.^{2,3} With these findings in hand, the new guidance divides early menopause into three stages.

According to the new guidance, stages +1a and +1b each last one year and end at the time point at which FSH and estradiol levels stabilize. Stage +1a marks the end of the 12-month period of amenorrhea required to define that the final menstrual period has occurred; it corresponds to the end of perimenopause.

Stage +1b includes the remainder of the period of rapid changes in mean FSH and estradiol levels. Menopausal symptoms, most notably vasomotor symptoms, are most likely to occur during the +1a and +1b period.¹ Stage +1c represents the period of stabilization of high FSH levels and low estradiol values; it is estimated to last 3-6 years.

Stage +2 marks the late post menopause period, a time in which changes in reproductive endocrine func-

tion are more limited and processes of somatic aging become apparent. Clinicians need to note this stage, as symptoms of vaginal dryness and urogenital atrophy become increasingly prevalent at this time, the report states.¹

More research needed

While scientific advances have provided a greater insight into ovarian aging, important gaps in scientific knowledge persist, say 2011 workshop participants. Seven research priorities have been identified:

- development of an international standard for the assessment of AMH;
- empirical analysis across multiple cohorts to develop precise menstrual cycle criteria for Stages -3b and -3a;
- studies to characterize the hormonal changes of postmenopause from Stage +1 to +2;
- application of STRAW + 10 staging criteria to reanalyze key findings on clinical changes that occur across the menopausal transition;
- characterization of the pattern, timing, and level of reproductive biomarkers across nations;
- research into reproductive aging and appropriate staging criteria for women with polycystic ovary syndrome and primary ovarian insufficiency, as well as those who have had removal of a single ovary and/or hysterectomy;
- studies to better evaluate staging in women with chronic illness such as HIV infection and those undergoing cancer treatment.¹

REFERENCES

1. Harlow SD, Gass M, Hall JE, et al. Executive summary of the Stages of Reproductive Aging Workshop + 10: addressing the unfinished agenda of staging reproductive aging. *Menopause* 2012. Doi:10.1097/gme.0b013e31824d8f40
2. Sammel MD, Freeman EW, Liu Z, et al. Factors that influence entry into stages of the menopausal transition. *Menopause* 2009; 16:1,218-1,227.
3. Randolph JF Jr, Zheng H, Sowers MR, et al. Change in follicle-stimulating hormone and estradiol across the menopausal transition: effect of age at the final menstrual period. *J Clin Endocrinol Metab* 2011; 96:746-754. ■

Case report: Use texts to reach young people

Reaching young people with an HIV prevention message is important: The Centers for Disease Control and Prevention (CDC) estimates young people

ages 13-29 accounted for 39% of all new HIV infections in 2009.¹ This challenge is accelerated when it comes to youth of minority races and ethnicities; in 2009, young black persons accounted for 65% of diagnoses of HIV infection reported among persons ages 13-24.¹

An innovative service known as Text 2 Survive is providing minority youth and young adults ages 13-35 in Illinois with accurate information about HIV/AIDS, and it is connecting them with sites offering testing and related preventive services. Through the service, cell phone users receive a list of nearby sites offering free services, obtain information about upcoming health events, and receive monthly alerts with helpful health tips and information. With a minimal investment of staff time and financial resources, the program has enhanced access to HIV testing and accurate sexual health information for this at-risk population.

The Center for Minority Health Services, a division of the Illinois Department of Public Health, launched the Text 2 Survive program in 2010 as part of its efforts to connect African-American and other minority youth to needed HIV testing and related services. Through its Brothers and Sisters United Against HIV / AIDS program, the agency already had created public awareness about HIV through a public awareness campaign, a Web site, a peer educator program, and other outreach activities.

Program developers sought to identify new outreach methods that would appeal to minority youth. They found that African-American and Latino youth often use cell phones — especially for texting — more than white youth, thus making texting a logical vehicle to reach them. (*To read more about how programs are using text services, see the Contraceptive Technology Update article “Use new technology for communication,” March 2012, p. 32.*)

Program developers contacted Rip Road of New

York City, the company responsible for the technology platform for the Kaiser Family Foundation’s “Get Text-Ed” service used during the launch of its 2009 national Get Yourself Tested event. To remove financial barriers to young people getting tested, program developers reorganized the CDC’s database of test sites so that state-funded clinics offering free testing would be listed first in the mobile locator service.

