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Point-of-care tests eyed in stemming rise in STDs

Search is on for accurate, efficient tests to reduce transmission

What is your facility's protocol when it comes to testing for sexually transmitted diseases (STDs)? It probably involves patient testing, with treatment provided after test results are completed. What happens, though, if tests results aren't available at the time of the initial patient visit? Some patients might never return for results and subsequently will miss out on needed care.

It's time to change the rules when it comes to testing: Five of the top 10 reportable diseases in the United States are STDs.[1] The burden of disease is greatest in young people. Statistics estimate that one in two sexually active people will contract an STD by the time they turn 25.[2] Are clinicians stepping up their game when it comes to STD testing? A 2002 national survey indicates "no" — less than one-third of U.S. physicians said they routinely screen for such infections.[3]

Point-of-care (POC) testing allows clinicians to provide immediate and confidential test results and treatment, state authors of a new review of current STD tests.[4] The tests also provide a teachable moment so clinicians can provide immediate patient feedback that might impact their risk

EXECUTIVE SUMMARY

Point-of-care testing allows clinicians to provide immediate and confidential test results and treatment of sexually transmitted diseases. The tests also provide a teachable moment so clinicians can provide immediate patient feedback that might impact their risk behaviors.

- Clinicians look at sensitivity, which is the proportion of infected people who have a positive test, and specificity, which is the proportion of uninfected people who have a negative test, in looking at a test's characteristics.
- Use World Health Organization criteria for judging point of care tests: the ASSURE (affordable, sensitive, specific, user-friendly, rapid and robust, equipment-free, and delivered) criteria.

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behaviors. For these reasons, POC tests may be of great importance for the care of adolescents and young adults, the authors state.[4] Effective communication of results can increase patient understanding and compliance with risk reduction strategies, which might affect the STD epidemic.[5]

In looking at a test's characteristics, clinicians look at sensitivity (the proportion of infected people who have a positive test) and specificity (the proportion of uninfected people who have a negative test). While point-of-care tests might be less sensitive than other lab tests, when return rates are below a certain rate, a less sensitive test with immediate treatment might treat more cases.[6]

How can clinicians evaluate point-of-care tests when it comes to STD detection? Authors of the current review of POC tests developed a scoring system based on the ASSURED criteria set forth by the World Health Organization's STI Diagnostics Initiative. ASSURED is an acronym for STI diagnostics that meet specific criteria:

- Affordable by those at risk for infection;
- Sensitive — few false negatives;
- Specific — few false positives;
- User-friendly — simple to perform (3-4 steps required with minimal training necessary);
- Rapid and robust — to enable treatment at first visit (rapid) and not require refrigerated storage (robust);
- Equipment-free — easily collected noninvasive specimens such as saliva and urine;
- Delivered to end users.[4]

Look at HIV tests

Clinicians might be most familiar with rapid tests for HIV. A survey conducted by the National Alliance of State and Territorial AIDS Directors shows that 94% of health departments use rapid HIV testing in conjunction with health department-supported HIV testing programs.[7] *(*Contraceptive Technology Update *reported on the increase in testing. See "Research focuses on rapid HIV testing," November 2008, p. 124.)* Certain tests are Clinical Laboratory Improvements Amendments (CLIA) waived, which categorizes them as simple tests.

The following rapid HIV tests are approved by the Food and Drug Administration (FDA) and are CLIA waived on the medium named:

- OraQuick Rapid HIV-1/2 Antibody Test (OraSure Technologies, Bethlehem, PA), oral fluid and whole blood (finger stick or venipuncture);
- Uni-Gold Recombigen HIV (Trinity Biotech, Dublin, Ireland), whole blood (finger stick or venipuncture);
- Clearview HIV 1/2 Stat-Pak (Inverness Medical, Princeton, NJ), whole blood (finger stick or venipuncture);
- Clearview Complete HIV 1/2 (Inverness Medical, Princeton, NJ), whole blood (finger stick or venipuncture).[8]

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Chembio Diagnostics, a New York-based company that develops, manufactures, licenses, and markets proprietary rapid diagnostic tests, developed the technology behind the Clearview HIV tests, which are marketed by Inverness Medical. The company is developing has developed a rapid oral fluid HIV test, says **Larry Siebert**, Chembio president. The test is based on the company's patented Dual Path Platform technology. The trial is under way in the United States, he confirms.

