

# CONTRACEPTIVE TECHNOLOGY

U P D A T E<sup>®</sup>

Interpreting News and Research on Contraceptives and STIs

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## LARC use sees substantial increase — How to boost use in women at risk

*Include counseling on IUD use for emergency contraception*

**G**ood news: More women are choosing long-acting reversible contraceptives (LARC methods) such as the intrauterine device (IUD) and the contraceptive implant. The proportion of U.S. women using these highly effective methods increased significantly between 2002 and 2009, growing from 2.4% to 8.5%, according to results of a new analysis of data from the 2006-2010 National Survey of Family Growth.<sup>1</sup> The increase occurred among women in almost every age, race, education, and income group, researchers state.

Data indicate the highest use of LARC methods was among women ages 25-39 and among those who already had at least one child. Just 2% of women with no children had used long-acting methods, compared with 15% of women with one or two children.<sup>1</sup> Could provider misperceptions be playing a role in the lower use of LARCs in women most at risk for unintended pregnancy?

Previous research points to “yes,” according to Lawrence Finer, PhD, director of domestic research at the Guttmacher Institute in New York City and lead author of the

### EXECUTIVE SUMMARY

The proportion of U.S. women using highly effective long-acting reversible contraceptives (LARC methods) increased significantly between 2002 and 2009, growing from 2.4% to 8.5%, according to results of a new analysis of data from the 2006-2010 National Survey of Family Growth.

- Data indicate the highest use of LARC methods was among women ages 25-39 and among those who already had at least one child. Just 2% of women with no children had used long-acting methods, compared with 15% of women with one or two children.
- Results of a new meta-analysis indicate that intrauterine devices inserted shortly after unprotected intercourse have a failure rate of less than one per 1,000 and are more effective than emergency contraceptive pills in protecting women from unwanted pregnancies.

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current study. A 2008 survey among physicians, nurse practitioners, and physician assistants indicates that many providers are less likely to offer IUDs to young women and those without children, two groups at high risk of unintended pregnancy, he notes.<sup>2</sup>

The challenge is to bring providers' knowledge and attitudes in line with the latest evidence-based

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### Editorial Questions

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practice guidelines from the Centers for Disease Control and Prevention, the American College of Obstetricians and Gynecologists (ACOG), and other professional groups, states Finer. (To help clinicians obtain needed information on LARC methods, ACOG now offers a dedicated web space to LARC methods, <http://bit.ly/MpQ63R>. Click on "LARC Clinical Resources" to download copies of ACOG practice bulletins, committee opinions, and other guidance on LARC use.)

In the remarkable St. Louis Contraceptive CHOICE Project, 69% of adolescents ages 14-17 chose to use an IUD or an implant, notes **Robert Hatcher, MD, MPH**, professor of gynecology and obstetrics at Emory University School of Medicine in Atlanta. Of these young teen-agers using LARC methods, 63% chose the implant.<sup>3</sup>

Since contraception is covered as a preventive service under the Affordable Care Act, there are more opportunities for women to access LARC methods, says **Susan Wysocki, WHNP-BC, FAANP**, president & chief executive officer of Washington, DC-based iWomansHealth, which focuses on information on women's health issues for clinicians and consumers. It is more important than ever for clinicians to be trained to place intrauterine contraceptives and implants, she says. "Any clinician who knows how to do an accurate pelvic exam has the basic skills for placement" of the IUD, Wysocki states. "Now that cost isn't the issue, the time is right for clinicians to get up to speed." (Clinicians can take advantage of insertion training of the Nexplanon implant at a preconference session of the November 2012 Contraceptive Technology Quest for Excellence conference in Atlanta. The training session is limited to 50 participants. Go to the Contemporary Forums web site, [www.contemporaryforums.com](http://www.contemporaryforums.com). Under "Upcoming Conferences," select "View Complete Calendar," then "November" to access information on the Quest for Excellence conference and preconference sessions.)

### Look at the IUD for EC

Clinicians also need to consider intrauterine devices for emergency contraception. Results of a new meta-analysis by international researchers indicate that IUDs inserted shortly after unprotected intercourse have a failure rate of less than one per 1,000 and are more effective than emergency contraceptive pills (ECPs) in protecting women from unwanted pregnancies.<sup>4</sup>

To conduct the research, investigators looked

at 42 studies conducted in six countries between 1979 and 2011. The studies involved eight types of IUDs and 7,034 women. Analysis yielded a pregnancy rate of 0.09% among women using IUDs inserted from two to 10 or more days after unprotected intercourse (74% of devices inserted within five days).

