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U.S. teen pregnancy rates decline due to improved contraceptive use

Abstinence promotion alone won't stem unintended pregnancy rate

Results of a new analysis of national data indicate that 86% of the recent drop in U.S. teen pregnancy rates is the result of improved contraceptive use, while 14% of the decline can be attributed to teens waiting longer to start having sex.[1]

Between 1995 and 2002, U.S. teen pregnancy rates declined by almost one-quarter.[1] While the news is good for those who advocate adolescent health, family planning experts are questioning the value of the federal government's funding of abstinence-only-until-marriage programs that prohibit information about the benefits of condoms and contraception. Since 1996, more than $1 billion in federal- and state-matching funds have been committed to abstinence-only programs, according to the Sexuality Information and Education Council of the United States in New York City.[2]

"We need to redouble our efforts on contraception and get rid of curricula that limit information on contraceptive use," states **John Santelli**, MD, MPH, department chair and professor of the Heilbrunn Department of

EXECUTIVE SUMMARY

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- Between 1995 and 2002, U.S. teen pregnancy rates declined by almost one-quarter. When researchers looked at results by age, they found that delays in sexual activity played a greater role than improved contraceptive use for younger teens ages 15-17, while among those ages 18-19, the decline in the risk was due entirely to improved contraceptive use.
- Since 1996, more than $1 billion in federal- and state-matching funds have been committed to abstinence-only programs.

Population and Family Health at Columbia University in New York City and lead author of the new research. "The problem is a strongly held belief system that giving information on contraception leads to having sex."

The new analysis was performed by Santelli and researchers at the Guttmacher Institute, a research, policy analysis, and public education organization. They looked at information from the National Survey of Family Growth (NSFG), a nationally representative survey that offers comprehensive information about adolescent females. The scientists used data from the 1995 and 2002 cycles of the survey to develop two indexes:

- the contraceptive risk index, which encompassed the overall effectiveness of contraceptive use — including nonuse — among sexually active teens;
- the overall pregnancy risk index, which looked at the contraceptive risk index score and the percentage of individuals reporting sexual activity.

According to the new research paper, most of the decline in teen pregnancies can be attributed to more sexually active teens using contraceptives, using more effective methods, and using dual methods. When researchers looked at results by age, they found that delays in sexual activity played a greater role than improved contraceptive use for younger teens ages 15-17, while among those ages 18-19, the decline in the risk was due entirely to improved contraceptive use.[1]

What's the message?

While most states require public schools to teach some form of sex or sexually transmitted disease (STD)/HIV education, there are differences in what types of information are presented, according to the Guttmacher Institute. Most states provide guidance on how abstinence or contraception should be handled when included in a school district's curriculum. Such guidance is "heavily weighted toward stressing abstinence; in contrast, while many states allow or require that contraception be covered, none require that it be stressed."[3]

Santelli and fellow researchers again looked to the NSFG to look at the scope of sex education among adolescents.[4] They found that from 1995 to 2002, formal instruction about birth control methods fell for adolescent males and females, from 81% to 66% in teen males and from 87% to 70% in adolescent females. While education about contraception dipped, more teens reported receiving instruction only about abstinence; for adolescent males, the number grew from 9% to 24% and, in females, it rose from 8% to 21%.[4]

Concern about abstinence-only education programs has been heightened since 2004, when a congressional staff analysis of 13 of the most commonly used curricula uncovered misleading information in 11 of the programs.[5,6] The 11 programs,

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in use by 69 organizations in 25 states, included such statements as:

- A 43-day-old fetus is a "thinking person."
- HIV, the virus that causes AIDS, can be spread via sweat and tears.
- Condoms fail to prevent HIV transmission as often as 31% of the time in heterosexual intercourse.[5,6]

Findings from the analysis, prepared at the request of Rep. Henry Waxman (D-CA), led to an October 2006 legal opinion released by the Government Accountability Office's general council office. The opinion states that the Department of Health and Human Services should ensure that abstinence education material prepared and used by groups receiving federal funding include accurate information on sexually transmitted infections and the effectiveness of condoms.[7]

On tap: 'Prevention first'

Look for action in the current congressional session on comprehensive sexual education, says **Heather Boonstra**, senior public policy associate at the Guttmacher Institute's Washington, DC, bureau. Senate Majority Leader Harry Reid has introduced the Prevention First Act bill (S21), which calls for federally funded programs to provide medically accurate information, as well as seeks more funding for Title X programs.