Chembio also is testing a unique combination screen and confirm point-of-care test for syphilis. At the current time, no rapid test is available in the United States [POC chlamydia tests are available in Europe] for detecting the STD.

Public health officials are zeroing in syphilis. Data released at the 2010 National STD Prevention Conference shows the rate of primary and secondary syphilis among men who have sex with men (MSM) is more than 46 times that of other men and more than 71 times that of women.[9] The new analysis reports the range as 91-173 cases per 100,000 MSM versus two per 100,000 other men and one per 100,000 women.[9]

Chembio is working with the CDC in developing the Dual Path Platform Syphilis Screen and Confirm test, says Siebert. The test is designed to detect both of the markers that together offer an indication of a confirmed case of active untreated syphilis. The company has identified U.S. clinical sites for study of the test and forecasts study initiation at the end of the second quarter of 2010, says Siebert.

How about chlamydia?

Screening with nucleic acid amplification tests is recommended to decrease levels of chlamydia infection in young women; however, such tests are costly and time-consuming.

The FDA has approved three rapid tests for detecting chlamydia infection: the BioStar optical immunoassay (no longer available), Clearview Chlamydia (Inverness Medical), and QuickVue (Quidel, San Diego, CA).[4] In the current review, the three tests are listed as moderately complex to perform and demonstrate sensitivity rates of 25%-65% compared with nucleic acid amplification tests.[4]

One rapid test that might hold promise is the Chlamydia Rapid Test, developed by scientists at Diagnostics for the Real World and the University of Cambridge, both in Cambridge England. The test, a urine-based screening tool that can be used with minimal training, is available in Europe, but not in the United States. *(In* CTU*, see "Rapid chlamydia test for men examined," November 2009, p. 125; "New research focuses on rapid chlamydia test," February 2008 STD Quarterly supplement, p. 3; and "Research eyes rapid testing of chlamydia," March 2004, p. 31.)*

Researchers are examining other chlamydia rapid tests. Preliminary research on two potential tests indicate disappointing sensitivities for both devices for cervical and vaginal samples.[10] Specificity of one device was poor but was very good for the other, researchers report. A larger sample size might provide more reliable estimates of test performance in high and low risk women, they conclude.[10]

There are other tests in the pipeline which are significantly promising, says **Charlotte Gaydos**, MS, MPH, DrPH, professor of medicine in the Division of Infectious Diseases at Johns Hopkins University (JHU) and principal investigator of the Center for Point-of-Care Tests for Sexually Transmitted Diseases funded by the National Institute of Biomedical Imaging and Bioengineering. One such test involves a microwave-accelerated, metal–enhanced, fluorescence-based assay. It is being developed by the Center for Point-of-Care Tests for Sexually Transmitted Diseases, says Gaydos. Other tests in the pipeline include cartridge based amplification tests, which are simple to perform and should have much higher sensitivity than available tests, says Gaydos.

"Trials for these products are currently under way," says Gaydos. "Future months show exciting progress for POC diagnostics for sexually transmitted infections."

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Hormonal birth control: more than contraception

The American College of Obstetricians and Gynecologists (ACOG) has published a new review of data supporting the noncontraceptive uses of hormonal contraceptives to treat specific conditions.[1]

During their reproductive years, more than 80% of women in the United States use some form of hormonal contraception, such as oral contraceptive (OC) pills, patches, single-rod progestin and other implants, injections, vaginal rings, and the intrauterine device.[2] In addition to preventing unplanned pregnancies, hormonal contraceptives are used off-label to effectively treat menstrual disorders including dysmenorrhea and menorrhagia.

"We've known for many years that hormonal contraceptives have health advantages beyond preventing pregnancy," said **Robert Reid**, MD, professor in the Department of Obstetrics and Gynaecology and chairperson of the Division of Reproductive Endocrinology & Infertility at Queens University, Kingston, Ontario, in a statement accompanying the publication. "These recommendations examine the scientific data supporting the non-contraceptive uses of hormonal contraceptives to treat specific conditions."

