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INSIDE

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New Analysis Looks at Pelvic Inflammatory Disease

Screen female patients for gonorrhea, chlamydia to reduce PID incidence

About 2.5 million American women have experienced pelvic inflammatory disease (PID), an often-symptomless infection of the reproductive tract that can cause infertility.[1] According to a new report from the CDC, the prevalence of a self-reported lifetime PID diagnosis was 4.4% among sexually experienced reproductive-aged women, equating to 2.5 million prevalent PID cases in women ages 18-44 years nationwide. Prevalence of a self-reported lifetime PID diagnosis varied by sexual behaviors and sexual health history and differed by race/ethnicity in women without a prior sexually transmitted infection (STI) diagnosis, the analysis indicates.[1]

"BECAUSE CHLAMYDIA AND GONORRHEA ARE OFTEN ASYMPTOMATIC AND MAY GO UNDIAGNOSED OR UNTREATED, SCREENING OF ALL SEXUALLY ACTIVE WOMEN YOUNGER THAN 25 IS CRITICAL FOR REDUCING THE BURDEN OF DISEASE AND POTENTIAL LONG-TERM CONSEQUENCES LIKE PID."
KRISTEN KREISEL, PHD

PID occurs when certain bacteria move from the vagina or cervix into reproductive organs. Many different microorganisms can cause PID, with *Chlamydia trachomatis* and *Neisseria gonorrhoeae* causing as many as half of these cases.[2,3]

What led researchers from the CDC's National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention to study the subject of PID prevalence?

PID often is associated with STIs, says the study's lead author, **Kristen Kreisel**, PhD, a CDC epidemiologist. With reported cases and rates of gonorrhea and chlamydia increasing in

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recent years, and because there is no single diagnostic test for PID, it is important to assess the burden of PID and specific factors that may increase the risk of PID for some women, she notes.

"Because chlamydia and gonorrhea are often asymptomatic and may go undiagnosed or untreated, screening of all sexually active women younger than 25 is critical for reducing the burden of disease and potential long-term consequences like PID," Kreisel says.

Sleepwalking into infertility is a problem that presents in a number of ways, says **Robert Hatcher**, MD, MPH, professor emeritus of gynecology and obstetrics at Emory University School of Medicine in Atlanta. Perhaps the most important is undiagnosed chlamydia infections that are damaging a young woman's fallopian tubes, he says.

A 2014 analysis of national data indicated chlamydia prevalence at 1.7% among U.S. residents ages 14-39 years. However, among sexually active women 14-24 years of age, chlamydia prevalence was 4.7% overall and 13.5% among non-Hispanic blacks.[4]

Evaluate Evidence

To assess the burden of self-reported PID in a nationally representative sample, researchers used data from the 2013-2014 National Health and Nutrition Examination Survey (NHANES). Starting in 2013, NHANES female participants 18-44 years of age were asked about a lifetime history of PID diagnosis. Based on these data, the estimated prevalence of self-reported lifetime PID was 4.4% in sexually experienced women of reproductive age (18-44 years).

The prevalence of self-reported lifetime PID was highest in women at increased risk, such as women reporting a previous STI diagnosis. When stratified by race/ethnicity and having a previous STI diagnosis, non-Hispanic black (black) and non-Hispanic white (white) women reporting a previous STI diagnosis had nearly equal self-reported lifetime PID prevalence (10.0% vs. 10.3%). However, the lifetime prevalence of PID among black women was 2.2 times higher than among white women if no previous STI was diagnosed (6.0% vs. 2.7%).

Researchers concluded these findings suggest that PID is prevalent and associated with previous STI diagnoses. Therefore, it is important for clinicians to screen female patients for chlamydia and gonorrhea to reduce the incidence of PID.[1]

"Given the potential for asymptomatic infections to lead to PID and the costs associated with treatment, it is important for clinicians to adhere to U.S. Preventive Services Task Force guidelines[5] for chlamydia and gonorrhea screening in an effort to decrease the PID burden in sexually experienced women of reproductive age nationwide," the researchers concluded.

Check Symptoms

Women suffering from PID can present with symptoms that could be characterized as mild all the way to severe and everything in between. Both patients and clinicians might not recognize these signs if they are mild. Because PID signs can exhibit nonspecifically, clinicians should consider urinary and gastrointestinal tract diseases as well other reproductive tract maladies in sexually active women complaining of pain in the

lower abdomen. However, clinicians must exclude pregnancy, including ectopic pregnancy, because PID has been known to happen concurrently with pregnancy.

So what should clinicians check? The CDC says symptoms include, but are not limited to:

- mild pelvic pain;
- increased vaginal discharge;
- irregular menstrual bleeding;
- pain with intercourse;
- painful and frequent urination;
- pelvic organ tenderness;
- uterine tenderness;
- adnexal tenderness; and
- inflammation.[6]

According to the CDC, clinicians should begin presumptive treatment for PID in sexually active young women and other women at risk for STIs if those patients complain about pelvic or lower abdominal pain, if the clinician cannot identify any other cause for the illness other than PID, and if the clinician discovers one or more of the following minimum clinical criteria on a pelvic exam: cervical motion tenderness or uterine tenderness or adnexal tenderness.

The CDC warns that the requirement that all three minimum criteria be present before starting empiric treatment could result in insufficient sensitivity for the diagnosis of PID. After deciding about treatment, clinicians should consider the patient's risk for STIs.

There are several other criteria clinicians can use to boost the specificity of the minimum clinical criteria and support a provider's PID diagnosis:

- Oral temperature greater than 101°F;
- Abnormal cervical mucopurulent discharge or cervical friability;
- Presence of abundant numbers of WBC on saline microscopy of vaginal fluid;
- Elevated erythrocyte sedimentation rate;
- Elevated C-reactive protein; and
- Laboratory documentation of cervical infection with *N. gonorrhoeae* or *C. trachomatis*.[6]

EXECUTIVE SUMMARY

According to a new report from the CDC, the prevalence of a self-reported lifetime diagnosis of pelvic inflammatory disease (PID) was 4.4% among sexually experienced reproductive-aged women, equating to 2.5 million prevalent PID cases in women ages 18-44 years nationwide.

- Pelvic inflammatory disease is an often-symptomless infection of the reproductive tract that can cause infertility.
- Women suffering from PID can present with many symptoms, from subtle to severe. Women and even clinicians may not recognize these signs if they are mild.

How to Treat?