In an Asian study, not one of 1,963 women who received a copper T IUD for emergency contraception became pregnant.<sup>5</sup>

One of the unintended but foreseen consequences of ECPs going over the counter is that women get them without seeing a provider, thus the opportunity for emergency IUD insertion is lost, observes **James Trussell**, PhD, professor of economics and public affairs and director of the Office of Population Research at Princeton (NJ) University and a co-author of the meta-analysis. Providers could be proactive by discussing IUDs for EC in advance of need, he notes.

## What's your stance?

When it comes to IUDs for EC, a 2012 study indicates many clinicians are slow to embrace its use. A study of California contraceptive providers reveals 85% of clinicians never recommended the IUD for emergency contraception, and 93% require at least two visits for an IUD insertion.<sup>6</sup>

If patients demand the service, providers will deliver it, says **David Turok**, MD, MPH, assistant clinical professor

in the Department of Obstetrics and Gynecology at the University of Utah School of Medicine in Salt Lake City. Hopefully, more women will find out about the IUD EC option and request it, thus encouraging providers to offer it, Turok states. He will present data this month at the 2012 North American Forum on Family Planning in Denver on the effectiveness of the copper T IUD when used for EC. (*Look to Contraceptive Technology Update to report on the findings in an upcoming issue.*)

Look for accumulating data on Quick Start methods to include the copper IUD, the LNG IUD, and the contraceptive implant, says Turok. Providers are getting the message that it is safe to begin contraceptive injections and combined oral contraceptives on the day that people present requesting contraception, he says. More progress might be made by encouraging providers to screen for contraceptive use/risk of unplanned pregnancy AND offer patients the method they want, Turok states.

“When women have had unprotected intercourse in the last five days, these instances could be perceived as emergency contraception,” says Turok. “My opinion is that it will seem more sensible to providers to screen for contraceptive need/risk of unplanned pregnancy and deliver any method, than to screen for EC.”

It might be time to try a new approach, Turok suggests. Providers should be encouraged to screen for contraceptive need and give patients the available data to provide the methods, as well as counsel on oral EC and offer the copper IUD when appropriate, he notes. Based on existing data, providers should encourage use of the copper IUD within five days of unprotected intercourse, says Turok.

“I think it is reasonable if a patient understands the risk of pregnancy with the use of EC to insert a levonorgestrel [LNG] IUD or contraceptive implant at that time, with the understanding that if they have a pregnancy, the LNG IUD would need to be removed, and if they choose to continue a pregnancy, they would need to have the implant removed,” Turok suggests.

All of these approaches are aimed toward overall increased use and access to highly effective reversible methods, says Turok.

“I think we can make significant advances on the provider side by packaging the message,” he states. “The IUD for EC is just a part of that.”

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# Oral drug no longer first-line for gonorrhea

Update your practice: The Centers for Disease Control and Prevention (CDC) no longer recommends the oral antibiotic cefixime as a first-line treatment option for gonorrhea due to possible drug resistance.<sup>1</sup>

The most effective treatment for gonorrhea is now a combination therapy: the injectable antibiotic ceftriaxone along with one of two other oral antibiotics, either azithromycin or doxycycline. The revised guidance was published in the Aug. 10, 2012, edition of the CDC's *Morbidity and Mortality Weekly Report* (<http://1.usa.gov/NLL4W5>).

The change in first-line treatment was prompted after recent trends in laboratory data showed that cefixime is becoming less effective in treating the sexually transmitted infection (STI). [*Contraceptive Technology Update reported on the findings; see "Threat up for gonorrhea that is multi-drug resistant," May 2012, p. 54. Also, did you receive the CTU bulletin on this latest CDC guidance? To receive breaking news as it occurs, provide your e-mail address to AHC Media customer service at (800) 688-2421 or [customerservice@ahcmedia.com](mailto:customerservice@ahcmedia.com).*]

"As cefixime is losing its effectiveness as a treatment for gonorrhea infections, this change is a critical pre-emptive strike to preserve ceftriaxone, our last proven treatment option," said **Kevin Fenton**, MD, director of the CDC's National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, in a statement accompanying the new guidance. "Changing how we treat infections now may buy the time needed to develop new treatment options."