"It is a real answer to the abstinence-only move," she says of the proposed legislation. "It recognizes the need for medically accurate information."

On the House side, there may be hearings conducted on the issue, says Boonstra. "There is a drumbeat going," she states. "There are hopes that adjustments can be made."

What can providers do?

Family planning clinicians have been effective in delivering prevention messages, notes Santelli. The fact that more teens are choosing dual methods for protection against HIV and pregnancy is heartening, he observes.

"We wrote some of the first articles in the early 1990s on dual use,[8] and I used to hear, 'Teens won't use condoms,'" recalls Santelli. "Clinicians have done a good job."

What can providers do to see that teens get the information they need when it comes to pregnancy and HIV prevention? The Society for Adolescent Medicine has issued a position statement calling for "a comprehensive approach to sexual risk reduction including abstinence as well as correct and consistent use of condoms and contraception among teens who choose to be sexually active."[9] The organization also is calling for current funding for abstinence-only programs to be replaced with funding for programs that offer comprehensive, medically accurate sexuality education.[9]

"Messages on abstinence are important, but messages on contraception are just as important," says Santelli.

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Research supports safety of continuous regimen pill

Research regarding the safety and efficacy of the first continuous regimen oral contraceptive (OC) has just been published, with results indicating a good safety profile and efficacy similar to cyclic OCs.[1]

Lybrel (20 mcg ethinyl estradiol/90 mcg

EXECUTIVE SUMMARY

Research regarding the safety and efficacy of the first continuous regimen oral contraceptive has just been published, with results indicating a good safety profile and efficacy similar to cyclic pills.

- The median and mean number of bleeding days decreased progressively. Researchers report 79% of women reported an absence of bleeding after one year, while 58.7% reported cessation of menstrual cycles.
- Lybrel (20 mcg ethinyl estradiol/90 mcg levonorgestrel tablets) is a low-dose, continuous, noncyclic combination pill in development by Wyeth. The drug was given approvable status by the Food and Drug Administration in 2006 and is awaiting a final decision.

levonorgestrel tablets) is a low-dose, continuous, noncyclic combination oral contraceptive in development by Wyeth, of Madison, NJ. The drug was given approvable status by the Food and Drug Administration (FDA) in June 2006 and is awaiting a final decision from the regulatory agency. If given the go-ahead from the FDA, Lybrel will be the only combination oral contraceptive approved with this regimen designed to be taken daily, 365 days a year, without a placebo phase or pill-free interval.

If such a pill becomes available, who would be a potential candidate? Look to women who don't want to have menstrual periods and are willing to accept some degree of unanticipated endometrial bleeding or spotting, says **David Archer**, MD, professor of obstetrics and gynecology at Eastern Virginia Medical School in Richmond and lead author of the current study.

Review the results

To perform the study, researchers at 92 sites in North America enrolled sexually active women ages 18-49. A total of 2,402 women were enrolled in the study; 2,134 took at least one dose of the study drug, and 921 completed the study. The study drug was supplied in 28-day pill packs; women took one pill daily for 12 months with no pill-free intervals.

During the study, which lasted more than 18 months, the median and mean number of bleeding days decreased progressively. Researchers report 79% of women reported an absence of bleeding after one year, while 58.7% reported cessation of menstrual cycles.[1]

About 85% of the women noted one or more treatment-emergent adverse event, with headache and dysmenorrhea listed as the most common complaints. Discontinuations due to adverse events occurred in 17% of women and included discontinuations due to uterine bleeding.

Nineteen women became pregnant while using the drug, yielding an on-treatment Pearl Index of 1.60 (95% CI=0.96–2.49). Fifteen of these pregnancies were attributed to method failure (Pearl Index=1.26; 95% CI=0.71–2.08), and four were attributed to user failure (Pearl Index=0.34; 95% CI=0.09–0.86).[1]

While researchers report that the incidence of uterine bleeding decreased with longer use, 21% of women had uterine bleeding by Pill Pack 13, with a median of four days of bleeding and three days of spotting per 28-day pill pack. More than three-quarters (77%) of women who experienced bleeding on Pill Pack 13 reported they were satisfied with the method, with 7% as neutral and 16% as dissatisfied.[1]

"This suggests that there is a subset of women who may not achieve amenorrhea with prolonged use of continuous OC," researchers note. "The lack of amenorrheic outcome may lead to the discontinuation of OCs in these women."