How can clinicians treat PID once it is diagnosed? The CDC says broad-spectrum antibiotics will take care of likely pathogens, while other types of antibiotics can cure PID. However, the CDC warns that antibiotic treatment won't reverse any scarring that infection already has caused. This finding emphasizes the importance of immediate care if a woman experiences pelvic pain or other symptoms of PID. Timely antibiotic treatment could prevent severe damage to reproductive organs.

Refer to recommended treatment regimens in the 2015 STD Treatment Guidelines.[7] *(Check the guidance online at: http://bit.ly/2k86xqp.)* Counsel patients that although symptoms may alleviate before an infection is cured, patients should complete the prescribed course of medicine. Also, the patient's sex partner(s) should receive treatment to reduce reinfection risks, even if the partner has yet to report any symptoms. Sex partners may not complain of symptoms, but the CDC warns that the partners still may be infected with organisms that can lead to PID. ■

REFERENCES

1. Kreisel K, Torrone E, Bernstein K, et al. Prevalence of pelvic inflammatory disease in sexually experienced women of reproductive age – United States, 2013-2014. *MMWR Morb Mortal Wkly Rep* 2017;66:80-83.
2. Haggerty CL, Ness RB. Epidemiology, pathogenesis and treatment of pelvic inflammatory disease. *Expert Rev Anti Infect Ther* 2006;4:235-247.
3. Ness RB, Soper DE, Holley RL, et al. Effectiveness of inpatient and outpatient treatment strategies for women with pelvic inflammatory disease: Results from the Pelvic Inflammatory Disease Evaluation and Clinical Health (PEACH) Randomized Trial. *Am J Obstet Gynecol* 2002;186:929-937.
4. Torrone E, Papp J, Weinstock H; Centers for Disease Control and Prevention. Prevalence of Chlamydia trachomatis genital infection among persons aged 14-39 years — United States, 2007-2012. *MMWR Morb Mortal Wkly Rep* 2014;63:834-838.
5. LeFevre ML; U.S. Preventive Services Task Force. Screening for chlamydia

and gonorrhea: U.S. Preventive Services Task Force recommendation statement. *Ann Intern Med* 2014;161:902-910.
6. Centers for Disease Control and Prevention. Pelvic Inflammatory Disease. Fact sheet. Available at: http://bit.ly/2l303ts. Accessed Feb. 20, 2017.
7. Workowski KA, Bolan GA; Centers for Disease Control and Prevention. Sexually transmitted diseases treatment guidelines, 2015. *MMWR Recomm Rep* 2015;64(No. RR-3): 1-137.

First Steps Toward Bringing an OTC Pill to Market

Pharma company partners with nonprofit group to offer contraceptive in the United States

International drug manufacturer HRA Pharma in Paris is partnering with advocates and experts from Ibis Reproductive Health, a Cambridge, MA-based international nonprofit research organization for reproductive health, to start the process of bringing an over-the-counter (OTC) oral contraceptive to the U.S. market.

While it may take several years before the FDA actually approves a pill for use without a prescription, the first steps of the process are underway.

"It's past time we had an FDA-approved over-the-counter birth control pill, which would give people greater control over their lives and reproductive health regardless [of] their insurance status, age, or access to a clinic, and we're excited about this progress," says **Britt Wahlin**, vice president for development and public affairs at Ibis Reproductive Health. "We've built a broad coalition of healthcare providers and activists who are spearheading the effort to move a birth control pill over the counter, and we'll be working in the next several months and years to educate and raise awareness of the benefits of expanding access to birth control."

Teens and women in the United States are interested in using an OTC progestin-only pill (POP) if it were available.[1] In the first national survey to include teen perspectives and the first to explore interest in using an OTC POP, 39% of adults and 29% of teens reported likely POP use, with higher likelihood of use (46% of adults, 40% of teens) if the pill were fully covered by insurance. The median highest amount women were willing to pay per month was $15 among adults and $10 among teens.[1]

EXECUTIVE SUMMARY

International drug manufacturer HRA Pharma is partnering with advocates and experts from Ibis Reproductive Health, a U.S.-based nonprofit research organization for reproductive health, to start the process of bringing an over-the-counter (OTC) oral contraceptive to the U.S. market.

- It may take several years before the FDA actually approves a pill for use without a prescription. However, the first steps of the process are underway.
- Proponents plan to seek FDA approval for a progestin-only pill. Progestin-only pills, which do not contain estrogen, have even fewer contraindications and complications than combined oral contraceptives, making them an excellent candidate for the first OTC birth control pill.

Support for OTC access has been voiced by medical groups such as the American Academy of Family Physicians and the American College of Obstetricians and Gynecologists. *(To see more on the subject, read "Should oral contraceptives move over the counter? Readers speak out" in the February 2016 issue of* Contraceptive Technology Update *at: http://bit.ly/2cMLmsN.)* Ibis convened the OCs (Oral Contraceptives) OTC Working Group, which was formed in 2004 by researchers, advocates, and healthcare providers to work toward moving a pill over the counter to improve access to safe and highly effective contraception.

HRA Pharma and Ibis plan to seek FDA approval for a POP. This medication, which does not contain estrogen, exhibits even fewer contraindications than combined oral contraceptives, making it an excellent candidate for the first OTC birth control pill in the United States. A very small proportion of women present with health conditions that would make use of a POP harmful.[2]

"We'll continue to work closely with HRA Pharma to submit the necessary research to the FDA over the course of the approval process," Wahlin says.

Wahlin notes that a number of states are taking up legislation that would increase access and ensure that all birth control, including OTC methods, is covered by insurance and

affordable for more women.

Currently, pharmacists in California, Oregon, and Washington are allowed to prescribe the pill and other hormonal methods, including the birth control patch, the vaginal ring, and/or the shot.

"Medicaid reimburses pharmacists for their prescribing, too, so there is no out-of-pocket cost for those women," notes **Anita Nelson**, MD, professor and chair of the obstetrics and gynecology department at Western University of Health Sciences in Pomona, CA. "That is an important issue for OTC pills: Will insurance cover their cost?"

According to the OCs OTC Working Group, U.S. Sens. Joni Ernst, R-IA, and Cory Gardner, R-CO, and Reps. Barbara Comstock, R-VA, and Mia Love, R-UT, have reintroduced the Allowing Greater Access to Safe and Effective Contraception Act in the Senate and the House. This bill, originally introduced in 2015, would push forward the process for FDA review of an application for an OTC OC and provide incentives for manufacturers who are pursuing an OTC switch for an OC product. However, this bill does not address the need for insurance coverage for contraceptives and would provide incentives to manufacturers only if their products are available for women 18 years of age and older.