The new CDC guidance calls for additional follow-up steps to monitor for ceftriaxone treat-

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## EXECUTIVE SUMMARY

The Centers for Disease Control and Prevention no longer recommends the oral antibiotic cefixime as a first-line treatment option for gonorrhea due to possible drug resistance.

- The most effective treatment for gonorrhea is now a combination therapy: the injectable antibiotic ceftriaxone along with one of two other oral antibiotics, either azithromycin or doxycycline.
- The new guidance calls for additional follow-up steps to monitor for ceftriaxone treatment failure. Patients who have persistent symptoms should be retested with a culture-based gonorrhea test, which can identify antibiotic-resistant infections. These patients should return one week after re-treatment for a test-of-cure to ensure treatment success.

ment failure. Patients who have persistent symptoms should be retested with a culture-based gonorrhea test, which can identify antibiotic-resistant infections, the CDC advises. These patients should return one week after re-treatment for a test-of-cure to ensure treatment success, according to the new recommendations.

## Cefixime sometimes needed as alternative

Cefixime might be needed as an alternative treatment option in some instances, the CDC notes. If ceftriaxone is not readily available, providers may prescribe a dual therapy of cefixime plus either azithromycin or doxycycline, the CDC states. Azithromycin may be given alone if a patient has a severe allergy to cephalosporins, the new guidance states. If either of these alternative regimens is used, clinicians should perform a test-of-cure one week after treatment to closely monitor for resistance, the CDC states.

The new changes may make treatment more challenging for some providers and patients, CDC officials note. Clinics that might not have been keeping injectable medications in stock will now need to begin carrying ceftriaxone, and all patients will need to undergo an injection to ensure effective treatment for gonorrhea.

Partner treatment might be complicated by the change. The CDC calls for every effort to be made to ensure that the sex partners of all patients with gonorrhea from the past 60 days are evaluated and treated for gonorrhea with ceftriaxone and either azithromycin or doxycycline, if possible, or an alternative treatment, if ceftriaxone cannot be prescribed. If a partner cannot be brought in for treatment, clinicians may consider expedited partner therapy, or having the patient deliver an oral combination regimen of cefixime with azithromycin to their partner.

## New drugs needed

The revised guidelines are just one aspect of CDC's response to the threat of untreatable gonorrhea. The agency has issued a public health response plan to offer guidance to state and local health departments in monitoring the emergence of drug resistance. (*To review the plan, visit the "Antibiotic-Resistant Gonorrhea" page at the CDC web site, <http://1.usa.gov/GFutpE>.*) In addition to its monitoring of U.S. resistance, CDC is working with the World Health Organization to track emerging resistance on the global level.

There are few new promising gonorrhea drugs in

the pipeline, and only one clinical trial is under way to examine treating gonorrhea using new combinations of existing drugs, CDC officials state. The agency is partnering with the National Institutes of Health to test new combinations of existing drugs.

**Gail Bolan, MD**, director of CDC's Division of STD Prevention, says, "It is imperative that researchers and pharmaceutical companies prioritize research to identify or develop new, effective drugs or drug combinations. Health departments and labs can help CDC monitor for emerging resistance by enhancing or re-building their ability to do culture testing."

Be sure that you are providing appropriate screening for gonorrhea. The CDC recommends that sexually active gay and bisexual men and high-risk sexually active women be tested for gonorrhea at least once a year. Women who are considered high risk include those with previous gonorrhea infection, other STIs, new or multiple sex partners, and inconsistent condom use; those who engage in commercial sex work and drug use; women in certain demographic groups; and those living in communities with a high prevalence of disease.<sup>2</sup>

Also remember to counsel on condom use. When used consistently and correctly, condoms can reduce the risk of transmission of gonorrhea.

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## Check interim guidance for PrEP in men, women

The Centers for Disease Control and Prevention (CDC) has issued new interim guidance for use of pre-exposure prophylaxis (PrEP) for in heterosexual men and women at high risk for HIV. The daily drug regimen may be used by HIV-uninfected individuals to reduce their risk of HIV infection.