Combined oral contraceptives are effective in normalizing irregular periods, reducing symptoms of premenstrual dysphoric disorder, improving acne, and allowing women to avoid having their period at inconvenient times, such as during a business trip, vacation, or honeymoon, observes Reid, who led development of the review. Although there is little data on the newer forms of hormonal contraception in terms of their off-label benefits, experts suggest that they might be as effective as the more studied ones in treating the same conditions, he notes.

EXECUTIVE SUMMARY

The American College of Obstetricians and Gynecologists has published a new review of data supporting the noncontraceptive uses of hormonal contraceptives to treat specific conditions.
• Combined oral contraceptives are effective in normalizing irregular periods, reducing symptoms of premenstrual dysphoric disorder, improving acne, and allowing women to avoid having their period at inconvenient times.
• Awareness that a method of contraception has major noncontraceptive benefits might increase the likelihood that a patient will continue with a chosen method.

Check recommendations

After reviewing available research on various methods, the ACOG review lists the following recommendations, which are all based on good, consistent scientific evidence (Level A):

• Combined OCs should not be used to treat existing functional ovarian cysts.

• Use of combined hormonal contraception has been shown to lower the risk for endometrial and ovarian cancer.

• Combined OCs have been shown to regulate and reduce menstrual bleeding, treat dysmenorrhea, reduce symptoms of premenstrual dysphoric disorder, and ameliorate acne.

• Continuous combined hormonal contraception, depot medroxyprogesterone acetate (DMPA), and the levonorgestrel intrauterine system may be considered for long-term menstrual suppression.[1]

Specific ACOG recommendations based on limited or inconsistent scientific evidence (Level B), include:

• Based on the limited data available, it appears

overall that combined OCs do not increase the risk of the development of uterine leiomyomas.

• Hormonal contraception should be considered for the treatment of menorrhagia in women who may desire further pregnancies.[1]

In addition, the ACOG review calls for a proposed performance that measures the percentage of women using hormonal contraception for symptomatic relief of menorrhagia or dysmenorrhea or both who have no contraindications and wish to preserve reproductive function.

Review the data

In looking at available data, the review finds that oral contraceptives and the single-rod contraceptive progestin implant help relieve or reduce the symptoms of dysmenorrhea, the pain that results from intense uterine contractions triggered by the release of endometrial prostaglandins. Dysmenorrhea is the most commonly reported menstrual disorder; it affects up to 90% of young women and is a leading cause of women missing school and work.[3]

A variety of hormonal contraceptives also are useful in treating menorrhagia, which, if left untreated, can lead to anemia. Menstrual blood loss is reduced in women who use cyclic combined OCs, extended cycle and continuous combined OCs, as well as progestin-only methods as progestin-only pills, DMPA, progestin implants, and the levonorgestrel intrauterine system.[1]

The review notes that all combined OCs have the potential to improve hirsutism and acne, since they increase sex hormone binding globulin and suppress luteinizing hormone-driven ovarian androgen production. This chemical mechanism reduces the levels of free androgen, which initiate and maintain acne and hair growth.[1] Other potential benefits of hormonal contraceptives include prevention of menstrual migraines, treatment of pelvic pain due to endometriosis, and treatment of bleeding due to uterine fibroids.

Counsel on benefits

Although the noncontraceptive benefits provided by certain methods are not generally the main determinant for women selecting a birth control method, they certainly can help patients decide among suitable options, according to the authors of *Contraceptive Technology*.[4]

Potential noncontraceptive benefits include menstrual cycle regularity, treatment of menorrhagia, treatment of dysmenorrhea, inducing amenorrhea for lifestyle considerations, treatment of premenstrual syndrome, prevention of menstrual migraines, decrease in the risk of endometrial cancer, ovarian cancer, and colorectal cancer, treatment of acne or hirsutism, improved bone mineral density, treatment of bleeding due to leiomyomas, and treatment of pelvic pain due to endometriosis.[1]

Awareness that a method of contraception has major noncontraceptive benefits might increase the likelihood that a patient will continue with a chosen method. Make it a practice to tell patients about the noncontraceptive benefits of various methods, advises *Contraceptive Technology*.

"If patients have additional reasons for using the contraceptive method, their motivation to use it correctly and consistently will probably be improved," it states.[4]

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Options might expand with vaginal rings

The options in birth control might be set to expand: Watson Pharmaceuticals of Corona, CA, has signed an exclusive licensing agreement to commercialize the Population Council's investigational contraceptive vaginal ring in the United States, Canada, and Mexico. The ring, which contains ethinyl estradiol and a new progestin, Nestorone, is in Phase 3 clinical development.