The OCs OTC Working Group also reports it has yet to learn of any reintroduction of the Affordability Is Access Act, which also was introduced in the House and Senate in 2015. This bill would guarantee insurance coverage of a future OTC OC.[3]

In state legislative action, New Hampshire lawmakers are considering allowing women 18 years of age or older to obtain pills without a prescription.

Legislation is pending in both the Senate and the House. A House committee recommended the formation of a study commission to consider the proposed policy and questions about protocols and implementation. The Senate bill would allow pharmacies, including mail-order pharmacies, to dispense oral contraceptives without a prescription after an initial consultation with a licensed or certified healthcare provider.[4] ■

REFERENCES

1. Grindlay K, Grossman D. Interest in over-the-counter access to a progestin-only pill among women in the United States. *Contraception* 2016:94:406.
2. OCs OTC Working Group. Moving the birth control pill over the counter in the United States. Fact sheet. July 2015. Available at: http://bit.ly/2lk8VzA. Accessed on Feb. 20, 2017.
3. OCs OTC Working Group. OCs OTC bill reintroduced in Congress. OCs OTC Working Group 2017. Jan. 23, 2017. Available at: http://bit.ly/2k2Xebh. Accessed on Feb. 20, 2017.
4. Tuohy D. Bill would dispense with prescription requirement for birth control pills. *New Hampshire Union Leader*, Feb. 2, 2017. Available at: http://bit.ly/2lkhgDs. Accessed on Feb. 20, 2017.

Female Condom Important Tool in Zika Prevention

Experts recommend discussing, making available this lesser-known contraceptive

When talking about the Zika virus with patients, clinicians mention that the disease can be transmitted through sex, which includes vaginal, anal, and oral sex, and the sharing of sex toys. But when it comes to transmission prevention, how often do clinicians include the female condom in the conversation?

The Zika virus can be transmitted through sex from a person who already has Zika to his or her partners. Both male and female condoms can reduce the chance of contracting Zika from sex. The CDC recommends that pregnant women not travel to areas with Zika. If a pregnant woman plans to travel to or lives in an area with Zika, she should speak with her healthcare provider about how to prevent Zika transmission. Women who are considering pregnancy and live in areas with reported outbreaks or the potential for outbreaks of Zika, along with their partners, should work with their healthcare providers to craft a pregnancy plan so the couple knows the risks and methods to reduce them, according to the CDC.

Since the onset of the Zika virus outbreak, The Female Health Company, a division of Veru Healthcare of Miami, has worked with national

and local partners to ensure that women are aware of and have access to female condoms as a method to help prevent the transmission of Zika through sexual contact.

"We have been putting the FC2 female condom into the prevention conversation," says **Judy Palmore**, MEd, senior education and partnership manager at The Female Health Company.

The Female Health Company has provided FC2 condoms for health department Zika kits, sent FC2 educational supplies and materials to help providers better educate their communities, and joined the discussions at several high-level decision-making meetings during which Zika prevention strategies were discussed and solidified. All of these efforts have been made to keep the FC2 condom on the "prevention radar," Palmore says.

Women cannot use the FC2 as a prevention tool unless they have access to and education about the product, Palmore notes. The Female Health Company is working with national and local partners to ensure FC2 education and product is available throughout communities, she adds.

Offer a Female-controlled Option

The FC2 condom consists of a nitrile (non-latex) sheath and outer ring, and a polyurethane inner ring. It includes no spermicidal additives, and is lubricated with a silicone-based lubricant inside and out.

The female condom is a user-friendly, dual-protection tool, preventing both HIV and other sexually transmitted infections, as well as unintended pregnancy. Data indicate its effectiveness is comparable to that of the male condom,[1-3] and research shows high acceptability among both women and men.[4-5] The female condom exhibits perfect use (5% of women experiencing unintended pregnancy in first year of use) and typical-use (21% of women experiencing unintended pregnancy in first year of use) failure rates, compared to 2% and 18% respective rates for the male condom.[1]

By offering the female condom, providers can provide to women the only dual-protection method they can use without their partner's active participation, providing women with control over safer sex and their health.

Get Out the Prescription Pad

Providers must include the condom message in providing family planning care in the context of Zika. A toolkit developed by the Office of Population Affairs is designed to help implement recent CDC recommendations for providing Zika-related care to nonpregnant women and men of reproductive age. *(Read more about the toolkit in the September 2016* Contraceptive Technology Update *article, "Pregnancy Prevention Toolkit Helps Prevent Spread of Zika Virus," available at: http://bit.ly/2kU5EE5. The toolkit is available for download at: http://bit.ly/2fCDkCv.)*

One important way to increase protection is to write prescriptions for the female condom. The Affordable Care Act only requires insurance plans to cover prescribed female contraceptives without cost-sharing, so writing a prescription for the method will remove the financial burden for those with insurance coverage. *(For more information, The Female Health Company offers a fact sheet available at: http://bit.ly/2khn37A.)*

For providers who may need a refresher course on the female condom, Palmore suggests viewing online video resources at: http://bit.ly/2l52NtV. The CDC offers an easy-reading handout on the method at: http://bit.ly/2keLUxB. ■

EXECUTIVE SUMMARY

The CDC advises that Zika can be passed through sex from a person who has Zika to his or her sex partners, with condoms reducing the chance of contracting Zika from sex. Such condoms include both male and female condoms.

- The FC2 female condom consists of a nitrile (non-latex) sheath and outer ring, and a polyurethane inner ring. It includes no spermicidal additives and is lubricated with a silicone-based lubricant inside and out. It provides protection from both unwanted pregnancy and sexually transmitted infections.
- By offering the female condom, providers can give women the only dual protection method that women can initiate and use without their partner's active participation.

REFERENCES

1. Trussell J. Contraceptive failure in the United States. *Contraception* 2011;83:397-404.
2. French PP, Latka M, Gollub EL, et al. Use-effectiveness of the female versus male condom in preventing sexually transmitted disease in women. *Sex Transm Dis* 2003;30:433-439.