The interim guidance follows the July 2012 Food and Drug Administration's approval of once-daily oral Truvada (emtricitabine and tenofovir disoproxil fumarate, Gilead Sciences, Foster City, CA), with condoms and other safer-sex

measures, for use for HIV prevention in men who have sex with men, persons in discordant couples, and other individuals at risk for acquiring HIV through sexual activity. *[Did you receive the Contraceptive Technology Update bulletin on the FDA approval? To receive future bulletins, provide your e-mail address to AHC Media customer service at (800) 688-2421 or customerservice@ahcmedia.com.]*

"With 50,000 new HIV infections every year in the United States, we urgently need additional prevention options," said **Kevin Fenton, MD**, director of CDC's National Center for HIV/AIDS, Viral Hepatitis, STD, and Tuberculosis Prevention in a statement issued with publication of the interim guidance. "To facilitate the safe and effective use of PrEP as an additional tool, the guidance we're releasing today gives healthcare providers information to help them evaluate and support its use for their patients who may be considering this method."

## Check key points

The new CDC guidance is similar to information issued for use of PrEP among men who have sex with men. *(CTU reported on the guidance; see "Update: Use of HIV drugs shrinks infection risk in uninfected people," March 2011 STI Quarterly supplement, S1, and "Pre-exposure prophylaxis for HIV prevention under review by Food and Drug Administration," July 2011 STI Quarterly supplement," S1.)*

Key points of the new guidance include the following:

- PrEP should be targeted to individuals at very high risk for HIV infection, such as those with a partner who is HIV-positive.
- Counseling must emphasize that it is critical that

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## EXECUTIVE SUMMARY

The Centers for Disease Control and Prevention has issued new interim guidance for use of pre-exposure prophylaxis (PrEP) for in heterosexual men and women at high risk for HIV.

- The daily drug regimen may be used by HIV-uninfected individuals to reduce their risk of HIV infection.
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patients using PrEP take the daily medication consistently, as the level of protection has been shown to be closely related to levels of adherence.

- For female patients who are pregnant or trying to conceive, discussion must include available information about potential risks and benefits of beginning or continuing the PrEP regimen so that an informed decision can be made. Why? While no adverse effects have been found among infants exposed to Truvada during pregnancy, most of the data comes from those children born to HIV-positive women using the drug during course of treatment in clinical trials. Data are incomplete for children of HIV-negative women who become pregnant while using PrEP. Women who are breastfeeding should not be prescribed PrEP.

- PrEP is not considered a stand-alone solution. Clinicians should include it as part of a comprehensive package of prevention services, including counseling to reduce risk behavior and advocate adherence to the daily pill regimen, access to condoms, and management of other sexually transmitted infections.

- Patients who are prescribed PrEP must be confirmed to be HIV negative prior to use, and their HIV status, experience of side effects, adherence, and risk behaviors must be monitored regularly during use.<sup>1</sup>

### Review checklist

After determining that an individual is HIV-negative and at high risk of infection, clinicians will need to confirm that a patient's calculated creatinine clearance is at least 60 mL or above per minute before PrEP is initiated. Why? A side effect of Truvada use includes new or worsening kidney problems.<sup>2</sup> Be sure to check serum creatinine and calculate creatinine clearance three months after drug initiation, then every six months while the patient is on PrEP medication.

All patients should be screened for hepatitis B infection, as well as other sexually transmitted infections. PrEP candidates should be vaccinated against hepatitis B if susceptible, or treated if active infection exists, regardless of the clinician's decision regarding prescribing PrEP. Testing for hepatitis B has been recommended because worsening of hepatitis B infections has been reported in those who have both HIV-1 and hepatitis B when treatment with Truvada was stopped.

The most common side effects reported with Truvada use include diarrhea, nausea, abdominal pain, headache, and weight loss.

Need more information on PrEP use? Gilead

Sciences has established a dedicated web site, <https://www.truvadapreprems.com>. Developed as a risk evaluation and mitigation strategy site, the Internet portal provides materials to educate and inform healthcare providers and uninfected individuals at high risk for acquiring HIV-1. The CDC also has developed a provider fact sheet that encapsulates the interim guidance. It is available at <http://1.usa.gov/esua27>.

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## Dapivirine vaginal ring eyed for HIV prevention

Two sister studies have been launched in Africa to evaluate the ability of a new monthly vaginal ring containing the antiretroviral drug dapivirine to safely prevent new HIV infections in women.

