

# CONTRACEPTIVE TECHNOLOGY

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## Data mixed on increased risk of HIV in women using contraceptive shots

*Researchers plan randomized controlled trial in 2015 to clarify issue*

Injectable contraceptives are among the world's most popular family planning options. In Eastern Africa and Southern Africa, injectables account for more than 40% of contraceptive use. About 2.4% of contracepting women in the United States choose the method.<sup>1,2</sup>

Use of progestin-only contraceptive injectables, particularly depot medroxyprogesterone acetate (DMPA), has come under question after findings from some studies suggest that use might be associated with an increased risk of acquiring HIV from an infected partner.<sup>3-4</sup>

Two presentations at the recent AIDS 2014 conference in Melbourne, Australia, offer differing outlooks on increased risk of HIV in women using contraceptive injections. In a meta-analysis that included individual-level data on 37,000 women, results indicate use of DMPA is linked with a higher rate of new HIV infections in women.<sup>5</sup> However, findings from a separate longitudinal study of serodiscordant couples suggest no link between hormonal contraceptives and a woman's risk for HIV.<sup>6</sup>

To get more definitive answers on the subject, a large randomized controlled trial is being planned by the Evidence for Contraceptive Options and

## EXECUTIVE SUMMARY

Presentations at the AIDS 2014 conference offer differing outlooks on increased risk of HIV in women using contraceptive injections.

- In a meta-analysis that included individual-level data on 37,000 women, results indicate use of depot medroxyprogesterone acetate (DMPA) is linked with a higher rate of new HIV infections. However, findings from a separate longitudinal study of serodiscordant couples suggest no link between hormonal contraceptives and a woman's risk for HIV.

- A large randomized controlled trial in which participants will be openly randomized to use DMPA, the levonorgestrel implant, or the copper intrauterine device might offer a more definitive answer.

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HIV Outcomes (ECHO) consortium. Members of the consortium include FHI 360 in Durham, NC, the Wits Reproductive Health and HIV Institute in Johannesburg, South Africa, the University of Washington in Seattle, and the World Health Organization (WHO) in Geneva, Switzerland.

The trial plans to enroll approximately 8,600

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### Editorial Questions

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HIV-negative women from 14 sites in east and southern Africa who desire contraception. Study participants will be openly randomized to use DMPA, the levonorgestrel implant, or the copper intrauterine device, and they will be followed for an average of 15 months. Researchers will look at the rates of HIV acquisition among the three groups of women, Rates of pregnancy, contraceptive method continuation, and contraceptive method-related adverse events also will be examined. The trial will take approximately four years to complete, with enrollment expected to begin in early 2015.

While the timeline might be somewhat delayed by funding challenges, researchers hope to move forward in examining this issue, says **Charles Morrison**, PhD, director of clinical sciences at FHI 360. "We feel by doing a randomized trial, which has not been done before, that we will get the most definitive answer that we can get to this question," says Morrison. "Women, policymakers, and clinicians really need this information, especially in sub-Saharan Africa."

### Look at meta-analysis

Morrison presented results of FHI 360's and collaborators' meta-analysis of individual participant data on hormonal contraception and HIV acquisition from 18 prospective studies and HIV prevention trials in sub-Saharan Africa at the recent AIDS 2014 conference.<sup>5</sup> By using data from individual participants, the research team aimed to help overcome some of the methodological challenges of simply combining estimates of the effects from multiple studies.

In looking at contraceptive methods, 28% of the cohort reported DMPA use, 19% of women used oral contraceptives, 8% used norethisterone enanthate, and 43% used nonhormonal methods. Of the individual data on 37,124 women that were pooled, there were 1,830 incident HIV infections. In the primary analysis, researchers estimated the hazard ratio (HR) using two-stage random effects meta-analysis, controlling for region, marital status, age, number of sex partners, and condom use. The team conducted sensitivity analyses to assess whether results were influenced by risk of methodological bias in component studies, HIV incidence, pregnancy status, or limiting person-time to periods with no condom use.

Relative to non-users, the pooled adjusted HR for HIV acquisition was 1.50 (95% confidence interval [CI]:1.24-1.83) for DMPA, 1.24 (95% CI:0.84-

1.82) for norethisterone enanthate, and 1.03 (95% CI:0.88-1.20) for combined oral contraceptives. Studies at lower risk of bias showed lower hazard ratios [DMPA (1.22; 95% CI:0.99-1.50), norethisterone enanthate (0.67; 95% CI:0.47-0.96), combined oral contraceptives (0.91; 95% CI:0.73-1.14)] than those at higher risk of bias: [DMPA (HR 1.73; 95% CI:1.39-2.16), norethisterone enanthate (HR 1.50; 95% CI:1.14-1.96) and combined pills (HR 1.16; 95% CI:0.93-1.45)].<sup>5</sup>

Researchers found evidence that DMPA, but not norethisterone enanthate or combined oral contraceptive use, increased women's risk of HIV. However, the estimated risks associated with hormonal contraceptive use were substantially lower in studies at less risk of methodological bias, which highlights the limitations of observational data, researchers concluded.