Counseling is key

If a dedicated continuous regimen pill becomes available, be ready to counsel women about bleeding, says Archer. While a woman may not have a regular withdrawal bleeding episode with a continuous regimen pill, she would have to accept the unanticipated bleeding as a trade-off, he notes.

"Many women may start with the expectation that they will not have any bleeding at all; those women who do not experience any bleeding, or only some inconvenience, will be those who continue this method," notes Archer. "There is no way that we can identify those who will vs. those who will not bleed."

For most women, breakthrough bleeding with continuous dosing improves with increasing duration of use, but for a small number, it may never improve, agrees **Alison Edelman**, MD, MPH, assistant professor of obstetrics and gynecology at Oregon Health & Science University, who served as lead author of a review of continuous- or extended-cycle OCs.[2] "I think future studies will focus on formulations or interventions that will improve the rate of breakthrough bleeding," Edelman notes.

To provide education about the menstrual cycle

and the effects of hormonal contraception on cycles, the Association of Reproductive Health Professionals has launched an on-line Menstruation Resource Center (www.arhp.org/menstruationRC), which includes a variety of information, resources, recent headlines, and links to other sources of evidence-based information on menstruation.

A pill that women can take indefinitely has many potential benefits, says **Robert Hatcher**, MD, MPH, professor of gynecology and obstetrics at Emory University School of Medicine in Atlanta. Most important is the fact that women will know they have to do the same thing every day — take one pill, he says.

"The concern I have is that women will only be provided pills in 28-day packages and will have to return to a pharmacist every month for a very expensive pill," observes Hatcher. "If women have to return every month for a new package of pills, it defeats the main purpose of this medication. My hope is that once women find that they can tolerate this medication, they are provided a full year's supply of pills."

For this pill to have any impact in the public sector, it is going to have to be available inexpensively to health departments, hospital-based programs, and Planned Parenthood affiliates, says Hatcher.

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Hormonal contraception use doesn't up HIV risk

Using hormonal contraception does not appear to increase women's overall risk of infection with the AIDS virus, according to results from a new study commissioned by the National Institute of Child Health and Human Development (NICHD).[1]

Understanding whether hormonal contraceptive use alters a woman's risk for HIV is a "critical public health issue," say the study's authors: More than 100 million women around the world use hormonal contraception, and 18 million women have been infected with HIV, most during heterosexual relations.[2,3] To perform the study, researchers followed thousands of women in Africa and Asia and compared their patterns of contraceptive use to their risk of infection with HIV.

Do the findings provide a basis for changing current recommendations regarding contraceptive use? No, says **Trent MacKay**, MD, MPH, chief of the NICHD Contraception and Reproductive Health Branch. "The study findings do not alter the fact that, although hormonal contraception is effective for preventing pregnancy, it does not protect against HIV or other sexually transmitted infections," he says. "The only sure way to prevent sexual transmission of HIV is through abstinence; barring abstinence, using a latex condom, consistently and correctly, is highly effective against HIV infection."

EXECUTIVE SUMMARY

Using hormonal contraception does not appear to increase women's overall risk of infection with the AIDS virus, according to results from a new international study.

- The findings are significant, given that more than 100 million women around the world use hormonal contraception and 18 million women have been infected with HIV, most during heterosexual relations.
- While hormonal contraception provides an effective means of pregnancy prevention, it does not protect against HIV or other sexually transmitted infections. Outside of abstinence, correct and consistent use of latex condoms is the most effective protection against HIV infection.

Review the results

A total of 6,109 women participated in the study: 2,235 in Uganda, 2,296 in Zimbabwe, and 1,578 in Thailand. At the time of enrollment, the women were using no hormonal contraception, or had used oral contraceptives or depot medroxyprogesterone acetate (DMPA) for at least three months before the study began. Women who were not using hormonal contraception used such methods as condoms alone, diaphragms and spermicides, sterilization, withdrawal, or periodic abstinence, or used no birth control method.