The Ring Study, under the aegis of the Silver Springs, MD-based International Partnership for Microbicides (IPM), plans to enroll a total of 1,650 women at four sites in South Africa. Researchers look to start enrollment at additional sites in Rwanda and Malawi, pending regulatory and ethics approvals. The second study, known as

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### EXECUTIVE SUMMARY

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- The Ring Study, under the aegis of the International Partnership for Microbicides, plans to enroll 1,650 women at four sites in South Africa. Researchers look to start enrollment at additional sites in Rwanda and Malawi pending regulatory and ethics approvals.
- The second study, ASPIRE (A Study to Prevent Infection with a Ring for Extended Use), is being led by the Microbicide Trials Network. Investigators plan to enroll some 3,476 women at 17 sites in Malawi, Uganda, South Africa, Zambia, and Zimbabwe.

ASPIRE (A Study to Prevent Infection with a Ring for Extended Use) is being led by the Microbicide Trials Network, based at Magee — Womens Research Institute and the University of Pittsburgh (PA). Investigators plan to conduct the study at 17 sites in Malawi, Uganda, South Africa, Zambia, and Zimbabwe. The ASPIRE trial is designed to enroll approximately 3,476 women.

Both trials will look at women ages 18 to 45, all who will be randomly assigned to use the dapivirine ring or a placebo device. Participants will be instructed how to insert and remove the ring, which they will replace every four weeks. All participants will receive ongoing HIV risk reduction counseling, condoms, and diagnosis and treatment of sexually transmitted infections.

The two studies are the first effectiveness trials of a vaginal ring for HIV prevention, say study officials. The two studies also represent the first large-scale prevention trials involving an antiretroviral other than tenofovir or a tenofovir combination.

### Ring offers benefits

The ring, developed by IPM, uses an innovative delivery method to slowly release the drug over one month. Dapivirine is in the class of antiretroviral drugs known as non-nucleoside reverse transcriptase inhibitors, all which have long been used to successfully treat HIV-1 and prevent mother-to-child transmission.

The ring has a number of attractive features for HIV prevention, both for its usability and for its potential HIV protective effects, observes **Jared Baeten**, MD, PhD, associate professor in the Departments of Global Health and Medicine at the University of Washington in Seattle. He, along with **Thesla Palanee**, PhD, of the Wits Reproductive Health and HIV Institute in Johannesburg, South Africa, are leading the ASPIRE trial.

The ring offers ease of use, says Baeten. It is a method that women will not have to remember to use on a daily basis, and it is discreet, representing a method that can be used privately and under a woman's control. With drug delivery administered at the site of HIV exposure, the ring can be a "quite powerful" tool in HIV prevention, Baeten observes.

The sister trials are being run as part of a comprehensive licensure program that will involve thousands of women in its approximate three-year span. In addition to the Ring Study and the

ASPIRE study, the program also will include studies to examine the ring's safety in adolescents and peri- and postmenopausal women, condom compatibility, and drug-drug interactions. If the study results show the ring to be safe and effective, IPM will seek regulatory approval for product licensure and work with other partners to see that the ring is made available at low cost to women in developing countries as soon as possible.

**Zeda Rosenberg**, ScD, chief executive officer at IPM, explains, "Regulatory approval for products by the Food and Drug Administration, European Medicines Agency, and especially African national regulatory agencies requires adequate and well-controlled trials to determine safety and efficacy of a product, and [the agencies'] strong preference is to have two trials that are run in parallel to determine the efficacy."

### IPM has agreement with Janssen R&D

IPM is developing dapivirine for use as a microbicide through a royalty-free licensing agreement with Janssen R&D Ireland (formerly Tibotec Pharmaceuticals), one of the Janssen pharmaceutical companies of Johnson & Johnson. It also is developing multipurpose technologies, including a 60-day dapivirine-contraceptive ring under a grant from USAID.

The combination contraceptive/HIV prevention ring is now in pre-clinical studies, says Rosenberg. If the dapivirine ring does receive approval for HIV prevention, proponents hope to move forward quickly with development of the combination device, she notes.

HIV/AIDS is the leading cause of death globally in women ages 15-44.<sup>1</sup> It exacts a high toll in sub-Saharan Africa, where young women are at least twice as likely to become infected as young men.<sup>2</sup>

In a statement accompanying The Ring Study announcement, **Annalene Nel**, MD, PhD, chief medical officer at IPM, said, "We are very excited that this program is now underway and that the ring has the potential to be groundbreaking for women in Africa. This product could expand the menu of HIV prevention options and give women a very practical way to protect their own health."