“Implementing the texting program was easy because we started small and already had a built-in audience: our grantees and community partners, and our target population that they work with,” explains **Veronica Halloway**, MA, a public service administrator with the health department’s Center for Innovation and Technology Education. “Also, the program lists organizations that provide free HIV testing, so it was an easy sell to the organizations so they can increase their test numbers, and the target group, because they can seek free test sites anonymously.”

How to get the word out?

How does the program get the word out to at-risk youth and young adults about Text 2 Survive? Program organizers look to grantees, local health departments, and community partners in distributing information, says Halloway. Printed palm cards are placed in clinics, mobile units, and office sites, and they are distributed at health fairs and community events.

Partners also can use the program at no cost for polling or quizzes at events, which adds a level of interaction between them and the youth, notes Halloway. “For example, an event was held at three public schools where the kids used the quiz portion of the program to answer questions about HIV testing among youth,” says Halloway. “Not only were the kids inviting others to participate in the quiz, it sparked a debate among them about what age they can get tested without their parents’ consent.”

The program also has a widget (a small customizable piece of code) that can be promoted on interested parties’ websites and blogs. The text service has branched out in other avenues; anyone with a cell phone can text the word “event” to 36363 and receive a list of health fairs and other free events sponsored by community partners and other health organizations in the area.

The service costs about \$36,000 a year to operate, program organizers estimate. Text 2 Survive saves money by using an already existing computer programming code rather than one developed just for the program, organizers note.

EXECUTIVE SUMMARY

An innovative service known as Text 2 Survive is providing Illinois minority youth and young adults ages 13-35 in with accurate information about HIV/AIDS and connecting them with sites offering testing and related preventive services.

- Through the service, cell phone users receive a list of nearby sites offering free services, obtain information about upcoming health events, and receive monthly alerts with helpful health tips and information. Information is available in English and Spanish.
- With a minimal investment of staff time and financial resources, the program has enhanced access to HIV testing and accurate sexual health information for this at-risk population.

Text in English, Spanish

Text 2 Survive is now available in Spanish. By using a cellphone, Illinois citizens can send a text with the message “centro,” plus their five digit zip code to the phone number 36363 for Spanish, or text “IL” plus their five digit zip code to the same number for English. A confidential text message is immediately sent back to the phone with the nearest HIV/AIDS testing center contact information. To help spread the benefits of getting tested, that person can then send their friends a text message urging them to get tested as well.

The service has been highly successful in English because it’s private, convenient, and confidential, explains Halloway. Program organizers have experienced some hesitation with the Spanish locator because some Latino users are hesitant that their phone numbers will be used to locate them, especially if they are in the United States illegally or undocumented, says Halloway. Program organizers are working with community partners to educate potential Latino users that their phone numbers are not traceable, she notes.

REFERENCE

1. Centers for Disease Control and Prevention. HIV Among Youth. Fact sheet. Atlanta, 2011. Accessed at <http://www.cdc.gov/hiv/youth>. ■

New HIV program launched by CDC

African-American women at risk for HIV are the focus of a new prevention program launched by the Centers for Disease Control and Prevention (CDC). “Take Charge. Take the Test” is running in 10 cities where such women are especially hard-hit by the disease.

The program, which features advertising, a website, and community outreach, is designed to increase HIV testing and awareness among African-American women. The campaign was kicked off in conjunction with March 8, 2012, National Women and Girls HIV/AIDS Awareness Day in Atlanta; Chicago; Detroit; Fort Lauderdale, FL; Houston; Memphis, TN; Newark, NJ; New Orleans; Hyattsville, MD; and St. Louis.

“At current rates, nearly 1 in 30 African-American women will be diagnosed with HIV in their lifetimes,” said Kevin Fenton, MD, director of CDC’s National Center for HIV/AIDS, Viral Hepatitis, STD, and TB

Prevention, in an announcement accompanying the program kickoff. “To help reduce this toll, we are working to remind black women that they have the power to learn their HIV status, protect themselves from this disease, and take charge of their health.”

Black women at risk

The program is part of CDC’s commitment to address the urgent HIV prevention needs of African-American women, who account for nearly 60% of all new HIV infections among women and 13% of new infections overall.¹ The rate of new infections among these women is 15 times higher than among white women, CDC officials state.¹

The federal agency is working with health departments and local organizations in the 10 participating cities to develop local campaigns for the communities they serve. The campaign initially was piloted in Cleveland and Philadelphia, where “Take Charge. Take the Test” community events were attended by nearly 10,000 women, and campaign messages were seen more than 100 million times. (Contraceptive Technology Update *reported on the program*. See “Time to step up HIV testing in women,” November 2008, p. 125.)