3. Vijayakumar G, Mabude Z, Smit J, et al. A review of female-condom effectiveness: Patterns of use and impact on protected sex acts and STI incidence. *Int J STD AIDS* 2006;17: 652-659.
4. Fontanet AL, Saba J, Chandelying V, et al. Protection against sexually transmitted diseases by granting sex workers in Thailand the choice of using the male or female condom: Results from a randomized controlled trial. *AIDS* 1998;12:1851-1859.
5. Farr G, Gabelnick H, Sturgen K, Dorflinger L. Contraceptive efficacy and acceptability of the female condom. *Am J Public Health* 1994;84: 1960-1964.

Data: Cervical Cancer Worse for Specific U.S. Demographics

Recent findings may push healthcare providers to broaden and accelerate prevention efforts

New research from the Johns Hopkins Bloomberg School of Public Health indicates that U.S. black women are dying from cervical cancer at a rate 77% higher than previously thought, while white women are dying at a rate 47% higher.[1] The new figures reflect a change in how mortality rates are calculated, according to the researchers. By excluding women who have received hysterectomies, the researchers say these data give a more accurate indication of who is contracting cervical cancer and how providers can better prevent it.[1]

Estimates from the American Cancer Society indicate that in 2017, about 12,820 new cases of invasive cervical cancer will be diagnosed, while some 4,210 women will die from cervical cancer.[2] While cervical cancer was once one of the most common causes of cancer death for U.S. women, the cervical cancer death rate has gone down by more than 50% during the past 40 years. The main reason for this change lies in the increased use of the Pap test, which can find changes in the cervix before cancer develops.[2]

Cervical cancer is a preventable disease, and women should not be getting it or dying from it, says study leader **Anne Rositch**, PhD, MSPH, an assistant professor in the Department of Epidemiology at the Bloomberg School.

"Since the goal of a screening program is to ultimately reduce mortality from cervical cancer, then you must have accurate estimates within the population targeted by those programs — adult women with a cervix," Rositch said in a statement accompanying the study's publication. "These findings motivate us to better understand why, despite the wide availability of screening and treatment, older and black women are still dying from cervical cancer at such high rates in the United States."

Review the Findings

To conduct the study, researchers used estimates for deaths due to cervical cancer, stratified by age, state, year, and race, derived from the National Center for Health Statistics 2000-2012 county mortality data. Equivalently stratified data on the prevalence of hysterectomy for women 20 years of age or older from the Behavioral Risk Factor Surveillance System survey were used to remove women who were not at risk from the denominator. Age-specific and age-standardized mortality rates were computed, and trends in mortality rates were analyzed with

EXECUTIVE SUMMARY

New research from the Johns Hopkins Bloomberg School of Public Health indicates that U.S. black women are dying from cervical cancer at a rate 77% higher than previously thought, while white women are dying at a rate 47% higher.

- The new figures reflect a change in how mortality rates are calculated, according to the researchers. By excluding women who have had hysterectomies, the researchers say these data give a more accurate indication of who is contracting cervical cancer and how providers can help better prevent it.
- According to 2017 estimates from the American Cancer Society, an estimated 12,820 new cases of invasive cervical cancer will be diagnosed, while some 4,210 women will die from cervical cancer.

Joinpoint regression.

The analysis indicated a rate of cervical cancer mortality among black women older than 20 years of age at 5.7 per 100,000 each year and 3.2 per 100,000 each year in white women. When adjusted for hysterectomy, the rate in black women increased to 10.1 per 100,000 per year, a rate similar to less developed nations, and to 4.7 per 100,000 per year for white women.[1]

Black women are more likely to undergo hysterectomy surgery, and at younger ages, compared to white women, largely because black women are more susceptible to fibroids, which can require surgery to remove.[3] Placing all women in calculations of mortality underestimated the racial difference in death rates between black and white women by 44%, researchers estimated.[1]

"While trends over time show that the racial disparities gap has been closing somewhat, these data emphasize that it should remain a priority area," Rositch said. "Black women are dying of cervical cancer at twice the rate as white women in the United States and we need to put in place measures to reverse the trend."

Take Steps Toward Prevention

Virtually all cervical cancers are caused by infection with certain types of the human papillomavirus (HPV). Here are the American Cancer Society guidelines to help find cervical cancer early, and also to help find pre-cancers, which can be treated to keep cervical cancer from forming.

• All women should begin cervical cancer screening at age 21. Women younger than age 21 should not be screened regardless of the age of sexual initiation or other risk factors.

• Women between 21 and 29 years of age should receive a Pap test every three years. They should not be tested for HPV, unless it is needed after an abnormal Pap test result.

• Women 30-65 years of age should receive both a Pap test and an HPV test every five years. While this is the preferred approach, the American Cancer Society indicates it is acceptable to undergo a Pap test alone every three years.

• Women older than 65 years of age who have undergone regular screenings with normal results should not be screened for cervical cancer. Women who have been diagnosed with cervical cancer or pre-cancer should continue to be screened according to the recommendations of their doctor.

• Women who have had their uterus and cervix removed in a hysterectomy and have no history of cervical cancer or pre-cancer should not be screened.

• Women who have received the HPV vaccine still should follow the screening recommendations for their age group.

Women who are at high risk for cervical cancer may need to receive screenings more frequently. High-risk indicators include those infected with HIV, those who have received an organ transplant, or those who have been exposed to the drug DES.[5]

One simple way to prevent cervical cancer is to receive the HPV vaccine. To get the best benefit from the HPV vaccine, it should be administered at an early age. The American Cancer Society recommends that the vaccine series be started at 11 or 12 years of age, although it can be administered to girls and women up to 26 years of age. The CDC recommends that 11- to 12-year-olds receive two doses of HPV vaccine at least six months apart, rather than the previously recommended three doses.[4] Teens and young adults who start the series later, at 15-26 years of age, will continue to need three doses of HPV vaccine to protect against cancer-causing HPV infection. ■

REFERENCES

1. Beavis AL, Gravitt PE, Rositch AF. Hysterectomy-corrected cervical cancer mortality rates reveal a larger racial disparity in the United States. *Cancer* 2017; doi: 10.1002/cncr.30507.
2. American Cancer Society. What Are the Key Statistics About Cervical Cancer? Available at: http://bit.ly/2kUcifg. Accessed on Feb. 20, 2017.
3. Bower JK, Schreiner PJ, Sternfeld B, Lewis CE. Black-White differences in hysterectomy prevalence: The CARDIA study. *Am J Public Health* 2009;99:300-307.
4. Iversen OE, Miranda MJ, Ulied A, et al. Immunogenicity of the 9-valent HPV vaccine using 2-dose regimens in girls and boys vs a 3-dose regimen in women. *JAMA* 2016;316:2411-2421.
5. American Cancer Society. What You Need to Know About Testing for Cervical Cancer. Available at: http://bit.ly/2lidoBl. Accessed Feb. 21, 2017.