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# Herd protection seen with HPV immunization

Findings from a just-published study of young women ages 13-16 in Cincinnati are the first to document herd protection after introduction of the human papillomavirus (HPV) vaccine.<sup>1</sup>

The first HPV vaccine, the quadrivalent formulation Gardasil (Merck & Co.), was licensed for use in the United States in June 2006. The bivalent formulation Cervarix (GlaxoSmithKline Biologicals) was approved in 2009. HPV vaccines are routinely recommended for girls and boys ages 11 and 12. The vaccine series can be started beginning at age 9. Vaccination also is recommended for females ages 13 through 26 and males ages 13 through 21 who have not completed the vaccination series. Males ages 22 through 26 also may be vaccinated.<sup>2</sup>

Herd immunity, which is defined as a drop in infection rates among unimmunized individuals when a critical mass of individuals is immunized against a contagious disease, is an important public health goal, says **Kevin Ault**, MD, professor of gynecology and obstetrics at Emory University in Atlanta.

Much research has been published about the benefits to the individual who receives the HPV vaccination, says Ault. A body of evidence now demonstrates the vaccine's protection against genital warts and cervical cancer, anal cancer, vulvar cancer, and vaginal cancer, he notes. However, many of the public health policies that were made about who should get the vaccine were made on the assumption of herd immunity, Ault observes.

"Now that the vaccine has been out long

enough, we are beginning to see some real-world research that confirms herd immunity," says Ault.

While the news about the vaccine's herd immunity effect is heartening, there are still so many people under age 27 who have not received the immunization, says **Susan Wysocki**, WHNP-BC, FAANP, president & chief executive officer of Washington, DC-based iWomansHealth, which focuses on information on women's health issues for clinicians and consumers.

HPV is ubiquitous, notes Wysocki. Clinicians should encourage parents and those under age 27 to obtain the vaccination. With more data developing about HPV and head and neck cancers, as well as other cancers, there are many more reasons to be vaccinated, Wysocki states.

"We have been looking for cures for cancer for as long as I can remember," she observes. "Isn't it better to prevent than cure?"

## Review the research

To perform the current study, researchers at Cincinnati Children's Hospital Medical Center recruited 368 young women between the ages of 13 and 16 from two Cincinnati primary care clinics during 2006 and 2007. All young women enrolled in the study had sexual contact, but none were vaccinated. In 2009 and 2010, investigators recruited a different group of 409 young women in the same age range, more than half of whom had received at least one dose of the vaccine. Mean age was about 19 years for both groups of participants; most were African American and non-Hispanic.

To perform the analysis, researchers compared pre- and post-vaccination HPV prevalence rates. After propensity score weighting, the prevalence rate for vaccine-type HPV decreased substantially (31.7%-13.4%,  $P < .0001$ ). The decrease in vaccine-type HPV not only occurred among vaccinated (31.8%-9.9%,  $P < .0001$ ), but also among unvaccinated postsurveillance study participants (30.2%-15.4%,  $P < .0001$ ).

The increase in nonvaccine-type HPV in vaccinated participants should be interpreted with caution, but warrants further study, study authors note. Larger studies with more representative samples are needed to definitively determine the public health impact of the HPV vaccine, said **Jessica Kahn**, MD, MPH, a physician in the division of Adolescent Medicine at Cincinnati Children's Hospital Medical Center, in a statement accompanying the study's publication. Kahn

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## EXECUTIVE SUMMARY

Findings from a new study of young women ages 13-16 in Cincinnati are the first to document herd protection after introduction of the human papillomavirus (HPV) vaccine.

- Researchers first recruited young women in 2006 and 2007; all had sexual contact, but none were vaccinated. In 2009 and 2010, investigators recruited a different group of 409 young women in the same age range, more than half of whom had received at least one dose of the vaccine. To perform the analysis, researchers compared pre- and post-vaccination HPV prevalence rates.

- Larger studies with more representative samples are needed to definitively determine the public health impact of the HPV vaccine, researchers say.

served as lead author of the study.