A multi-prong attack is being used in the current effort to emphasize the importance of HIV testing as a gateway to peace of mind and better health. Outdoor, transit, and radio advertising are being used; posters and handouts also are being distributed in salons, stores, community organizations, and other venues. A dedicated campaign website, <http://hivtest.org/take-charge>, allows women to find HIV testing locations in their communities. The campaign encourages African-American women to talk openly with their partners about HIV and insist on safe sex, as well as to talk about the issue with other women in social settings, workplaces, living rooms, and religious congregations.

“We hope to extend the reach of this campaign to multiple cities throughout the nation, help empower

EXECUTIVE SUMMARY

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- The program, which features advertising, a website, and community outreach, is designed to increase HIV testing and awareness among African-American women.
- It is operational in Atlanta; Chicago; Detroit; Fort Lauderdale, FL; Houston; Memphis, TN; Newark, NJ; New Orleans; Hyattsville, MD; and St. Louis.

many more women to take control of their health, and help break the silence about HIV in their communities,” said **Jonathan Mermin**, MD, director of CDC’s Division of HIV/AIDS Prevention.

Many factors at play

Research shows that African-American women are no more likely than women of other races to engage in risky behaviors; however, a range of social and environmental factors put them at greater risk for HIV infection.² These factors include higher prevalence of HIV and other sexually transmitted infections in some African-American communities, which increase the likelihood of infection with each sexual encounter. Also, limited access to healthcare can prevent women from getting HIV tested. Data indicates that financial dependence on male partners might limit some women’s ability to negotiate safe sex.³ HIV stigma also might discourage such women from seeking HIV testing.

“This campaign is just one part of the solution,” said **Donna Hubbard McCree**, PhD, associate director for health equity at CDC’s Division of HIV/AIDS Prevention. “All of us have a role to play in stopping the spread of HIV among black women, by talking to our sisters, daughters, husbands, and boyfriends about how to protect ourselves against HIV and the importance of getting tested; by speaking out against stigma; and by tackling the social inequities that place so many of us at risk for HIV.”

REFERENCES

1. Prejean J, Song R, Hernandez A, et al. (2011) Estimated HIV incidence in the United States, 2006-2009. *PLoS ONE* 2011; 6:e17502.
2. Chandra A, Billioux VG, Copen CE. HIV risk-related behaviors in the United States household population aged 15-44 years: Data from the National Survey of Family Growth, 2002 and 2006–2010. Accessed at <http://1.usa.gov/wBZrjV>.
3. Adimora AA, Schoenbach VJ, Floris-Moore MA. Ending the epidemic of heterosexual HIV transmission among African Americans. *Am J Prev Med* 2009; 37:468-471. ■

COMING IN FUTURE MONTHS

- Check out enhancements to “I Know” program
- Washington state program uses text to tap patients
- Counsel on consistent condom use in college-age women
- Answers for your questions on trichomoniasis

CNE/CME QUESTIONS

1. What was the clarification added in early 2012 to the World Health Organization’s medical eligibility criteria for contraceptive use?
 - A. Women at high risk of HIV who choose progestin-only contraceptive injections should be strongly advised to also use condoms and other HIV-preventive measures.
 - B. Use of progestin-only contraceptive injections in women at high risk of HIV is now ranked as Category 2 — a condition for which the advantages of using the method usually outweigh the theoretical or proven risks.
 - C. Use of progestin-only contraceptive injections in women at high risk of HIV is now ranked as Category 3 — a condition for which the theoretical or proven risks usually outweigh the advantages of using the method.
 - D. Use of combined oral contraceptives in women at high risk of HIV is now ranked as Category 4 — a condition that represents an unacceptable health risk if the method is used.
2. What is the oral contraceptive with suspect lots that underwent a February 2012 voluntary recall by Glenmark Generics?
 - A. Norgestimate and Ethinyl Estradiol Tablets
 - B. Heather
 - C. Briellyn
 - D. Alyacen
3. What drug is considered the most effective treatment in curing gonococcal infections at genital and extragenital sites?
 - A. Sulfadiazine
 - B. Ceftriaxone
 - C. Demeclocycline
 - D. Ciprofloxacin
4. According to new STRAW +10 guidance on the reproductive health cycle, what stage is indicated by increasing prevalence of vaginal dryness and urogenital atrophy?
 - A. Stage -3b
 - B. Stage -3a
 - C. Stage +1c
 - D. Stage +2

CNE/CME OBJECTIVES & INSTRUCTIONS

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.

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

1. Read and study the activity, using the provided references for further research.
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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%.
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