In the study, the women were offered their choice of oral contraceptives or DMPA, as well as condoms. Researchers counseled women on how to use their chosen methods, as well as how to

reduce their risk of HIV infection. Women also were examined for sexually transmitted infections and offered treatment if needed. HIV tests were administered four to five times a year for 15 to 24 months.

By the study's end, 213 African women had become infected with HIV, while only four Thai women were identified with the infection. Why the difference in infection rates? The Thai government policy of mandated condom use in brothels, implemented during the 1990s, may have affected the heterosexual spread of HIV, researchers surmise. Since there were too few Thai cases for a valid statistical interpretation, the researchers excluded them from the final analysis.

When the scientists analyzed all of the African HIV cases, they found no evidence that use of hormonal contraceptives increased a woman's chances of becoming infected with HIV. However, analysis findings indicated that the risk of HIV infection was two times greater for women with genital herpes (herpes simplex virus 2 or HSV-2) infection than it was for women without herpes infection at enrollment in the study, regardless of whether the women used hormonal contraception.

The researchers also noted differences in HIV infection risk among the subgroup of women not infected with genital herpes at enrollment, which comprised about half the women in the study. In this subgroup, women who used hormonal contraceptive methods had an increased HIV infection risk. Oral contraceptive users had almost three times and DMPA users had four times the risk of acquiring HIV when compared to women not using hormonal contraceptives. The authors state that "a solid biological explanation for our finding among the HSV-2-negative women is elusive."

What are the ongoing research needs when it comes to hormonal contraception and HIV acquisition?

"We need the results from other studies evaluating the modifying effect of HSV-2 infection on the hormonal contraception-HIV relationship," says **Charles Morrison**, PhD, senior epidemiologist in the Clinical Research Department at Family Health International, a Research Triangle Park, NC-based research organization. Morrison served as lead author of the research publication.

More studies also are needed to fully explore the potential modifying effect of age, observes Morrison. In particular, science needs to examine whether hormonal contraception, particularly DMPA, increases HIV acquisition risk among young women (15-24 years), he says. Other forms of hormonal contraception, such as contraceptive implants that contain different progestins from those found in DMPA, should be examined to see if they affect HIV acquisition risk differently, Morrison points out.

"Finally, we need to determine the risks and benefits of hormonal contraceptive use among HIV-infected women," he states. "In particular, we need to better understand whether or not HIV-infected, hormonal contraceptive users are more infectious to a sex partner, whether they are more likely to have rapidly progressive HIV infection, and whether they can safely use commonly prescribed antiretroviral therapies when compared to women not using hormonal contraception."

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Adult male circumcision reduces risk for HIV

Two clinical trials of adult male circumcision have been halted after an interim review of data showed medically performed circumcision significantly lowers a man's risk of acquiring HIV through heterosexual intercourse.

Interim data from one trial in Kisumu, Kenya, of 2,784 HIV-negative men showed a 53% reduction of HIV acquisition in circumcised men compared to uncircumcised men, while a trial of 4,996 HIV-negative men in Rakai, Uganda, reflected a 48% drop in HIV acquisition in circumcised men. Both trials were funded by the National Institute of Allergy and Infectious Diseases (NIAID); the Kenyan trial also was supported by the Canadian Institute of Health Research.

The results from the two trials support similar findings from the earlier South Africa Orange Farm Intervention Trial, conducted near Johannesburg, South Africa. The Orange Farm trial demonstrated at least a 60% reduction in HIV infection among circumcised men.[1]

EXECUTIVE SUMMARY

Two trials of adult male circumcision have been halted after an interim review showed medically performed circumcision significantly lowers a man's risk of acquiring HIV through heterosexual intercourse.

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- While the studies' findings offer hope in fighting HIV on the international front, they may have less impact on the U.S. epidemic. Most U.S. men have been circumcised; also, most infections among men in the United States are in men who have sex with men, in which case the benefit of circumcision is not presently known.