The Nestorone/ethinyl estradiol contraceptive vaginal ring is designed to simultaneously release Nestorone along with a low dose of ethinyl estradiol for up to 13 cycles. The ring remains in the vagina for three weeks per cycle, followed by one

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- The Nestorone/ethinyl estradiol contraceptive vaginal ring is designed to release Nestorone along with a low dose of ethinyl estradiol for up to 13 cycles.
- The ring remains in the vagina for three weeks per cycle, followed by one ring-free week.
- Early research indicates the device, used on a 21-day-in and seven-day-out regimen, provides women safe and effective contraception.

ring-free week. Early research indicates the device, used on a 21-day-in and seven-day-out regimen, provides women safe and effective contraception.[1] *(See the* Contraceptive Technology Update *article, "Science circles in on vaginal ring technology," August 2009, p. 88.)*

The ring, if approved by the Food and Drug Administration, will provide women with an important new user-controlled long-term contraceptive method, says **Peter Donaldson**, PhD, president of the Population Council in New York City.

In signing the agreement with the Population Council, Watson Pharmaceuticals will be responsible for future development, regulatory, and marketing expenses related to the commercialization of the contraceptive ring. In addition, the company will allow product discounts on the ring for qualified public health agencies should the device receive regulatory approval, says Patty Eisenhaur, a Watson Pharmaceuticals spokesperson.

Focus on new progestin

Many of the contraceptive options under development by the Population Council contain Nestorone, a synthetic progestin similar to the natural hormone progesterone. About 2¼ inches in diameter, the contraceptive ring in development is a thin, flexible drug-delivery system that fits into the vagina and can be inserted easily by the patient. Once in place, the ring slowly releases hormones that are absorbed into the bloodstream.

The Phase 3 study of the ring was conducted at 27 locations throughout the United States, Latin America, Europe, and Australia. Women in the study were healthy, ages 18-40, and were seeking contraception. The study enrolled 2,277 women and was completed in June 2009. Results have not yet been published.

According to the Population Council, preliminary results indicate the efficacy and safety of the ring appear to be comparable to that of other marketed hormonal methods. Preliminary acceptability data indicate that most women in the trial are satisfied with the contraceptive method and find it easy to use, the council states.

Population Council scientists also are looking at use of Nestorone in a transdermal gel. Scientists have completed a dose-finding, open-label, crossover study to evaluate the effect of the transdermal gel on ovulation suppression in normal women of fertile age. *(See "Science explores new contraceptive pathways,"* CTU*, April 2010, p. 43.)* Antares Pharma of Ewing, NJ, and the Population Council are partners in developing the transdermal gel.

Nestorone also is being eyed for use in a spray-on contraceptive; Acrux, a Melbourne, Australia, pharmaceutical company, has partnered with the Population Council to develop the novel birth control method. Acrux and the Population Council began working together in 2003, combining Acrux's Metered Dose Transdermal System (MDTS) technology to deliver Nestorone to the skin. MDTS is a hand-held aerosol drug delivery system. The spray, delivered via MDTS, would be painless, easy to use, and convenient for women. *(*CTU *reported on the spray formulation in the articles, "Spray-on contraceptive moves to next step," May 2006, p. 57, "Clinical trials begin for spray-on contraceptive," February 2005, p. 23, and "Spray-on birth control: New application eyed," March 2004, p. 28.)*

Vaginal rings, topical gels, and sprays all offer the benefit of being entirely under the user's control. They are convenient to use and easy to discontinue when the woman wishes to restore her fertility, according to the council.

Scientific exploration of Nestorone is not being limited to women. The Population Council is collaborating with the National Institutes of Health to examine a transdermal gel containing Nestorone, combined with testosterone gel, for male contraception. A clinical trial is under way to determine effective doses of the hormones to decrease sperm production.

The Population Council is familiar with vaginal technology. It has developed two vaginal rings that release natural progesterone: one for contraception during lactation trademarked as Progering, and one for hormone supplementation and pregnancy maintenance during in vitro fertilization known as

Fertiring. Both rings are approved and licensed for distribution in Bolivia, Chile, Ecuador, and Peru.