Male Contraception Moving Forward

New funding will allow researchers to expand on current knowledge

Approximately 30% of couples worldwide rely on male contraceptive methods, namely condoms and vasectomy.[1] Shortcomings of these methods have led to efforts to develop new types of male contraceptives. However, when it comes to development of a male contraceptive, scientists have to grapple with the physiology of sperm production. Approaches include:

- preventing sperm from reaching the egg by physical barriers (condoms, vasectomy, and experimental vas occlusion methods);
- stopping sperm production (experimental hormonal and nonhormonal methods); or
- killing or inhibiting the function of sperm or the sperm's ability to bind the egg after ejaculation (spermicides, experimental antimotility agents).[2]

Novel approaches will get a boost with new funding to be administered by the Durham, NC-based Male Contraception Initiative. This nonprofit organization will deliver $500,000 for up to three years to at least one research project focused on the development of a new, reversible male contraceptive. The funding has been made available through an anonymous donor.

"What really sets this request for proposal apart is that this funding is exclusively for male contraceptive research," said Executive Director **Aaron Hamlin**, MPH. "This is long overdue."

Funding for the first year will be for up to $175,000, with monies beyond the first or second year to be dispersed contingent on satisfactory progress and availability of funds.

Projects that may be greenlighted include those that focus on late stages of sperm maturation, sperm function, or sperm transport. Proposals that look to potentially problematic routes, such as hormones, early-stage sperm development, or immunological approaches, will not be considered.

Grant recipients will be required to provide a plan ensuring public sector pricing. All publications stemming from funded research will be required to be in public-access journals or to pay a journal fee to ensure public access. All letters of interest were to be filed with the initiative by March 1, 2017.

Vasalgel Eyed in Early Research

In current research news, scientists are now looking at Vasalgel, a high molecular weight polymer consisting of styrene-alt-maleic acid, dissolved in dimethyl sulfoxide. The polymer forms a hydrogel after injection into the vas deferens, creating a blockage to the passage of sperm. Researchers believe that fluids are able to pass slowly through the gel, reducing back-pressure on the epididymis.

In a study just released online, use of Vasalgel was examined in 16 adult male rhesus monkeys. After a one-week recovery, each male was returned to outdoor group housing, which included three to nine intact, breeding females with a successful reproductive history. All males were monitored for at least one breeding season; seven of the 16 were almost continually housed with females for two years. There were no conceptions after Vasalgel injections, data indicate. Complications were minor and included one incident of incorrect placement of Vasalgel into the vas deferens and the development of a sperm granuloma in one animal. Unilateral vasectomy was performed in each subject without further complication.[2]

With proof of efficacy in monkeys and rabbits now published,[3] preparations are underway for the

EXECUTIVE SUMMARY

Fresh approaches to male contraception will receive a boost with funding to be administered by the Male Contraception Initiative. This nonprofit organization will deliver $500,000 for up to three years to at least one research project focused on the development of a new, reversible male contraceptive. The funding has been made available through an anonymous donor.

- Projects that may be greenlighted include those that focus on late stages of sperm maturation, sperm function, or sperm transport. Proposals that look to potentially problematic routes, such as hormones, early-stage sperm development, or immunological approaches, will not be considered.
- Approximately 30% of couples worldwide rely on male contraceptive methods, namely condoms and vasectomy. Shortcomings of these methods have led to efforts to develop new types of male contraceptives.

first clinical trial in humans. If trials are successful, Parsemus Foundation, a nonprofit organization based in Berkeley, CA, plans for Vasalgel to be available worldwide, with a tiered international pricing structure to ensure affordability to all men. The first study will explore effectiveness; later studies will attempt reversal (flushing the gel to restore sperm flow), which has been demonstrated in rabbits, but not yet in larger animals, according to the foundation.

What About a Shot?

Scientists still look to a possible contraceptive injection for men. Data from a Phase II study, which focused on injections of 200 milligrams of a long-acting progestogen, norethisterone enanthate, and 1,000 milligrams of a long-acting androgen, testosterone undecanoate, indicate the combination was successful. However, frequency of side effects was relatively high, which included: acne, injection site pain, increased libido, and mood disorders. Because of these adverse events, the study was terminated before its completion.[5] *(*Contraceptive Technology Update *reported on the study; see the January 2017 article, "Data Indicate Male Birth Control Shot May Be Effective," available at: http://bit.ly/2kxhPWk.)*

Given the efficacy and acceptability of the method, there continues to be a strong rationale for continuing research, despite the side effects, researchers believe. ■

REFERENCES

1. Page ST, Amory JK, Bremner WJ. Advances in male contraception. *Endocr Rev* 2008;29:465-493.
2. Amory JK. Male contraception. *Fertil Steril* 2016;106:1303-1309.
3. Colagross-Schouten A, Lemoy MJ, Keesler RI, et al. The contraceptive efficacy of intravas injection of Vasalgel™ for adult male rhesus monkeys. *Basic Clin Androl* 2017;27:4.
4. Waller D, Bolick D, Lissner E, et al. Azoospermia in rabbits following an intravas injection of Vasalgel™. *Basic Clin Androl* 2016;26:6.
5. Behre HM, Zitzmann M, Anderson RA, et al. Efficacy and safety of an injectable combination hormonal contraceptive for men. *J Clin Endocrinol Metab* 2016;101:4779-4788.

Examining Women's Bones During Menopause May Help Prevent Fractures

New research suggests that bones age in very different ways, setting the groundwork for new ways to identify women at risk of bone fractures far in advance.[1]

Bone fragility is a concern for women as they age. Factors that may alter bone structure and mass during aging are not well understood. The new study, which examined the bone traits of 198 midlife women transitioning through menopause for 14 years, focused on identifying women who will experience bone fragility well in advance of fracture.

Current identification for bone fragility takes place when the patient is around 65 years of age, says the study's lead author, **Karl Jepsen**, PhD, associate chair of research and professor of orthopaedic surgery at The University of Michigan.