## Check Zambian results

To look at the relationship between HIV risk and use of hormonal contraception, a separate group of investigators looked at longitudinal data gathered by the Rwanda Zambia HIV Research Group, with headquarters at the Rollins School of Public Health at Emory University in Atlanta. The research group has maintained one of the longest-standing and largest discordant cohorts in the world, notes **Kristin Wall**, PhD, research assistant professor in the Rollins School. Wall presented 17 years of follow-up data on the cohort at the AIDS 2014 conference.<sup>6</sup>

“Understanding HIV risk among discordant couples is advantageous due to their relatively homogeneous level of HIV exposure,” explains Wall. “We also collect multiple measures of unprotected sex, an important confounder, and provided contraceptive methods on site with high frequency: every three months.”

Researchers hoped that by using such rigorously collected and robust data, they could add important findings to the controversial evidence surrounding this issue, said Wall. “We felt an obligation to explore this potential association as findings indicating increased HIV acquisition risk for hormonal contraception users could directly effect the health of women in the communities we work where unintended pregnancy and HIV are epidemic,” she notes.

To perform the study, researchers looked at 1,393 couples, each with an HIV-positive man and HIV-negative woman. A total of 252 women acquired HIV. Incidence of HIV infection was 11.5% for women using oral contraceptives, 10.7%

for women using injectable contraceptives, 8.4% for women who used condoms or no contraception, and 7.3% for women using a contraceptive implant. After thorough consideration of confounding, misclassification, effect measure modification, interaction, and mediation, researchers found no association between hormonal contraception and HIV acquisition risk among women over 17 years of follow-up.<sup>6</sup>

## What does the WHO say?

WHO presented its latest recommendations at the AIDS 2014 conference. The guidance recommends no restrictions on the use of combined hormonal contraceptives (pills, patch, vaginal ring, or injectable) or progestin-only contraceptives (pills, injectable, or implants) for women with or vulnerable to HIV. Women taking antiretroviral therapy now are generally eligible for all hormonal contraceptive methods, although special consideration might be necessary, the guidance notes.<sup>7</sup>

“Because any risk of HIV acquisition associated with progestogen-only injectable use remains on open question, women and couples at high risk of HIV infection should be informed about (and have access to) HIV preventative measures, including male and female condoms,” the guidance states. “WHO is committed to continually review its recommendations in light of the accumulating evidence, and strongly supports the need for further research to identify definitive answers that address concerns around increased biological vulnerability to HIV among women using progestogen-only injectables.”

Four systematic reviews of epidemiological, clinical, and pharmacological evidence available through January 2014 were conducted to inform the guidance. Results of the two studies presented at the July 2014 AIDS conference were not available for inclusion in the reviews.

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## Biomedical prevention spotlighted at AIDS 2014

Data presented at the recent AIDS 2014 international conference indicates that oral HIV pre-exposure prophylaxis (PrEP) provides a high degree of protection against HIV infection, even for individuals who miss some daily doses.<sup>1</sup>

Findings from the study are particularly important in relation to emerging guidelines recommending expanded use of PrEP, said **Robert Grant, MD, MPH**, senior investigator at the Gladstone Institutes in San Francisco and professor of medicine at the University of California, San Francisco. The project provides critical insight into what happens as PrEP transitions from clinical trials to clinical practice, noted Grant in a release accompanying his conference presentation.

In the cohort study, men and transgender women who have sex with men who were previously enrolled in the ATN 082, iPrEx, and U.S. Safety Study PrEP trials were enrolled in a 72-week open-label extension. Scientists measured drug concentrations in plasma and dried blood spots in seroconverters and a random sample of seronegative participants. Investigators then assessed PrEP uptake, adherence, sexual practices, and HIV incidence.

A total of 1,603 HIV-negative people were enrolled; 1,225 (76%) received PrEP. Researchers report that PrEP uptake was high when made available free of charge by experienced providers. The effect of PrEP is increased by greater uptake and adherence during periods of higher risk, data indicates.<sup>1</sup>

Study findings suggest PrEP is highly effective at preventing HIV in the study population, even when some doses of the daily regimen were missed.