The Population Council plans a large Phase 3 clinical trial in India for the contraceptive progesterone ring in women who are breastfeeding and need to space births. The trial will compare the efficacy and safety of the ring with that of a Copper T 380A intrauterine device.

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U.S. research update: Herpes rates remain high

The test results are in: Your patient tests positive for herpes simplex virus type 2 (HSV-2). What is your next step?

If results of a new study are any indication, there is a good chance you will fail to educate your patient about the protective effects of condom use or the effectiveness of suppressive therapy.[1]

Although clinicians usually discuss condoms and suppressive therapy with patients diagnosed with genital herpes, only a minority discuss suppressive therapy to prevent transmission, and only a quarter of patients take suppressive therapy, researchers reported at the 2010 National STD Prevention Conference. Most patients in the study could not estimate the effectiveness of condoms or suppressive therapy in preventing transmission, and few were offered routine follow-up care.[1]

To conduct the study, Washington state researchers used surveillance data collected in King and Pierce counties, WA, to identify persons 18 years of age and above with newly diagnosed symptomatic genital herpes. They interviewed patients and reporting clinicians regarding treatment. Patients were eligible for interviews if they had newly diagnosed symptomatic genital herpes, spoke English, and their provider agreed. Scientists interviewed clinicians regarding 246 (92%) of 267 reported cases and interviewed 134 (63% of 212 eligible) patients.

Patients reported condom use was discussed in 78% of encounters, suppressive therapy in 68%, and suppressive therapy to decrease transmission in 40% of visits. About one-fourth (26%) reported taking suppressive therapy. A follow-up appointment was recommended for 34% of patients, and 21% reported attending a follow-up appointment.

About one-third (30%) of patients correctly responded that condoms provide a protective effect in preventing herpes transmission, and just 21% estimated that suppressive therapy is effective in preventing transmission. Most (60%) of the surveyed patients were unsure of the effect of suppressive therapy on disease transmission.[1]

Women are at risk

About one in six Americans (16.2%) between ages 14-49 is infected with HSV-2, according to new research from the Centers for Disease Control and Prevention (CDC).[2] The new estimate, compiled for 2005-2008, comes from the CDC's National Health and Nutrition Examination Survey, a nationally representative survey of the U.S. household population that assesses a broad range of health issues.

Women and blacks were most likely to be infected with HSV-2, according to the new analysis. Prevalence was nearly twice as high among women (20.9%) than men (11.5%), and was more than three times higher among blacks (39.2%) than whites (12.3%). The most affected group was black women, with a prevalence rate of 48%, researchers report.[2]

"This study serves as a stark reminder that herpes remains a common and serious health threat in the United States," says **Kevin Fenton**, MD, director of CDC's National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention. "Everyone should be aware of the symptoms, risk factors, and

EXECUTIVE SUMMARY

About one in six Americans between ages 14-49 is infected with herpes simplex virus type 2, according to new research from the Centers for Disease Control and Prevention.

- Women and blacks were most likely to be infected with HSV-2. Prevalence was nearly twice as high among women than men, and prevalence was more than three times higher among blacks than whites. The most affected group was black women, with a prevalence rate of 48%.
- Although clinicians usually discuss condoms and suppressive therapy with patients diagnosed with genital herpes, only a minority discuss suppressive therapy to prevent transmission, and only a quarter of patients take suppressive therapy.

steps that can be taken to prevent the spread of this lifelong and incurable infection." Public health officials are particularly concerned about persistent high rates of herpes among African-Americans, which is likely contributing to disproportionate rates of HIV in the black community, he states.

As with other sexually transmitted diseases, biological factors might make women more susceptible to HSV-2 infection. Such susceptibility is of concern: Research indicates that people with herpes are two to three times more likely to acquire HIV and that herpes also can make HIV-infected individuals more likely to transmit HIV to others.

The CDC estimates that more than 80% of those with HSV-2 are unaware of their infection. Most patients have no or minimal signs or infection. When signs do occur, they typically present as one or more blisters on or around the genitals or rectum. When the blisters break, they leave small sores that might take 2-4 weeks to heal at the first time of occurrence. The initial outbreak typically is followed by subsequent outbreaks that can appear weeks or months after the first. Such reoccurrences almost always are less severe and shorter than the first outbreak. Although the infection can stay in the body indefinitely, the number of outbreaks tends to decrease over subsequent years.[3]

"Many individuals are transmitting herpes to others without even knowing it," says **John Douglas Jr.**, MD, director of the CDC's Division of STD Prevention. "We can't afford to be complacent about this disease. It is important that persons with symptoms suggestive of herpes, especially recurrent sores in the genital area, seek clinical care to determine if these symptoms may be due to herpes and might benefit from treatment."