Providers need to advocate for early initiation of the HPV vaccine. Results of a new study indicate that waiting until the teen years might be too late. A separate research team at Cincinnati Children's Hospital Medical Center tested 259 females ages 13-21. Among the 190 who said they already were sexually active, 70% were already infected with HPV. Even among girls who'd had sexual experience without intercourse (sexual contact defined as genital, skin-to-skin contact), 11% were infected with HPV.<sup>3</sup>

In December 2011, the Advisory Committee on Immunization Practices of the Center for Disease Control and Prevention recommended the routine use of the quadrivalent HPV vaccine in boys beginning at the age of 11 or 12.<sup>4</sup> Public health officials are looking for the routine use recommendation to aid in rapid uptake of the vaccine. (*Contraceptive Technology Update reported on the recommendation; see "Finally! HPV male shot routinely recommended," January 2012, p. 6.*)

Australian public health officials are taking it one step further. Beginning in 2013, the quadrivalent HPV vaccine will be funded for all Australian 12- and 13-year-old boys as part of the country's National Immunization Program. Immunization of Australian females began in 2007, with a drop in cervical cancer documented in subsequent research.<sup>5</sup> It is estimated that a quarter of new infections will be avoided by extending the vaccine to boys, Australian officials state.

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## Hormone therapy focus of new joint statement

The North American Menopause Society, the American Society for Reproductive Medicine, and The Endocrine Society have issued a joint statement concluding that hormone therapy (HT) is still an acceptable treatment for menopausal symptoms.<sup>1</sup> The statement has been endorsed by 12 other medical societies. (*Access a copy of the statement at <http://bit.ly/MVMfha>. See list of endorsing societies on p. 118.*)

Hormone therapy is considered an acceptable option for the "relatively young" (defined as up to age 59 or within 10 years of menopause) and healthy women who are bothered by moderate to severe menopausal symptoms, according to the joint statement.<sup>1</sup>

"Individualization is key in the decision to use hormone therapy," the statement reads. "Consideration should be given to the woman's quality-of-life priorities, as well as her personal risk factors such as age, time since menopause, and her risk of blood clots, heart disease, stroke, and breast cancer."

The statement makes it clear that a large number of clinicians are in agreement that hormone therapy is an acceptable option for the management of menopausal symptoms for most women, says Margery Gass, MD, executive director of the North American Menopause Society. When the risks of hormone therapy were published in 2002, many clinicians and women themselves

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- Individualization is key in the decision to use hormone therapy. Clinicians should consider the woman's quality-of-life priorities, as well as her personal risk factors such as age, time since menopause, and her risk of blood clots, heart disease, stroke, and breast cancer.

turned away from using hormone therapy, not only for long-term use, which was appropriate, but they also rejected any use at all, she notes.

“This statement is intended to reassure women and their providers that short-term use of hormone therapy is still an acceptable option for most women who are experiencing moderate to severe menopausal symptoms,” states Gass.

According to the joint statement, hormone therapy is the most effective treatment for menopausal symptoms such as hot flashes and vaginal dryness. For women with vaginal dryness or discomfort with intercourse, the preferred treatments are low doses of vaginal estrogen. Hot flashes generally require a higher dose of hormone therapy that will have an effect on the entire body, the statement advises.

Women with an intact uterus should take a progestogen — progesterone or a similar product — along with the estrogen to prevent cancer of the uterus, the statement reads. While five years or less is usually the recommended duration of use for the combined treatment, length of time can be individualized for each woman, the statement reads. Women who have had their uterus removed can take estrogen alone; more flexibility can be used in prescribing estrogen therapy due to apparent safety of estrogen-along treatment, the statement advises.

## Discuss the risks

A discussion of hormone therapy must include the potential risks of the method. Both estrogen therapy and estrogen with progestogen therapy increase the risk of blood clots in the legs and lungs, similar to birth control pills, patches, and rings, the joint statement notes. Although the risks of blood clots and strokes increase with either type of hormone therapy, the risk is rare in the 50-59 year old age group, the statement reads.

How about breast cancer? The statement notes that an increased risk in breast cancer is seen with five or more years of continuous estrogen/progestogen therapy, and it may be documented earlier. However, the risk decreases after hormone therapy is stopped, the statement reads. Use of estrogen alone for an average of seven years in the Women’s Health Initiative trial did not increase the risk of breast cancer, the statement notes.