No study participant who took PrEP four or more times per week became HIV-infected, data suggests. “Daily dosing of PrEP is recommended, because it helps foster the habit of consistent PrEP use and increases drug levels in the body, providing the best safety cushion for individuals who occasionally miss doses,” said Grant. “At the same time, these results demonstrate that PrEP remains highly effective, even in real-world circumstances in which adherence may not be perfect.”

Some speculation has arisen that access to PrEP could cause individuals to increase their sexual risk-taking behavior. However, results of the current trial indicate no evidence of “risk compensation” among PrEP users. Sexual practices among PrEP receivers and those not receiving PrEP became safer by self-report, researchers note. Syphilis incidence, a marker of sexual risk behavior, was comparable between the two groups, the data reflect.<sup>1</sup>

Of the 1,603 study participants, 41 (2.6%) became HIV positive during the study. Thirteen of these were in the group that had elected not to take PrEP (annual incidence rate, 2.6%), while 28 were in the majority who had elected to receive PrEP (annual incidence rate 1.8%). Seven of these participants had actually stopped taking PrEP more than two months before they became HIV positive, in five cases because of side effects.<sup>1</sup>

### WHO issues new guidance

AIDS conference attendees also received information on the World Health Organization’s (WHO’s) new guidelines on HIV prevention, diagnosis, treatment, and care for key populations.<sup>2</sup> The new guidance addresses PrEP as part of a range of options in preventing HIV in men who have sex with men.

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### EXECUTIVE SUMMARY

Data presented at the AIDS 2014 international conference indicates that oral HIV pre-exposure prophylaxis (PrEP) provides a high degree of protection against HIV infection, even for individuals who miss some daily doses.

- Some speculation has arisen that PrEP access could cause individuals to increase their sexual risk-taking behavior. However, results of the current trial indicate no such evidence.

- PrEP is now included as part of a range of options in preventing HIV in men who have sex with men in new guidance issued by the World Health Organization. The guidance advises that PrEP be used as an additional option to prevent HIV infection, alongside the use of condoms.

The guidelines consolidate WHO's HIV advice for five "key population" groups: men who have sex with men (MSM), injecting drug users, sex workers, transgender people, and people in prisons. While progress has been made in HIV prevention, rates of HIV infection among these groups remain high, the WHO reports. "For example, recent data indicates that men who have sex with men are up to 19 times more likely to have HIV than the general population — transgender women are almost 50 times more likely," noted the WHO in a question-and-answer sheet on the new guidance.<sup>3</sup> "Recent UNAIDS analysis suggests that up to 50% of all new infections globally are among these population groups."

According to the new guidance, it is important that men who have sex with men can access the entire range of HIV services, including antiretroviral therapy for those with HIV, and a full package of prevention options, including condoms and lubricants. The agency also recommends men who have sex with men consider using PrEP as an additional option to prevent HIV infection, alongside the use of condoms.

"WHO recognizes that PrEP will not be an appropriate choice for all men who have sex with men and supports offering men who have sex with men the full range of prevention options to suit their circumstances, taking into account their risks and preferences," the guidance states.

## Get PrEP in practice

Now that evidence is available on the efficacy and effectiveness of oral daily PrEP with tenofovir disoproxil fumarate and emtricitabine (Truvada, Gilead Sciences, Foster City, CA) for HIV prevention among men who have sex with men, along with guidance from the WHO guidance and Centers for Disease Control and Prevention, and Food and Drug Administration approval, the crucial next steps for PrEP are in implementation, says **Chris Beyrer**, MD, professor in the Epidemiology Department in the Bloomberg School of Public Health at Johns Hopkins University (JHU) in Baltimore. Beyrer, who serves as director of JHU's Training Program in HIV Epidemiology and Prevention Science and the Center for Public Health & Human Rights, is the president of the International AIDS Society.

The United States is the only country actively using PrEP for any population, notes Beyrer. "There are multiple demonstration projects underway in many settings, and these are important," observes Beyrer. "But critically important now for countries

with HIV epidemics ongoing among MSM is to begin implementation of this new tool as a prevention strategy for the individual, and as part of public health programs to begin to have an impact on HIV among MSM at network and community levels."

Public health officials need to take PrEP to scale in epidemic contexts where high HIV incidence densities are being seen among these men, says Beyrer. This effort will require provider and community education and training efforts, appropriate testing and counseling services, negotiations over drug and other program costs, and efforts on the regulatory and other policy fronts, he states.

"We have delayed too long and seen too many young men become HIV infected, in both developed and developing countries, to delay implementation further," states Beyrer.

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## Future contraceptive? Microchip may be option

Science is looking at a wireless microchip implant, with remote drug delivery control, that is designed to last up to 16 years. Now in the very early stages of testing, such a device would provide long-lasting contraception — nearly half of a woman's reproductive life — and could be deactivated without a trip to the clinic and an outpatient procedure.