"We were hopeful that this study would give us an opportunity to identify those patients as early as 30 years before they fracture based on their bone traits," Jepsen said in a statement accompanying the study's publication. "That means we would have an opportunity to intervene before the fracture happens, instead of after the fact."

EXECUTIVE SUMMARY

Researchers have determined that bones age in very different ways, setting the groundwork for new ways to identify women at risk of bone fractures far in advance.

- Bone fragility is a concern for women as they age. Factors that may alter bone structure and mass during aging are not well understood.
- The new study, which examined the bone traits of 198 midlife women 42-52 years of age who were followed for 14 years, focused on identifying women who will experience bone fragility well in advance of fracture.

Check the Data

Researchers studied women who participated in the Study of Women's Health Across the Nation, a multisite longitudinal, epidemiologic study designed to examine the health of women during their middle years. Women who enrolled had to be 42-52 years of

age, present with an intact uterus, and experienced at least one menstrual period in the previous three months. In addition, the subjects underwent approximately 14 annual study visits that included measurements, such as bone density scans, of their hip and spine. The research team looked at dual-energy X-ray absorptiometry (DXA) images of the hip during the 14-year period to determine what changes, if any, were occurring in the study subjects.

The researchers observed that women experienced different changes in bone mineral content and bone area within the hip, yet incurred similar changes in areal bone mineral density. In addition, the change in bone mineral content and bone area correlated negatively with baseline external size of the neck of the femur just below the ball of the hip joint. Bone mineral density measured by DXA does not represent the volumetric density (grams per cubic centimeter), but rather the areal density (grams per square centimeter).

This finding means that the women showed similar changes in areal bone mineral density for different structural and biological reasons, Jepsen explains.

"Essentially, we found that women with narrow femoral necks showed smaller changes in bone mineral content, but greater increases in bone area compared to women with wide femoral necks who showed greater losses in bone mineral content, but didn't appear to be experiencing compensatory increases in bone area," he says.

This finding is opposite to expectations that periosteal expansion acts to mechanically offset bone loss, the researchers noted. Thus, changes in femoral neck structure and mass during menopause vary widely among women and are predicted by baseline external bone size but not areal bone mineral density (grams per square centimeter).[1]

What's the Next Step?

The U.S. Preventive Services Task Force currently recommends screening for osteoporosis in women 65 years of age and older and in younger women whose fracture risk is equal to or greater than that of a 65-year-old white woman who has no additional risk factors.[2]

Guidance from the American College of Obstetricians and Gynecologists (ACOG) calls for a fracture risk assessment tool (FRAX), developed by the World Health Organization, as an addition to screening. FRAX, which can help predict a person's risk of bone fracture in the next decade, can be used to determine if a patient is at high risk for fracture if her initial scan indicates low bone mass. The tool considers risk factors such as age, body mass index, fracture history, alcohol consumption, smoking habits, rheumatoid arthritis, and other secondary causes of osteoporosis. In the absence of new risk factors, ACOG says DXA screening should not be performed more than every two years. Further, ACOG says FRAX should be used annually to monitor the effect of age on fracture risk.[3]

Anita Nelson, MD, professor and chair of the obstetrics and gynecology department at Western University of Health Sciences in Pomona, CA, says that clinical trials will be needed to see if it is appropriate to treat women earlier than what is prescribed now because they have been identified as being higher risk.

Jepsen says the current study demonstrates for the first time that scientists can track bone changes happening individually in women during menopause. He looks to these results as a stepping stone for additional research.

"With further research, our goal is to use simple bone traits to identify those women that may benefit from early intervention when it comes to bone fragility, instead of the current strategy, which treats individuals after they have lost appreciable bone mass and strength," he adds. ■

REFERENCES

1. Jepsen KJ, Kozminski A, Bigelow EM, et al. Femoral neck external size but not aBMD predicts structural and mass changes for women transitioning through menopause. *J Bone Miner Res* 2017; doi: 10.1002/jbmr.3082.
2. Nordin C. Screening for osteoporosis: U.S. Preventive Services Task Force recommendation statement. *Ann Intern Med* 2011;155:276.
3. Committee on Practice Bulletins-Gynecology, The American College of Obstetricians and Gynecologists. ACOG Practice Bulletin N. 129. Osteoporosis. *Obstet Gynecol* 2012;120:718-734.

COMING IN FUTURE MONTHS

- Is early menarche signal of premature menopause?
- Cervical cancer screening: HPV testing gains proponents
- Mammograms – Women skip screening after initial false-positive results
- Uterine cancer – Weight loss tied to lower risk, data suggest

CONTRACEPTIVE TECHNOLOGY UPDATE®

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CME/CE QUESTIONS

1. **Which one of these symptoms is *not* a signal to begin empiric treatment for pelvic inflammatory disease, according to the CDC?**

   a. Cervical motion tenderness
   b. Uterine tenderness
   c. Adnexal tenderness
   d. Pain with intercourse

2. **What form of oral contraception will most likely become the first over-the-counter pill in the United States?**

   a. A progestin-only pill
   b. A low-dose estrogen combined pill
   c. A combined pill with a third-generation progestin
   d. A triphasic combined pill

3. **What is the material used in the FC2 condom?**

   a. Latex
   b. Nitrile
   c. Polyethylene terephthalate
   d. Polypropylene

4. **The CDC now recommends what dosing schedule for 11- to 12-year-olds for HPV vaccination?**

   a. Receive three doses of HPV vaccine at least six months apart
   b. Receive three doses of HPV vaccine at least three months apart
   c. Receive two doses of HPV vaccine at least six months apart
   d. Receive two doses of HPV vaccine at least three months apart

CME/CE OBJECTIVES

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

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

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A SUPPLEMENT TO CONTRACEPTIVE TECHNOLOGY UPDATE

Are Young Males Getting Needed HPV Vaccination?

Vaccine programs have long been available, yet U.S. men don't receive the necessary shots

Although overall genital human papillomavirus (HPV) infection prevalence appears to be widespread among all age groups of U.S. males, HPV vaccination coverage is low, according to a recent analysis of national data.[1]

HPV infection is the most common sexually transmitted infection in the United States and is a cause of several types of cancers.[2] Although male HPV vaccination programs have been available to the public since 2009, U.S. vaccination rates remain low. National data indicate that as of 2014, 42% of boys have received at least one round of the HPV vaccine, while 22% have completed the entire regimen.[3]

To conduct the current analysis, researchers from the Womack Army Medical Center in Fort Bragg, NC, used data for 1,868 men from the 2013-2014 National Health and Nutrition Examination Survey (NHANES). What prompted the research team to analyze these particular data, a nationally representative sample of the U.S. non-institutionalized, civilian population?