Available evidence suggests that estrogen therapy applied to the skin through patches, gels,

## Groups That Endorse Joint Statement on Hormone Therapy

Academy of Women’s Health  
American Academy of Family Physicians  
American Academy of Physician Assistants  
American Association of Clinical Endocrinologists  
American Medical Women’s Association  
Asociación Mexicana para el Estudio del Climaterio  
Association of Reproductive Health Professionals  
National Association of Nurse Practitioners in Women’s Health  
National Osteoporosis Foundation  
SIGMA Canadian Menopause Society  
Society for the Study of Reproduction  
Society of Obstetricians & Gynaecologists of Canada

and sprays and low-dose estrogen pills have been associated with lower risks of blood clots and strokes than standard doses of estrogen pills, but studies directly comparing oral and transdermal hormone therapy have not been done, the statement notes.

There are many forms of hormone therapy that have received clearance through the Food and Drug Administration (FDA), the statement reads. Scientific data is not available to determine whether custom compounded bioidentical hormone therapy is any safer or more effective than FDA-approved hormone therapies, the statement says.

Until research identifies the harms and benefits of the variety of available hormone regimens, women should be cautious about unproved claims, advises the 2011 edition of “Our Bodies, Ourselves.”<sup>2</sup> Data suggests that estrogen given through the skin (transdermal estradiol) bypasses the liver and is less likely to cause blood clots and possible strokes than pills, the book states.<sup>3</sup> However, transdermal estrogen appears to carry the same breast cancer risk as oral estrogen, the book notes.<sup>4</sup>

## Use “Menopause Map”

How can you and your patient enter into a productive dialogue about treatment of meno-

pausal symptoms? Look to the “Menopause Map,” an online interactive tool that guides a woman through available options. (*Access the tool at <http://bit.ly/Nrg6h7>.*)

Developed by The Endocrine Society and the Hormone Health Network, the map uses a series of prompting questions about symptoms and a patient’s personal health history. It also has links to questionnaires that help assess current risk for breast cancer, heart disease, and stroke. The tool weighs hormonal and non-hormonal therapies against the risks based on individual symptoms and medical history.

The map is quick and easy to navigate, says **Cynthia Stuenkel, MD**, a developer of the Menopause Map. Most women run through the questions several times, offering different responses to check out their various options. This online encounter provides the woman with a dry-run before her official conversation with her provider, says Stuenkel, an endocrinologist specializing in menopause at the University of California, San Diego. The map allows the woman to print out her responses to take with her to the appointment.

“For some women, having their answers in hand in a printed form might help initiate the conversation about menopausal symptoms and options for relief, while she can focus her questions on the issues and options that most resonate with her,” she notes.

The goal of the Menopause Map is to have each woman as informed as possible about her options to relieve specific symptoms and address other health concerns, such as risk of heart disease, osteoporosis, and breast cancer, says Stuenkel.

“We are each individuals with our own specific health profile and life story,” she says. “Relief of menopausal symptoms should accordingly also be individualized.”

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## CNE/CME QUESTIONS

**A**fter 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.

1. According to a new analysis (Cleland K, et al. *Hum Reprod* 2012), IUDs inserted shortly after unprotected intercourse have a failure rate of:  
A. Less than one per 500  
B. Less than one per 750  
C. Less than one per 1,000  
D. Less than one per 2,000
2. What drug is no longer recommended by the Centers for Disease Control and Prevention (CDC) as a first-line treatment option for gonorrhea due to possible drug resistance?  
A. Ceftriaxone  
B. Azithromycin  
C. Doxycycline  
D. Cefixime
3. According to new interim guidance issued by the CDC for use of pre-exposure prophylaxis (PrEP) for in heterosexual men and women at high risk for HIV, which women should NOT be prescribed PrEP?  
A. Breastfeeding women  
B. Women who are trying to conceive  
C. Women who are pregnant  
D. Women using hormonal contraception
4. What is the drug contained in the monthly vaginal ring that is the focus of two sister studies in Africa designed to evaluate its capability in preventing new HIV infections in women?  
A. Nestorone  
B. Dapivirine  
C. Zidovudine  
D. Emtricitabine

## COMING IN FUTURE MONTHS

- Science eyes IUD innovations
- Childbirth after 30 may lower endometrial cancer risk
- Time to update trichomoniasis information
- What's the impact of Affordable Care Act on your practice?

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