"We now have confirmation — from large, carefully controlled, randomized clinical trials — showing definitively that medically performed circumcision can significantly lower the risk of adult males contracting HIV through heterosexual intercourse," says **Anthony Fauci**, MD, NIAID director. "While the initial benefit will be fewer HIV infections in men, ultimately adult male circumcision could lead to fewer infections in women in those areas of the world where HIV is spread primarily through heterosexual intercourse."

At press time, the American Academy of Pediatrics had not changed its neutral stance on the procedure.

Both of the NIAID-funded trials enrolled adult, HIV-negative heterosexual men, who were randomized to circumcision performed by trained medical professionals in a clinic setting or no circumcision. All men were counseled in HIV prevention and risk reduction techniques.

Both trials originally were designed to continue follow-up until mid-2007; however, at a regularly scheduled review in December 2006, panel member reviewers concluded that the interim data demonstrated that medically performed circumcision is safe and effective in reducing HIV acquisition. The reviewers recommended the two studies be halted early, and all men who were enrolled be offered circumcision.

Two common circumcision procedures were used in the two trials. Researchers in the Kenyan trial performed circumcision using the foreskin clamp method, and stitches to control bleeding and improve wound closure. Scientists in the Ugandan trial used the sleeve method of circumcision and relied on cauterization of the blood vessels to control bleeding and stitches to close the wound.

While the current trials' results demonstrate the impact of male circumcision on male acquisition of HIV, the method does not provide complete protection against HIV infection, say international public health officials.

Circumcised men still can become infected with the virus and, if HIV-positive, can infect their sexual partners, according to a statement issued by the World Health Organization, the United Nations Population Fund, the United Nations Children's Fund, the World Bank, and the UNAIDS Secretariat.[2]

"Male circumcision should never replace other known effective prevention methods and should always be considered as part of a comprehensive prevention package, which includes correct and consistent use of male or female condoms, reduction in the number of sexual partners, delaying the onset of sexual relations, and HIV testing and counseling," officials note.

How does male circumcision reduce a man's risk of HIV infection? Medical experts point to a number of potential mechanisms:

- The foreskin's inner mucosal surface has more immune cells vulnerable to HIV infection than the external surface.
- The foreskin acts as a physical barrier that can trap HIV next to the mucosal surface of the penis. In this moist environment, the virus also can survive longer, potentially increasing the risk of infection.
- Small tears in the foreskin that may occur during intercourse can promote entry of the virus. The penile shaft and glans develop more epithelial keratinization following circumcision, making the penis less susceptible to viral invasion.[3]

While the findings from the African studies offer hope in fighting HIV on the international front, they may have less impact on the U.S. epidemic, say public health officials. Most men have been circumcised in the United States; also, most infections among men in the United States are in men who have sex with men, in which case the benefit of circumcision is not presently known. The Centers for Disease Control and Prevention is undertaking additional research and consultation to evaluate the potential value, risks, and feasibility of circumcision as an HIV prevention intervention in the United States.

Robert Hatcher, MD, MPH, professor of gynecology and obstetrics at Emory University School of Medicine in Atlanta, says, "My concern is that the important protective effect of male circumcision will be interpreted to mean, 'We don't need to use condoms.' Murphy's law tells us this is exactly what will happen, and all of us in reproductive health must be aware of this unfortunate response."

Does male circumcision extend its protective effect to women? Researchers at Johns Hopkins University in Baltimore currently have an ongoing trial to answer that question, says **Ronald Gray**, MBBS, MSc, the William G. Robertson professor of reproductive epidemiology at the university's Bloomberg School of Public Health; Gray led the investigative team responsible for the Uganda trial. The study involving women will not be finished until 2008, says Gray.

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Support is growing for HPV vaccine for girls

Acceptance of the first human papillomavirus (HPV) vaccine continues to grow, as the national immunization schedule for children and teens has been updated to include Gardasil, manufactured by Merck & Co., of Whitehouse Station, NJ.[1,2]

The Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP), the American Academy of Pediatrics, and the American Family of Physicians has published the Childhood Immunization Schedule, which indicates recommended ages for the routine administration of currently licensed vaccines for children. The publication follows ACIP's June 2006 recommendation for routine use of the vaccine for females ages 11-12, and permissive use of the vaccine in females as early as age 9 and up to age 26.