"Our research team was familiar with NHANES data in looking at female HPV prevalence before and after [the] HPV vaccination era," says **Jasmine Han**, MD, lead author of the current research paper. "It is a well-known data source to many researchers, because it is a well-designed systematic survey, conducted by CDC, that represents the U.S. population."

ALTHOUGH HPV INFECTION PREVALENCE APPEARS TO BE WIDESPREAD AMONG ALL U.S. MALES, VACCINATION COVERAGE IS LOW, ACCORDING TO A RECENT ANALYSIS.

Review the Results

To perform the analysis, researchers studied men 18-59 years of age who were examined in mobile exam centers during the NHANES 2013-2014 cycle. Scientists extracted DNA from self-collected penile swab specimens, and performed HPV genotyping by polymerase chain reaction amplification. Demographic and vaccination information was gathered via self-report during home-based standardized interviews, with binary multivariable logistic regression used to estimate the odds of HPV infection.

During the study period, the analysis indicated the overall genital HPV infection prevalence was 45.2% (95% confidence interval [CI], 41.3%-49.3%). The infection prevalence with at least one high-risk HPV subtype defined by DNA testing was 25.1% (95% CI, 23.0%-27.3%). In vaccine-eligible men, the prevalence of infection with at least one HPV strain targeted by the HPV quadrivalent vaccine and HPV 9-valent vaccine was 7.1% (95% CI, 5.1%-9.5%) and 15.4% (95% CI, 11.7%-19.6%), respectively. Among vaccine-eligible men, the HPV vaccination

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coverage was 10.7% (95% CI, 7.8%-14.6%).[1]

What's the Next Step?

The CDC recommends two doses of HPV vaccine at least six months apart for 11- to 12-year-olds, rather than the previously recommended regimen of three doses. Patients who start the vaccine regimen later (15-26 years of age) still will require three doses of HPV vaccine to protect against HPV infection. The FDA has approved a two-dose schedule for the 9-valent HPV vaccine (Gardasil 9) for patients 9-14 years of age. The CDC encourages clinicians to implement the two-dose schedule right away to protect their young patients. *(*Contraceptive Technology Update *reported on the issue; see "Just Two HPV Shots Recommended for Younger Teens," January 2017, available at: http://bit.ly/2li1dma.)*

Preteens generally receive the HPV vaccine along with whooping cough and meningitis vaccines. Two doses of HPV vaccine administered at least six months apart for patients 11 and 12 years of age will ensure long-lasting protection against HPV, according to the CDC. Patients 13-14 years of age also can receive the HPV vaccine on the two-dose schedule, the agency notes.

In January, the 69 National Cancer Institute (NCI)-designated cancer centers issued a consensus statement fully endorsing the revised recommendations. According to the statement, HPV vaccination represents a "rare opportunity" to prevent the nearly 40,000 cases of HPV-associated cancers diagnosed annually in the United States.[4]

RESEARCHERS RECOMMEND TRAINING HEALTHCARE PROVIDERS TO USE PRESUMPTIVE ANNOUNCEMENTS TO BOOST HPV VACCINATIONS.

Research indicates there are several barriers to improving vaccination rates, including few strong recommendations from providers as well as parents not understanding the HPV vaccine's protective effects against not only HPV but also certain cancers. To overcome these barriers, NCI-designated cancer centers organized an ongoing series of national summits to share new research, discuss best practices, and identify collective action toward improving vaccination rates.

"We encourage all healthcare providers to be advocates for cancer prevention by making strong recommendations for childhood HPV vaccination," the consensus statement reads. "We ask providers to join forces to educate parents, guardians, and colleagues about the importance and benefits of HPV vaccination."

To increase HPV vaccine uptake, researchers at the University of North Carolina at Chapel Hill evaluated the effectiveness of training healthcare providers to presumptively announce the vaccine or engage in conversations with families. Study results indicate that only the announcement training produced a meaningful increase in vaccine initiation.[5]

In 2015, researchers conducted a six-month randomized, controlled trial made up of 30 pediatric and family medicine clinics in central North Carolina. Clinics either received no training (control group), announcement training, or conversation training. The training in announcements consisted of educating providers to share brief statements that assumed parents would be ready to vaccinate. Clinicians use similar presumptive announcements for other early childhood vaccines, according to the researchers.

The conversations training consisted of conditioning providers to talk with parents in an open-ended way that possibly could build rapport and perhaps increase their openness to HPV vaccination.

After completing the training, the North Carolina Immunization Registry collected data on 17,173 patients (11-12 years of age) who visited participating healthcare facilities dur-

EXECUTIVE SUMMARY

There is widespread genital human papillomavirus (HPV) infection among all age groups of U.S. males; tellingly, HPV vaccination coverage is low among this population, according to a recent analysis of national data.

- HPV infection is the most common sexually transmitted infection in the United States. The infection also can spawn several types of cancer.
- Although male HPV vaccination programs have been available to the public since 2009, participation rates remain low. U.S. data indicate that as of 2014, 42% of boys have received at least one HPV vaccine injection, and 22% have completed the entire regimen.

ing the next six months. At the end of the study period, researchers noted increases in HPV vaccination coverage were 5.4% higher for patients who received announcement training compared to patients in control clinics. The coverage rates did not change in clinics that received the conversation training, the researchers said.[5]

Based on these results, researchers recommended training healthcare providers to use presumptive announcements as a way to increase HPV vaccination among young patients.

Use CDC Resources

In talking to parents about the HPV vaccine, the CDC suggests clinicians present information about the HPV vaccine in the fashion and at the same time as all other adolescent vaccines. Practitioners could lead with a statement such as, "Now that your son is 11, he is due for vaccinations today to help protect him from meningitis, HPV cancers, and pertussis." CDC experts urge clinicians to remind their patients' parents of the follow-up shots their children need and ask them to make appointments before departing. *(This provider fact sheet is available at: http://bit.ly/2ilIebN.)*

Parents may be interested in the HPV vaccine, but still ask questions or express doubt. Some parents may need further reassurance from clinicians. To help answer questions and reassure worried parents and patients, the CDC offers more resources at: http://bit.ly/2iEChTn.