MicroCHIPS of Lexington, MA, a developer of implantable drug delivery devices and biosensors, is aiming for testing of the contraceptive chip in 2015, with trials beginning in 2016, says **Robert Farra**, MSME, MicroCHIPS president.

The proposed contraceptive microchip measures 20 by 20 by 7 mm. It is designed to be implanted under the skin of the buttocks, upper arm, or abdomen. Scientists look to use a daily dose of 30 mcg of

levonorgestrel as the contraceptive. Tiny reservoirs holding 16 years of drug doses fit on a microchip 1.5 cm wide inside the device. A hermetic titanium and platinum seal on the reservoirs is activated each day through an internal battery to release a daily dose of the contraceptive. Components of the original microchip technology, such as the array of micro reservoirs used to contain drug and the first microchip opening mechanism, were developed at the Massachusetts Institute of Technology and licensed to MicroCHIPS.

Levonorgestrel has been widely used in oral contraceptives, intrauterine devices, and subdermal implants, says Farra. It has a well-understood and safe profile. “The chip stores discrete doses, providing long-term stability, and dosing can be turned on or off without an additional procedure to remove the device,” notes Farra. “It provides women with additional choices helping them plan their family. It also simplifies a woman’s life in that she doesn’t need to remember to take a pill.”

## Technology under review

MicroCHIPS began looking at the contraceptive microchip after its work with a similar chip designed to deliver an osteoporosis drug, teriparatide. In its trial, postmenopausal women diagnosed with osteoporosis received daily doses of the drug through microchip delivery rather than daily injection. The drug released from the implanted microchip demonstrated similar measures of safety and therapeutic levels in blood compared to standard subcutaneous injections.<sup>1</sup>

To conduct the study, seven osteoporotic postmenopausal patients between 65 and 70 received the microchip-based implant. The primary objective of the trial was to assess the pharmacokinetics of the released drug from the implanted devices. Safety measures included evaluation of the biological response to the implant and monitoring indicators of toxicity.

The device and drug combination were found to be biocompatible with no adverse immune reaction. The pharmacokinetic profiles from the implant were comparable to and had less variation than the profiles of multiple, recommended subcutaneous injections of the drug. The study also demonstrated that the programmable implant was able to deliver the drug at scheduled intervals.<sup>1</sup>

MicroCHIPS received a \$4.6 million grant from the Bill & Melinda Gates Foundation in January 2014 to advance its work on the contraceptive chip.

## EXECUTIVE SUMMARY

Science is looking at a wireless microchip implant, with remote drug delivery control, that is designed to last up to 16 years.

- The proposed contraceptive microchip measures 20 by 20 by 7 mm and is designed to be implanted under the skin of the buttocks, upper arm, or abdomen. Scientists look for the microchip to release a daily dose of 30 mcg levonorgestrel.
- A hermetic titanium and platinum seal on reservoirs in the chip is activated each day through an internal battery to release the daily drug dose.

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Despite the current variety of contraceptives, there still are existing gaps in the method mix, says **Laneta Dorflinger**, PhD, distinguished scientist and director of the Contraceptive Technology Innovation program at FHI 360, a global non-profit human development organization based in Durham, NC. There is a need for new contraceptive options that will fill these gaps and increase choices for women, notes Dorflinger. However, in recent decades, there has been limited investment in contraceptive research and development.

“Recently, the Bill & Melinda Gates Foundation has taken a leadership position making a variety of medium and longer-term investments in innovative contraceptive product development,” states Dorflinger. “Through FHI 360’s Contraceptive Technology Innovation Initiative, which is funded by the Gates Foundation, we are working to develop innovative, long-acting contraceptives to help expand choice and access for women most in need in low-income countries.”

The FHI 360 Initiative is building on projects now underway to develop a longer-acting injectable contraceptive and a new biodegradable contraceptive implant. The program also is looking to advance the Sino-implant (II), a highly effective, low-cost, subdermal contraceptive implant composed of two thin, flexible, silicone rods, with each rod filled with 75 mg of levonorgestrel.<sup>2</sup> Program officials hope to ensure the implant is affordable and accessible to women in the poorest countries.

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# How to make LARC first at your clinic

Long-acting reversible contraception (LARC) — the copper T and levonorgestrel intrauterine devices (IUDs) and the birth control implant — are highly effective in preventing pregnancy, last for several years, and are easy to use. Such methods are reversible, which allows women to remove them at any time when they want to become pregnant or stop using them.