Pediatricians routinely see young women in the 11-12 age range for a well-child check, notes **Renee Jenkins**, MD, professor and chair of the Department of Pediatrics and Child Health at Howard University College of Medicine in Washington, DC. The well-child visit already includes vaccinations for tetanus/diphtheria/acelular pertussis and meningitis, so it is not out of the ordinary to ask them to come in at this age group for care, she notes.

Many states are moving to mandate use of the HPV vaccination in young women. Kentucky legislators have introduced a bill to require girls in public and private middle schools to receive the shot, while District of Columbia legislators have proposed adding the vaccine to the list of required shots for girls prior to sixth-grade enrollment. Two similar bills have been introduced in the Virginia General Assembly, while a Maryland bill is calling for middle school vaccinations.[3] The Texas state legislature will consider legislation that would require girls entering the sixth grade to receive the vaccination, but it also would allow parents to apply for an exemption if they do not want their daughters to receive the shot.

New Hampshire and South Dakota have set up pools of vaccine to provide the shot free of charge to girls and young women.

Since the HPV vaccine now is included in the federal Vaccines for Children (VFC) program, it is available to young women 18 and younger who are Medicaid-eligible, uninsured, American Indian

EXECUTIVE SUMMARY

The national immunization schedule for children and teens has been updated to include Gardasil, the first human papillomavirus (HPV) vaccine.

- The Childhood Immunization Schedule follows an earlier recommendation for routine use of the vaccine for females ages 11 to 12, and permissive use of the vaccine in females as early as age 9 and up to age 26.
- Because the HPV vaccine is included in the Vaccines for Children program, it is available to young women 18 and younger who are Medicaid-eligible, uninsured, American Indian or Alaska Native, or underinsured. Insurance companies are setting policy for reimbursement for the vaccine.

or Alaska Native, or underinsured.

At the present time, many insurance plans are setting policy on coverage of the vaccine, reports **Alina Salganicoff**, PhD, vice president and director of women's health policy at the Menlo Park, CA-based Kaiser Family Foundation. The private foundation is tracking policy issues surrounding the HPV vaccine, and recently sponsored an expert roundtable on the subject. While it appears that private insurance is paying for vaccine coverage for girls, it remains to be seen how copays and deductibles will affect affordability, Salganicoff states. The vaccine, administered in three shots, runs $360, which does not include provider administration fees, she points out.

For women in the 19-26 age range, there are fewer sources for funding when it comes to the HPV immunization, says Salganicoff. About 30% of women in this age range have no health insurance coverage, while about 14% have Medicaid coverage, she states. Those who have private insurance coverage may find that their plan will not cover the shot, says Salganicoff. "We're hearing some anecdotal evidence that not all plans are covering the vaccine for this older age group," she states. "They actually may be liable for the cost themselves."

Merck has initiated a patient assistance program to aid women in this age group. Currently available in private physicians' offices, the program allows Gardasil and other proprietary vaccines to be provided free of charge to those ages 19 and older who are uninsured and who are unable to afford vaccines.

Patients may be eligible for the program if all three of the following conditions apply:

- United States resident, age 19 or older;
- no health insurance coverage (examples of coverage include private insurance, health maintenance organization, preferred provider organization, college health plan, Medicaid, veterans' assistance, or any other social service agency support);
- household income less than $19,600 for individuals, $26,400 for couples, or $40,000 for a family of four.

Will the Merck program help family planning patients? For clinics that are funded by the federal Title X program, patients would not qualify for assistance under the company's program.[4] *[Editor's note: The Association of Reproductive Health Professionals (ARHP) and the Planned Parenthood Federation of America have formed a partnership to develop the clinical education program,* HPV and Cervical Cancer: Comprehensive Prevention, Screening, and Treatment. *To request an ARHP speaker, contact the ARHP education staff at (800) 787-2747. Speaker honoraria and travel expenses will be covered by ARHP.]*

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Trichomoniasis in men — common, often undetected

As you review the chart for your next patient, a heterosexual women seeking treatment for a yellow-green vaginal discharge and vulvar irritation, you see her test results are positive for trichomoniasis. When you discuss the test results with the patient, she tells you her partner has had no symptoms of infection.