Although HSV-2 infection is not curable, there are effective medications available to treat symptoms and prevent outbreaks. Those with known herpes infection should avoid sex when herpes symptoms or sores are present and understand that HSV-2 still can be transmitted when sores are not present. Effective strategies to reduce the risk of HSV-2 infection include abstaining from sexual contact, using condoms consistently and correctly, and limiting the number of sex partners.

The CDC does not recommend HSV-2 screening for the general population. However, such testing may be useful for individuals who are unsure of their status and at high risk for the disease, including those with multiple sex partners, those who are HIV-positive, and gay and bisexual men.

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Women at risk for HIV: What is on the horizon?

In the United States, women and teen girls accounted for more than one-fourth of all new HIV/AIDS diagnoses in 2007 and more than 93,900 cumulative deaths from AIDS.[1] Black women are at heightened risk. The incidence rate of new diagnoses in black women is almost 15 times higher than that of white women, according to statistics compiled by the Centers for Disease Control and Prevention.[1]

Why are black women at increased risk? According to authors of a recent editorial in *The New England Journal of Medicine*, the increase in risk might be due more to vulnerable social and economic situations and sexual networks than women's own risky behaviors.[2]

"Socioeconomic disadvantage and instability of partnerships due to high rates of incarceration among men in their communities may lead women to engage in concurrent relationships or serial monogamy," the editorial states. "In addition, they may be unaware of their partners' HIV status or may be involved in abusive or economically dependent relationships and thus be unable to negotiate safer sex with their partners."

The National Alliance of State and Territorial AIDS Directors (NASTAD) has issued a new issue brief in its ongoing efforts to reduce racial and ethnic health disparities in the HIV/AIDS and viral hepatitis epidemics.[3] The release of the brief is part of the organization's efforts to draw atten-

EXECUTIVE SUMMARY

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- Manufacturers of the FC2 Female Condom are supporting a new social marketing campaign in Chicago designed to educate women about HIV/AIDS and boost awareness, availability, and access to the FC2 condom.
- The Vaginal and Oral Interventions to Control the Epidemic study is examining whether antiretroviral medications normally used to treat HIV infection also can prevent HIV infection in women when applied as a vaginal gel or taken as once-daily oral tablets.

tion to the impact of HIV/AIDS on women and the need to increase support for science-based, effective HIV and STD prevention programs for them. (**Download a copy of the brief at the organization's web site, www.nastad.org. Under "Highlights," click on "Black Women and HIV/AIDS: Findings from the Southeast Regional Consumer and Provider Focus Group Interviews."**)

NASTAD will continue to advocate for increased awareness and services for women impacted by HIV/AIDS, says Michelle Batchelor, MA, senior manager of racial and ethnic health disparities. While strides have been made, the collective response to women's needs have not been met at the level that the crisis deserves, she states.

Put a ring on it

One way to help women protect themselves against HIV/AIDS to boost female-controlled prevention methods. The Female Health Co. (FHC), manufacturers of the FC2 Female Condom, are supporting a new social marketing campaign in Chicago designed to educate women about HIV/AIDS and boost awareness, availability, and access to the FC2 condom.

The Chicago Female Condom Campaign includes a coalition of 20 HIV/AIDS, reproductive justice, and women's and men's health organizations that are mobilizing outreach to women and men living at risk of HIV in Chicago. The campaign was launched on March 10, the 2010 observance of National Women and Girls HIV/AIDS Awareness Day.

The campaign is conducting a multifaceted communications and marketing effort to promote the female condom as an acceptable and affordable HIV prevention option for women and men. With funding and technical support provided by FHC and other partners, it is sponsoring in-person trainings to equip Chicago-area service organizations with the skills to promote female condoms. Those skills include knowledge of correct use and strategies for negotiating female condom use with partners. Many of the community-based partners serve African American and Latino women, who are disproportionately impacted by the city's HIV/AIDS epidemic. The campaign is launching a mixture of social media channels to spread awareness including a female condom web site (www.ringonit.org), a Facebook fan page, and a Twitter account (twitter.com/ChiFemaleCondom).