Research from the Contraceptive CHOICE project in St. Louis, which was designed to evaluate reversible birth control methods, indicates dramatic differences in method effectiveness. Women who used birth control pills, the patch, or vaginal ring were 20 times more likely to have an unintended pregnancy than those who used longer-acting forms such as an IUD or implant.<sup>1</sup>

Ready to implement the “LARC First” principles of the Contraceptive CHOICE Project at your clinic? Colleen McNicholas, DO assistant professor of obstetrics and gynecology at Washington University School of Medicine in St. Louis and clinical researcher with the Contraceptive CHOICE Project, offered tips during a recent webinar sponsored by the American College of Obstetricians and Gynecologists.<sup>2</sup> (To view the webinar, go to <http://bit.ly/1pzwZZh>. Select “View Presentation.”)

In the CHOICE Project, non-clinicians were trained to serve as contraceptive counselors. The process used by the contraceptive counselor and the clinician worked to help each woman receive her desired method, as well as ensure that method was appropriate for her, given her medical history, says McNicholas.

Counselors employ a standardized script, which is used with all participants, regardless of age. The script includes commonly used reversible methods so that all the women hear about the full range of methods, said McNicholas.

Counselors lead off the session by presenting the most effective methods first, using evidence-based data from the Centers for Disease Control and Prevention’s *U.S. Medical Eligibility Criteria for Contraceptive Use*. Additional teaching aids also are used to help women understand contraceptive effectiveness.<sup>3</sup> (Check the “LARC First” web site, [www.larcfirst.com](http://www.larcfirst.com), developed by the Contraceptive CHOICE Project, for complete clinic and patient resources.)

To prepare nonclinicians for the counseling role,

## EXECUTIVE SUMMARY

Long-acting reversible contraception (LARC) — the copper T and levonorgestrel intrauterine devices (IUDs) and the birth control implant — are the most effective reversible methods available to prevent unintended pregnancy. They last for several years and are easy to use. Clinicians can draw lessons from the Contraceptive CHOICE project in St. Louis on how to make their clinics “LARC First.”

\* In the CHOICE Project, non-clinicians were trained to serve as contraceptive counselors.

\* Counselors employ a standardized script, which is used with all participants, covering commonly used reversible methods. The most effective methods are presented first.

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contraceptive knowledge training and evaluation of competency can be delivered via formal training, mostly through direct lectures, says McNicholas. Prospective counselors then undergo practice contraceptive counseling sessions with physicians for observation.

Once counselors are observed and deemed competent, both through evaluation of observed counseling sessions as well as knowledge based testing, they participate in direct-observation patient counseling. Once counselor trainees have undergone a certain number of directly observed patient counseling sessions, they are allowed to counsel alone, says McNicholas. (Go to the “Counseling” section of the LARC First site, <http://bit.ly/1o5VbxA>, for complete training resources.)

Counselors also are trained in collecting a medical history, with emphasis on the major medical co-morbidities associated with contraceptive use, McNicholas points out. At the end of each counseling session, every participant’s history and method choice are presented to the clinician for approval. This process is very much in the format of patient presentation taught in the residency training format, observes McNicholas.

## Clinician makes call

The CHOICE Project trained 54 contraceptive counselors: 38 CHOICE staff and 16 volunteers. Almost all (96%) of the trained contraceptive counselors had at least an undergraduate degree, and two had professional healthcare degrees (RN and NP). Among the 38 CHOICE staff members, 15 had no prior healthcare experience before joining the project.

Following the counseling session, the counselor presents a completed baseline clinical form to the clinician. It includes patient information, general health information, and histories of contraception,

menstrual cycle, obstetrics, infection, and surgeries, as well as information on allergies, current medications, and general medical information.

The contraceptive method ultimately is dispensed by the clinician, regardless of whether it is a prescription for pills or placement of a device, says McNicholas. This step provides the clinician the opportunity to assess the patient's comfort with the method choice, as well as check whether she has additional questions about the chosen or any other method.

"There really was a collaborative and non-punitive environment that facilitated a sense of comfort among the counselors, allowing them to ask clinicians questions when issues arose they were not comfortable with," McNicholas observes. "I think this is one strategy that can really help facilitate better and more complete contraceptive counseling in busy clinical practices."

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## EC: Progress made, but challenges remain

How has the emergency contraception (EC) landscape changed in the year after the Food and Drug Administration's (FDA's) approval of Plan B One-Step (Teva Women's Health, North Wales, PA) emergency contraception for use without a prescription for all women of child-bearing potential?

There have been several recent developments that serve to improve the availability of EC, according to the Washington, DC-based Reproductive Health Access Project. The FDA issued a letter in February 2014 indicating that generic EC could be sold on store shelves and would no longer require proof of age for purchase.