If this scenario is replayed in your practice, it is no surprise. Results of a new study indicate about three-quarters of the male sexual partners of women with trichomoniasis are infected, but have no symptoms.[1]

Trichomoniasis, caused by infection from the protozoan *T. vaginalis*, is a common sexually

COMING IN FUTURE MONTHS

- Contraceptive sponge seeks greater acceptance
- More convenient HIV treatment as effective as more complex regimens
- Is breast cancer decline affected by drop in hormone therapy use?
- Young women need more than screening and one-time counseling to cut STD risks
- Black cohosh fails to relieve hot flashes, study findings suggest

EXECUTIVE SUMMARY

Results of a new study indicate about three-quarters of the male sexual partners of women with trichomoniasis are infected, but have no symptoms.

- Trichomoniasis, caused by infection from the protozoan *T. vaginalis*, is a common sexually transmitted disease (STD). A recent study indicates an overall 3% prevalence among U.S. women.
- Rapid testing may not be currently available to test men for trichomoniasis; however, two point-of-care tests give quick results for tests in women. The OSOM Trichomonas Rapid Test relies on immunochromatographic capillary flow dipstick technology, and the Affirm VP III is a nucleic acid probe test.

transmitted disease (STD). A recent study conducted by the Centers for Disease Control and Prevention (CDC) indicates an overall 3% prevalence among U.S. women.[2] Transmitted by sexual intercourse, the infection is associated with the presence of other STDs, adverse reproductive outcomes, and HIV infection.[2]

Most male partners of women with trichomoniasis are coinfected but are asymptomatic, says **Arlene Sena**, MD, MPH, clinical associate professor in the division of infectious diseases at the University of North Carolina at Chapel Hill and medical director of the Durham (NC) County Health Department. The absence of symptoms may make it more difficult to encourage these sexual partners to come to a clinic for evaluation and treatment, observes Sena, lead author of the latest research paper.

"Other complicating issues are that most clinicians still consider trichomoniasis a minor STD, and there are limited methods for laboratory testing of *Trichomonas vaginalis* in men," she states.

Test men for infection

To conduct the prospective, multicenter study, researchers enrolled 540 women with trichomoniasis, diagnosed using wet mount microscopy and/or culture, and 261 of their male partners. *T. vaginalis* infection was detected in about 72% of the men, of which 77.3% were asymptomatic.[1]

Researchers also found that a vaginal pH of >4.5 in a woman was independently associated with infection in the male partner. Younger male age also was found to be an independent risk factor for concordant trichomoniasis.[1]

In men, culture testing of urethral swab, urine, and semen is required for optimal sensitivity when testing for trichomoniasis, according to the CDC.[3] While there is no polymerase chain reaction (PCR) test approved for *T. vaginalis* in men in the United States, such testing might be available from commercial laboratories that have developed their own PCR tests, states the CDC.[3]

While rapid testing currently is not available to test men for trichomoniasis, two point-of-care tests give quick results for tests in women:

- OSOM Trichomonas Rapid Test (Genzyme Diagnostics; Cambridge, MA), an immunochromatographic capillary flow dipstick technology;
- Affirm VP III (Becton, Dickinson & Co.; Franklin Lakes, NJ), a nucleic acid probe test that evaluates for *T. vaginalis*, *G. vaginalis*, and *C. albicans*.

Both tests are performed on vaginal secretions and have a sensitivity of more than 83% and a specificity of more than 97%. Results of the OSOM test are available in about 10 minutes, while results of the Affirm VP III test are available within 45 minutes.[3]

The OSOM test received a Clinical Laboratory Improvement Act (CLIA) waiver from the Food and Drug Administration in 2005, which has expanded the number of clinics and providers' offices that can use the test, reports **Erin Emlock**, Genzyme company spokeswoman. The test is easy to run, since it is a one-reagent, dipstick format, and its results are easy to read, she notes. **(See the resource box, below, for contact information.)** The test has just received a specific Current Procedural Terminology (CPT) code, 87808QW, which should aid in reimbursement, says Emlock.