Science eyes prevention

Women might have another option when it comes to HIV prevention if a current large-scale clinical trial proves successful. The Vaginal and Oral Interventions to Control the Epidemic (VOICE) study is examining whether antiretroviral medications normally used to treat HIV infection also can prevent HIV infection in women when applied as a vaginal gel or taken as once-daily oral tablets.

The study, launched in 2009, looks to enroll some 5,000 HIV-uninfected women at risk for HIV infection in multiple sites in Africa. Scientists are enrolling participants at sites in Zimbabwe, Uganda, and South Africa, with additional sites in South Africa expected to come on board soon, says **Jeanne Marrazzo**, MD, MPH, VOICE Study co-chair and associate professor of medicine in the Division of Allergy and Infectious Diseases at the University of Washington in Seattle. The study is expected to run about three and one-half years.

The trial will test the safety and efficacy of two HIV prevention strategies: an investigational microbicide gel containing the antiretroviral drug tenofovir, and oral tablets containing tenofovir or a combination of tenofovir and emtricitabine. The tablets are taken prior to exposure in an approach known as pre-exposure prophylaxis, or PrEP. Testing a microbicide and PrEP in the same trial will enable scientists to directly compare the two strategies' safety and acceptability.

To perform the study, women are randomly assigned to one of five regimens, each performed once daily: applying tenofovir gel vaginally, applying a placebo gel vaginally, taking a tenofovir pill and a placebo pill, taking a tenofovir/emtricitabine pill and a placebo pill, or taking two placebo pills.

Why are researchers hopeful that this particular

approach will be effective in women? Marrazzo points to two possible reasons. "First, the strategies we are using — vaginal and oral products — use antiretroviral drugs [ARVs] that we know work very well to treat HIV," she notes. "Second, use of ARVs has been successful in preventing mother-to-child transmission of HIV, so that provides a great real-world model of its potential."

However, until the trial is complete, scientists won't know for sure whether the ARV-based gel or the pill will be safe and effective, and whether one will be more acceptable than the other for women to use on a daily basis, states Marrazzo.

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Check your approach in taking sexual history

Learn to be more specific in your sexual health history taking. Results of a new study from the Kinsey Institute for Research in Sex, Gender and Reproduction at Indiana University in Bloomington indicate that no uniform consensus exists when the term "had sex" is used.[1]

The study examines the responses from 486 Indiana residents, ages 18-96, who took part in a telephone survey conducted by the university's Center for Survey Research. Participants, most of whom were heterosexual, were asked, "Would you say you 'had sex' with someone if the most intimate behavior you engaged in was ...," followed by 14 behaviorally specific items.

In evaluating the responses from the 204 men and 292 women, researchers found that replies did not differ significantly overall between the two genders. An overview of the complete findings shows:

• 95% of respondents considered penile-vaginal intercourse as having had sex, yet only 89% did so if there was no ejaculation.

• 81% saw penile-anal intercourse as having had sex, with the rate dropping to 77% for men in the youngest age group (18-29), 50% for men in the oldest age group (65 and up), and 67% for women in the oldest age group.

• 71% and 73% considered oral contact with a partner's genitals, performing or receiving, as having had sex.

• Men in the youngest and oldest age groups were less likely to answer "yes" compared with the middle two age groups for when they performed oral-genital sex.

• Significantly fewer men (77%) in the oldest age group answered "yes" for penile-vaginal intercourse.[1]

"These findings highlight the need to use behavior-specific terminology in sexual history taking, sex research, sexual health promotion, and sex education," state the researchers. "Researchers, educators, and medical practitioners should exercise caution and not assume that their own definitions of having 'had sex' are shared by their research participants or patients."

EXECUTIVE SUMMARY

Results of a new study from the Kinsey Institute for Research in Sex, Gender and Reproduction indicate that no uniform consensus exists when the term "had sex" is used. A phone survey was used to poll Indiana residents, ages 18-96.

• While most (95%) respondents considered penile-vaginal intercourse as having had sex, only 89% did so if there was no ejaculation. Less than 75% considered oral contact with a partner's genitals, performing or receiving, as having had sex.