Women can choose to take Plan B One-Step, Take Action (Teva), Next Choice One Dose (Actavis, Parsippany, PA), My Way (Gavis Pharmaceuticals,

Somerset, NJ) or AfterPill (Syzygy Healthcare Solutions, Westport, CT). AfterPill, a generic equivalent of Plan B One-Step, differs from other products in that it is only available online. It is sold at a price point of \$20 per dose, compared to \$48 on average for Plan B One-Step.

Lowering the price of the best-selling over-the-counter emergency contraceptive medicine to \$20 will help make access to emergency birth control more affordable for women, said Syzygy spokesperson **Alyson O'Mahoney** in a press statement accompanying the drug's July 2014 launch. Mahoney noted the ability to purchase AfterPill via a dedicated website ([www.AfterPill.com](http://www.AfterPill.com)) removes the risk of not finding EC at a local pharmacy and also affords a discreet way to obtain EC.

According to Syzygy officials, there are no purchase restrictions for AfterPill, and no proof of age is required. The product is an FDA-authorized, over-the-counter (OTC) product that can be purchased by any consumer regardless of age or gender. Its label indicates for use only by women 17 years of age or older, as mandated by the FDA, but there are no purchase restrictions, the company states.

An analogous product is the OTC Oxytrol product from Merck Consumer Products Co. (Whitehouse Station, NJ), note Syzygy officials. While it is indicated for the treatment of over-active bladder conditions among women 18 years of age or older, it also has no purchase restrictions.

## Check coverage status

While more options might help drive down price of emergency contraception pills, access might be hampered for many women whose insurance poli-

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## EXECUTIVE SUMMARY

Availability of emergency contraception (EC) has broadened since the FDA ruled that generic EC could be sold on store shelves and would no longer require proof of age.

- Pill options include Plan B One-Step, Take Action, Next Choice One Dose, My Way, and After Pill. After Pill is available only through its online website and is priced at \$20 per dose.
- Federal regulations do not require insurers to cover over-the-counter preventive products such as EC at no cost unless the consumer has a prescription. The Supreme Court decision allowing closely held corporations with a religious objection to exclude contraceptive services and methods in their employer-sponsored health plans puts no-cost coverage for prescription EC at risk for many women.



cies do not cover OTC products. According to the Reproductive Health Access Project, federal Health and Human Services regulations do not require insurers to cover OTC preventive products such as EC at no cost unless the consumer has a prescription, and the June 2014 Supreme Court decision on contraceptive coverage puts no-cost coverage for prescription EC at risk for millions of women. On June 30, 2014, the U.S. Supreme Court issued a ruling that closely held corporations that assert a religious objection do not have to cover contraceptive services and methods in their employer-sponsored health plans as required under the Affordable Care Act.

The Reproductive Health Access Project is calling for action on three fronts:

- Support legislative and administrative fixes to the Supreme Court decision to ensure women receive the coverage they need for all forms of contraception, including EC.
- Advocate for an interpretation of the women's preventive services section of the Affordable Care Act that would require no-cost coverage of any over-the-counter EC product without a prescription.
- Encourage market developments that will help to lower the price of EC so that cost does not remain a barrier to access.

## Check store shelves

Have you checked your local drug store shelves to see if EC is available? Because Plan B One-Step became available for sale without age or point-of-sale restrictions in July 2013, retail and pharmacist response has been “confusing at best and non-compliant at worst,” according to the Reproductive Health Access Project.

A survey completed in early 2014 by the Princeton, NJ-based American Society for Emergency Contraception found that only half of stores stocked Plan B One-Step on store shelves.<sup>1</sup> Among the stores that did stock EC on the shelf, more than half of these displayed the product in a locked, portable box or in a fixed case that had to be unlocked by a store employee, survey respondents note.

While the February 2014 letter from the FDA indicated generics could be sold without requiring proof of age, the labels for existing generic products must be updated before the products can be moved to store shelves. This need has caused additional confusion about what products are available without proof of age and where they can be stocked,

states the Reproductive Health Access Project.

Advocates should educate the public and retailers on the status of the various EC products and where they should be stocked. Also, advocates should seek accountability from retailers to ensure they stock EC in a manner that does not deter access and that removes unnecessary barriers.

While a great deal of progress has been made to improve and expand access to EC, financial and physical barriers and political threats to comprehensive access remain, said **Jessica Arons**, chief executive officer and president of the Reproductive Health Access Project in a statement on EC status.

“Advocates and policymakers alike have a role in taking action to ensure access to basic preventive health care like EC,” Arons noted.

**Robert Hatcher**, MD, MPH, professor emeritus of gynecology and obstetrics at Emory University School of Medicine in Atlanta, has a strong recommendation regarding emergency contraception.