REFERENCES

1. Han JJ, Beltran TH, Song JW, et al. Prevalence of genital human papillomavirus infection and human papillomavirus vaccination rates among US adult men: National Health and Nutrition Examination Survey (NHANES) 2013-2014. *JAMA Oncol* 2017; doi: 10.1001/jamaoncol.2016.6192. [Epub ahead of print.]
2. Weinstock H, Berman S, Cates W Jr. Sexually transmitted diseases among American youth: Incidence and prevalence estimates, 2000. *Perspect Sex Reprod Health* 2004;36:6-10.
3. Reagan-Steiner S, Yankey D, Jeyarajah J, et al. National, regional, state, and selected local area vaccination coverage among adolescents aged 13-17 years — United States, 2014. *MMWR Morb Mortal Wkly Rep* 2015;64:784-792.
4. NCI-designated Cancer Centers Endorse Updated HPV Vaccination Recommendations. Available at: http://bit.ly/2lhbyy3. Accessed on Feb. 21, 2017.
5. Brewer NT, Hall ME, Malo TL, et al. Announcements versus conversations to improve HPV vaccination coverage: A randomized trial. *Pediatrics* 2017; doi: 10.1542/peds.2016.2016-1764.

Online Risk Calculator May Refine PrEP Use

At least for one population in Los Angeles

An online risk calculator created by researchers at the UCLA Fielding School of Public Health and the Los Angeles LGBT Center may allow more men who have sex with men (MSM) to make a better decision about whether pre-exposure prophylaxis (PrEP) is right for them.[1]

PrEP is a mix of the anti-HIV drugs emtricitabine and tenofovir disoproxil fumarate (better known as Truvada). Currently, this combination drug is the only medication approved for HIV PrEP. Studies have shown that PrEP reduces HIV incidence by 92% in HIV-negative people who are at high risk for HIV, including MSM.[2,3] Patients who use PrEP must take the drug daily and visit their healthcare providers every three months for follow-up. Although PrEP can reduce the risk of HIV infection significantly if taken daily, patients who use it should take even further precautions, such as using condoms, to reduce risk.

EXECUTIVE SUMMARY

An online risk calculator developed by researchers at the UCLA Fielding School of Public Health and the Los Angeles LGBT Center may allow more men who have sex with men to make a better decision before determining whether pre-exposure prophylaxis (PrEP) is right for them.

- PrEP consists of the anti-HIV drugs emtricitabine and tenofovir disoproxil fumarate (Truvada), which is the only medication currently approved for HIV PrEP.
- Studies have shown that PrEP reduces HIV incidence by 92% in HIV-negative patients who are at high risk for HIV, including men who have sex with men.

The CDC recommends PrEP for gay or bisexual men who have engaged in condomless anal sex or have been diagnosed with a sexually transmitted infection in the past six months. The CDC also recommends PrEP for HIV-negative MSM and who are in a relationship with an HIV-positive partner. *(Refer to CDC guidelines on this matter, issued in 2014, at: http://bit.ly/2iLOPMa.)*

New research suggests that the CDC guidelines may not be stringent enough because the guidelines omit important characteristics that could put a patient at greater risk for contracting the virus that causes AIDS. However, according to researchers, the new online risk calculator may fill the gap.

"To the best of our knowledge, this PrEP calculator is the first of its kind to be based on real-world data," said **Robert Weiss**, MD, PhD, co-author of the study and a professor of biostatistics at the Fielding School in a statement accompanying the research publication. "We hope that our PrEP calculator will allow more MSM to make a more-informed decision before deciding whether or not PrEP is right for them."

Check the Data

The Los Angeles LGBT Center is one of the largest HIV testing providers in Los Angeles County for gay, bisexual, and MSM. The center serves approximately 13,000 individual clients annually, according to lead author **Matthew Beymer**, PhD, MPH, a post-doctoral scholar in the department of medicine, division of infectious diseases, at the David Geffen School of Medicine at UCLA.

Researchers scrutinized data on various behavioral risk factors for HIV at each visit among center clients between January 2009-June 2014. Scientists examined behavioral data and HIV test results to determine characteristics of MSM who were HIV-negative when the study began and then tested positive for HIV during a follow-up visit, compared to subjects who continued to test negative for HIV through their follow-ups. About 9,480 men were included in the study.

NEW RESEARCH INDICATES CURRENT CDC GUIDELINES MAY NOT BE STRINGENT ENOUGH BECAUSE THE GUIDELINES OMIT IMPORTANT CHARACTERISTICS THAT COULD PUT A PATIENT AT GREATER RISK FOR CONTRACTING AIDS.

Researchers developed an HIV-risk algorithm for recommending PrEP to clients of the Los Angeles LGBT Center. Unlike the CDC guidelines, these researchers asked about several factors that could put a subject at higher risk for infection, such as substance use, number of sex partners, age, race or ethnicity, and other partner-level factors.

Results suggest that if all individuals who scored 5 or higher on the test's risk scale had been administered PrEP, then 75% of HIV infections would be avoided during follow-up. These findings indicate the model performed better than the CDC guidelines since the researchers who created the model studied behaviors not considered in the current CDC recommendations.[1]

Researchers admitted that one limitation of the calculator may be its inapplicability to heterosexual and transsexual patients, those who use drugs by injection, or people who live outside Los Angeles. Also, the researchers noted the calculator does not take into account situations in which HIV-negative men are in long-term relationships with HIV-positive men.

What's the next step? Scientists say it is to evaluate whether MSM respond positively to the calculator as they assess their need to take PrEP. Even after receiving education about PrEP, 25% of center clients still remain unsure about their PrEP candidacy, researchers said. ■

REFERENCES

1. Beymer MR, Weiss RE, Sugar CA, et al. Are Centers for Disease Control and Prevention guidelines for pre-exposure prophylaxis specific enough? Formulation of a personalized HIV risk score for pre-exposure prophylaxis initiation. *Sex Transm Dis* 2017;44:48-56.
2. Grant RM, Lama JR, Anderson PL, et al; iPrEx Study Team. Preexposure chemoprophylaxis for HIV prevention in men who have sex with men. *N Engl J Med* 2010;363:2587-2599.
3. Thigpen MC, Kebaabetswe PM, Paxton LA, et al; TDF2 Study Group. Antiretroviral preexposure prophylaxis for heterosexual HIV transmission in Botswana. *N Engl J Med* 2012;367:423-434.