• The findings highlight the need to use behavior-specific terminology in sexual history taking. Clinicians should exercise caution and not assume that their own definitions of having "had sex" are shared by patients.

COMING IN FUTURE MONTHS

- ■ Stress the importance of condom fit
- ■ Do women on the Pill live longer?
- ■ Check contraceptive options for postpartum
- ■ Update on birth control for obese patients
- ■ How to help women with chronic pelvic pain

Specificity is important when clinicians are taking a sexual health history, says **William Yarber**, HSD, professor in the departments of applied health science and gender studies at Indiana University and senior research fellow at the Kinsey Institute. Clinicians might ask how many sexual partners a patient has had; however, the number will differ according to the patient's definition of sex, he observes.

"I think that if you just ask an individual if they 'had sex,' whether or not they answer yes or no is based on how they define sex," says Yarber, a co-author of the current study. "For example, if they don't consider oral sex as sex, then they may underreport their past behavior, and without that kind of specific information the health care provider may not know what type of risk reduction or preventive information to provide."

Don't be hesitant

Some health care providers might be hesitant to bring up specific sexual behaviors such as anal sex because they sense that it might be embarrassing to a patient and might influence the level of trust the provider has worked to develop, says Yarber. However, for the health of the individual, specificity is important, he notes.

Take a tip from material presented at a Contraceptive Technology conference. When initiating a sexual history, use such wording as "Tell me about your sexual activity" and "Do you have any concerns about your sexual life that you would like to discuss?" The elements of a sexual history can

CNE/CME INSTRUCTIONS

Physicians and nurses participate in this continuing nursing medical education/continuing education program by reading the articles, using the provided references for further research, and studying the questions at the end of the issue. Participants should select what they believe to be the correct answers and refer to the list of correct answers to test their knowledge. To clarify confusion surrounding any questions answered incorrectly, please consult the source material. After completing this activity with the **June** 2010 issue, you must complete the evaluation form provided and return it in the reply envelope provided in that issue to receive a certificate of completion. When your evaluation is received, a certificate will be mailed to you. ■

CNE QUESTIONS

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.

17. What type of tests are recommended to decrease levels of chlamydia infection in young women?
   A. Nucleic acid amplification tests
   B. Rapid plasma reagin tests
   C. Venereal disease research laboratory tests
   D. Treponemal confirmatory assays

18. Good, consistent scientific evidence shows that use of combined hormonal contraception has been shown to lower the risk for which types of cancers?
   A. Endometrial and colon cancer
   B. Endometrial and ovarian cancer
   C. Endometrial and lung cancer
   D. Ovarian and breast cancer

19. The Population Council is looking at use of Nestorone in what delivery mechanisms?
   A. Vaginal ring, transdermal gel, and implant
   B. Vaginal ring, implant, and pill
   C. Vaginal ring, transdermal gel, and spray
   D. Vaginal ring, pill, and contraceptive foam

20. What are the two drugs being examined in the Vaginal and Oral Interventions to Control the Epidemic trial?
   A. Tenofovir and zidovudine
   B. Tenofovir and lamivudine
   C. Tenofovir and didanosine
   D. Tenofovir and emtricitabine

Answers: 17. A 18. B 19. C 20. D

include such questions as "Are you currently sexually active?" "Do you have a sexual partner?" and "Do you have sex with men, women, or both?"[2]

Researchers with the current study now plan to look at how cultural differences might impact the definitions of "had sex," says **Brandon Hill**, research associate at the Kinsey Institute and a researcher in the university's Department of Gender Studies. The scientists have conducted similar surveys in the United Kingdom and are comparing responses to those in the United States to determine the influence of cultural differences, Hill says.

Researchers also hope to look at how responses might be shaped depending on the person asking the question, says Hill. Scientists hypothesize that the answer to "Have you had sex?" might be different when it is asked by a health care provider, rather than by a peer, he notes.

REFERENCES

1. Sanders SA, Hill BJ, Yarber WL, et al. Misclassification bias: diversity in conceptualisations about having 'had sex'. *Sex Health* 2010; 7:31-34.
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Contraceptive Technology Update *is endorsed by the National Association of Nurse Practitioners in Women's Health and the Association of Reproductive Health Professionals as a vital information source for health care professionals.*