“Stop recommending emergency contraceptive pills until we have an oral emergency contraceptive with considerably higher effectiveness,” states Hatcher.

“Professor James Trussell speaks of the ‘harsh reality’ of the fact that as taken today, emergency contraceptive pills have no global effect on women’s risk for an unintended pregnancy.”

Today, the copper T 380A intrauterine device (IUD) (ParaGard, Teva North America, North Wales, PA) is by far the best approach to emergency contraception, and if acceptable to a woman, will provide her effective contraception for the next 10 to 12 years, notes Hatcher. Only one in 1,000 women receiving a Copper T IUD for emergency contraception becomes pregnant, Hatcher states.

## REFERENCE

1. American Society for Emergency Contraception. Emergency Contraception Access Report. Accessed at <http://bit.ly/1mN4OWl>. ■

## HPV vaccine continues to be underutilized

According to new data from the Centers for Disease Control and Prevention’s (CDC) 2013 *National Immunization Survey — Teen*, the number of girls and boys ages 13-17 years receiving human papillomavirus (HPV) vaccine remains unacceptably low, despite a slight increase in vaccination coverage

since 2012.<sup>1</sup>

Data indicates that there is a substantial gap between the number of teens receiving tetanus, diphtheria, and pertussis (Tdap) vaccine, and those receiving HPV vaccine. While about 57% of teen girls and 35% of teen boys received one or more doses of HPV vaccine, nearly 86% of adolescents had received one dose of Tdap vaccine.<sup>1</sup>

Such gaps in coverage indicate missed opportunities to vaccinate boys and girls with HPV vaccine at the same time as other routinely recommended adolescent vaccines like Tdap and meningococcal vaccines. “The high coverage rate of Tdap vaccine shows us that it is certainly possible to reach our goal of vaccinating 80% of adolescents against cancers caused by HPV,” says **Anne Schuchat**, MD, assistant surgeon general and director of the CDC’s National Center for Immunization and Respiratory Diseases.

The CDC estimates that if missed opportunities to vaccinate adolescent girls before their 13th birthdays were eliminated, 91% of adolescent girls would gain some protection from cancers caused by HPV infection. Pediatricians and family physicians can help to prevent missed opportunities by giving the HPV vaccine during the same visit that Tdap and meningococcal vaccines are administered, says Schuchat.

There are several resources available to assist providers in preventing missed opportunities to completing the HPV vaccine series, says Schuchat. Healthcare professionals can use electronic medical records (EMR) or registry systems to set up reminders to recommend the vaccines preteen patients need. The CDC has developed the “You Are The Key” website (<http://1.usa.gov/1kH4yc0>) with resources to assist healthcare professionals in strengthening their recommendation for HPV vaccine, notes Schuchat.

The website includes a *Tips and Timesavers* factsheet (<http://1.usa.gov/1phjRrM>) to ease conversations with parents about HPV vaccine, says Schuchat. The site also has several educational videos that can help healthcare professionals give a strong recommendation for HPV vaccine.

“The key to preventing missed opportunities is to give a bundled recommendation for all three adolescent vaccines — Tdap, meningococcal, HPV — during the same visit without singling out HPV vaccine,” notes Schuchat.

It is important that parents understand three core concepts about HPV vaccination, said **Jill Roark**, MPH, a CDC health communication specialist. Roark spoke on “You Are the Key to HPV Cancer Prevention” at the May 2014 National Conference

on Immunization and Health Coalitions in Seattle.

Parents need to realize that the HPV vaccine is cancer prevention, understand that the HPV vaccine is best at 11 or 12 years old, and recognize the importance of their children receiving all three shots, said Roark. Recommend the HPV vaccine series the same way you recommend other adolescent vaccines, Roark suggested. She suggested this message: “Your child needs three shots today: HPV vaccine, meningococcal vaccine, and Tdap vaccine. Your child will get three shots today that will protect him/her from many cancers caused by HPV, as well as to prevent tetanus, diphtheria, pertussis, and meningitis.”

The “HPV vaccine is cancer prevention” message resonates strongly with parents, noted Roark. Try saying “HPV vaccine is very important because it prevents cancer. I want your child to be protected from cancer. That’s why I’m recommending that your daughter/son receive the first dose of the HPV vaccine series today.”

Parents might have questions. Try this message suggested by Roark: “HPV is so common that almost everyone will be infected at some point. It is estimated that 79 million Americans are infected, with 14 million new HPV infections each year. Most people infected will never know. Even if your child waits until marriage to have sex, or only has one partner in the future, he/she could still be exposed, if their partner already has been exposed.” Use handouts from the CDC for parents and teens on HPV vaccination, advised Roark. The handouts are available for free download at <http://1.usa.gov/1yFkTz5>.