In a population of women at high risk for STDs and in a research setting with expert microscopists, the OSOM test was more sensitive than wet mount for detecting *T. vaginalis*. The OSOM test was easier to perform and faster than culture, researchers report.[4]

Treatment regimens for trichomoniasis include:

- Metronidazole 2 g orally in a single dose; or
- Tinidazole (Tindamax, Mission Pharmacal, San Antonio) 2 g orally in a single dose.[3]

Be sure that patients understand how to take or

RESOURCE

For more information about Genzyme's OSOM Trichomonas Rapid Test, contact: Tom Krueger, Genzyme Diagnostics. Telephone: (858) 777-2633. Web: www.genzymediagnostics.com.

use prescribed medications, and that they will return if the problem is not cured or recurs, advise the authors of *Contraceptive Technology*. Make sure sex partners are treated, and advise on the use of condoms to prevent future infections. Counsel patients to avoid drinking alcohol until 24 hours after completing metronidazole therapy, they add.[5]

What can clinicians do now? "I think the current

In memory: Cynthia Dailard

Cynthia Dailard, 38, longtime "Washington Watch" columnist for *Contraceptive Technology Update*, died suddenly Dec. 24, 2006. She suffered cardiac arrest, probably caused by a previously undetected congenital heart defect, according to her family.

A senior public policy associate at the Washington, DC, bureau of the Guttmacher Institute, a nonprofit research and advocacy group on women's sexual and reproductive health issues, Dailard had served as *CTU* columnist since 1999. In addition to her columns for this newsletter, she wrote articles and spoke out on such reproductive health issues.

Prior to her work at the Guttmacher Institute, Dailard was associate director for domestic policy for President Bill Clinton, legislative assistant and counsel for Sen. Olympia J. Snowe (R-ME), and a fellow at the National Women's Law Center in Washington, DC.

A web site, http://inmemoryofcynthiadailard.wordpress.com, has been established to post remembrances. ■

CE/CME Instructions

Physicians and nurses participate in this continuing 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** 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. ■

CE/CME 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.

9. What was the bleeding profile reported in the safety and efficacy trial for the continuous regimen oral contraceptive Lybrel?

A. A total of 79% of women reported an absence of bleeding after one year, while 58.7% reported cessation of menstrual cycles.
B. Half of women reported an absence of bleeding after one year, while 25% reported cessation of menstrual cycles.
C. One-quarter of women reported an absence of bleeding after one year, while 15% reported cessation of menstrual cycles.
D. Almost all women reported an absence of bleeding after one year, with 75% reporting a cessation of menstrual cycles.

10. With findings from an international study indicating that using hormonal contraception does not appear to increase women's overall risk of infection with the AIDS virus, family planning experts advise:

A. Counsel that hormonal contraception has a protective effect against HIV.
B. Continued counsel that while hormonal contraception is effective for preventing pregnancy, it does not protect against HIV or other sexually transmitted infections.
C. Diminished messages about the protective effects of abstinence and correct/consistent use of latex condoms.
D. Counsel that nonhormonal contraceptives may not offer the same level of protection against infection as hormonal methods.

11. What is the name of the federal program that provides the HPV vaccine and other immunizations free of charge to young women 18 and younger who are Medicaid-eligible, uninsured, American Indian, or Alaska Native, or underinsured?

A. Federal Immunization Program
B. Vaccine Patient Assistance Program
C. Vaccines for Children
D. National Immunization Registry

12. What is the name of the point of care test for determining trichomoniasis in women that delivers results in about 10 minutes?

A. Trinity Biotech
B. Biokit
C. Affirm VP III
D. OSOM Trichomonas Rapid Test

Answers: 9. A; 10. B; 11. C; 12. D.

best option is through patient education with the infected patient regarding the sexual transmission of trichomoniasis, the complications of untreated infection, and the high likelihood of infection in her male partner(s) even in the absence of symptoms warranting his notification, evaluation, and treatment," states Sena.

References

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5. Hatcher RA, Trussell J, Stewart F, et al. Contraceptive Technology: 19th revised edition. New York City: Ardent Media; in press. ■

Correction

The February 2007 *Contraceptive Technology Update* article "Check options for acute uterine bleeding" should have said women in an open-label trial were randomized to receive 20 mg of oral medroxyprogesterone acetate or a monophasic oral contraceptive (OC) containing 35 mcg of ethinyl estradiol and 1 ***mg*** of norethindrone, each administered three times per day. ■

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.*