The following evidence-based strategies have been shown to improve vaccination coverage in healthcare settings, said Roark: reminder/recall system, standing orders, provider assessment and feedback, using immunization information systems.

Roark pointed to two studies that indicate effec-

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## EXECUTIVE SUMMARY

According to new data from the Centers for Disease Control and Prevention’s (CDC’s) 2013 *National Immunization Survey — Teen*, the number of girls and boys ages 13-17 years receiving human papillomavirus (HPV) vaccine remains unacceptably low, despite a slight increase in vaccination coverage since 2012.

- Data indicates that there is a substantial gap between the number of teens receiving tetanus, diphtheria, and pertussis (Tdap) vaccine, and those receiving HPV vaccine.
- While about 57% of teen girls and 35% of teen boys received one or more doses of HPV vaccine, nearly 86% of adolescents had received one dose of Tdap vaccine.

tiveness of such strategies. In the first one, a randomized controlled trial in four private pediatric practices in metropolitan Denver was conducted to assess the effectiveness of reminder/recall for immunizing adolescents in private pediatric practice. Data indicated that such a reminder/recall system was successful at increasing immunization rates in adolescents.<sup>2</sup> In the second study designed to determine the impact of text message immunization reminder-recalls in an urban, low-income population, researchers found that text messaging improved immunization coverage in the study population.<sup>3</sup>

Healthcare professionals need to be familiar with all of the indications for HPV vaccine, make strong recommendations for receiving vaccine at ages 11 or 12, and be aware of, and interested in, systems that can improve practice vaccination rates, said Roark. “Studies consistently show that a strong recommendation from you is the single best predictor of vaccination,” Roark stated.

**Robert Hatcher, MD, MPH**, professor emeritus of gynecology and obstetrics at Emory University School of Medicine in Atlanta, asks, “If cervical cancer is a bad disease -- and it is most certainly a bad disease — then why isn’t the vaccine against cervical cancer being used? It is a safe vaccine. It is an effective vaccine. What is in the heads of boys, girls, young women, young men, and their parents that stops them from getting an effective vaccine against a common reproductive tract cancer?”

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1. Stokley S, Jeyarajah J, Yankey D, et al. Immunization Services Division, National Center for Immunization and Respiratory Diseases, CDC. Human papillomavirus vaccination coverage among adolescents, 2007-2013, and postlicensure vaccine safety monitoring, 2006-2014 — United States. *MMWR* 2014; 63(29):620-624.
2. Suh CA, Saville A, Daley MF, et al. Effectiveness and net cost of reminder/recall for adolescent immunizations. *Pediatrics* 2012; 129(6):e1437-1445.
3. Stockwell MS, Kharbanda EO, Martinez RA, et al. Text4Health: impact of text message reminder-recalls for pediatric and adolescent immunizations. *Am J Public Health* 2012; 102(2):e15-21. ■

### COMING IN FUTURE MONTHS

- Do bone drugs protect against breast cancer?
- HIV rates in the United States — Where do we stand?
- How to improve teen health visits
- Science eyes injectable’s potential

## 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.

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# CNE/CME QUESTIONS

1. What guidance did the World Health Organization present at the AIDS 2014 international conference regarding contraceptive use and HIV?
  - A. It placed no restrictions on the use of combined hormonal contraceptives (pills, patch, vaginal ring, or injectable) or progestin-only contraceptives (pills, injectable, or implants) for women with or vulnerable to HIV, but advises that women and couples at high risk of HIV infection who use progestin-only injectables be informed about and have access to HIV preventative measures, including male and female condoms.
  - B. It rated use of progestin-only injectables as a "2," a condition for which the advantages of using the method generally outweigh the theoretical or proven risks.
  - C. It rated use of progestin-only injectables as a "3," a condition for which the theoretical or proven risks usually outweigh the advantages of using the method.
  - D. It rated use of progestin-only injectables as a "4," a condition that represents an unacceptable health risk if the contraceptive method is used.
2. What are the two drugs in Truvada, the drug used in HIV pre-exposure prophylaxis?
  - A. Maraviroc and emtricitabine
  - B. Tenofovir disoproxil fumarate and emtricitabine
  - C. Tenofovir disoproxil fumarate and dapivirine
  - D. Maraviroc and ripilvirine
3. What is the drug being examined in a possible contraceptive microchip developed by MicroCHIPS?
  - A. Desogestrel
  - B. Drospirenone
  - C. Levonorgestrel
  - D. Norgestimate
4. What is the name of the emergency contraceptive pill that is available only online at \$20 per dose?
  - A. My Way
  - B. Take Action
  - C. Next Choice One Dose
  - D. AfterPill

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