STI QUARTERLY™

A SUPPLEMENT TO CONTRACEPTIVE TECHNOLOGY UPDATE

Some groups continue to bear disproportionate burden of STIs

Despite progress, about 50% of new STIs in U.S. are for ages 15 to 24

While the latest national surveillance data show signs of progress in reducing chlamydia and gonorrhea among young people ages 15-24, the numbers and rates of reported cases of these two diseases continue to be highest in this group compared to other age groups.[1]

While young men and women are impacted by these sexually transmitted infections (STIs), young women face the most serious long-term health consequences. The Centers for Disease Control and Prevention (CDC) estimates that undiagnosed STIs cause 24,000 women to become infertile each year.[2]

Nearly half of the 20 million new STIs that occur every year in the United States are among young people ages 15-24, according to the CDC. These infections account for almost $16 billion in healthcare costs.[3]

Preventing STIs among youth remains a top priority for the CDC, says **Gail Bolan**, MD, director of the CDC's Division of Sexually Transmitted Disease (STD) Prevention at the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention. The agency is raising awareness and promoting testing among young people through the national "GYT: Get Yourself Tested" campaign, she notes. April marks the annual observance of STD Awareness Month, which provides a designated time to reinforce the importance of testing. *(Visit the GYT web site at http://on.mtv.com/1AMrk6t.)*

The CDC also is active in educating providers who work with young people, as well as advancing sound health policy, such as developing disease screening and treatment recommendations that help the most affected populations gain access to prevention services and overcome barriers, says Bolan. The agency also provides resources to state and local health departments to support on-the-ground prevention efforts, she states.

"However, CDC cannot do it alone. We all have a shared responsibility to increase screening rates and reduce STIs among youth," states Bolan. "Individuals should talk openly, get tested, and reduce their risk, doctors should proactively discuss STDs with patients, and community leaders should encourage parents to talk to teens about prevention and fight the stigma."

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Chlamydia rates change

Chlamydia continues to be the most commonly reported nationally notifiable disease, the new CDC data indicate.[1] A total of 1.4 million cases were reported in 2013. During 2011–2012, the national rate of reported cases remained stable (453.4 to 453.3 cases per 100,000); however, during 2012–2013, the rate decreased 1.5% to 446.6 cases per 100,000. These data are the first

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since national reporting began that show the rate of reported cases of chlamydia has decreased, the CDC notes.

Among women, the highest age-specific rates of reported chlamydia in 2013 were among those ages 15-19 (3,043.3 cases per 100,000 females) and ages 20-24 (3,621.1 cases per 100,000 females). After numbers for chlamydia steadily increased during 2000-2011 in women ages 15-19, the rate decreased 5.6% during 2011–2012 and fell again 8.7% during 2012–2013.[1]

In 2013, the CDC reports the overall rate of chlamydial infection in the United States among women was more than two times the rate among men: 623.1 cases per 100,000 females versus 262.6 cases per 100,000 males. While there are larger numbers of women screened for chlamydia, more men are being tested due to the increased availability of urine testing. During 2009–2013, the chlamydia rate in men increased 21%, compared with a 6.2% increase in women during this period.[1]

Rates also varied among different racial and ethnic minority populations, data indicate. In 2013, the chlamydia rate in blacks was 6.4 times the rate in whites, and the rate among American Indians/Alaska Natives was almost four times the rate among whites.[1]

Check gonorrhea rates

The national gonorrhea rate in 2013 decreased slightly to 106.1 cases per 100,000 population, which is a change from between 2009 and 2012, when it increased slightly each year to 106.7 cases per 100,000 population.[1] Rates decreased among all persons ages 15-19 and in women 20–24 years old; rates increased in other age groups.

For the first time since 2000, the rate of reported gonorrhea cases among men was higher than the rate among women, the CDC reports. During 2012–2013, the gonorrhea rate among men increased 4.3% and the rate among women decreased 5.1%.[1] "The increase among men compared with a decrease among women suggests either increased transmission or increased case ascertainment (e.g., through increased extra-genital screening) among gay, bisexual and other men who have sex with men," the report states.

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Clinicians should remember that antimicrobial resistance remains an important consideration in the treatment of gonorrhea, the CDC advises. With increased resistance to the fluoroquinolones and declining susceptibility to cefixime, dual therapy with ceftriaxone and azithromycin is the only recommended treatment for gonorrhea, the report states. *(*Contraceptive Technology Update *reported on the guidance. See "New STD guidance on way: Be prepared," January 2015, p. 5.)*

Focus on syphilis

In 2013, CDC data show there were 1,708 more cases of syphilis than in 2012, with the increase almost solely among men.[3] In 2013, men accounted for 91% of all primary and secondary syphilis cases. In the 49 states and the District of Columbia that provided information about sexual orientation of sex partners of patients with syphilis, men who had sex with men (MSM) accounted for 75% of all syphilis cases.

William Smith, executive director of the National Coalition of STD Directors in Washington, DC, says, "This second year of double digit increases of syphilis rates is completely unacceptable and also significantly intersects with our HIV

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epidemic. This continues to affect populations already disproportionally impacted by all STDs, including HIV, most notably gay men and other men who have sex with men."

News on CLIA

In December 2014, the Food and Drug Administration approved a Clinical Laboratory Improvement Amendments (CLIA) waiver for Syphilis Health Check, the first rapid syphilis test to receive a waiver for use outside of traditional laboratory settings.

Created by Diagnostics Direct of Cape May Court House, NJ, the test is distributed by Trinity Biotech of Dublin, Ireland, in the public health and hospital markets and by Diagnostics Direct in the physician's office market. When the test was initially approved in 2011, it was categorized as "moderate and high complexity" under CLIA. *(*CTU *reported on the test. See "Rapid syphilis test released in U.S.," January 2012, p. 5.)*

The test is a qualitative rapid membrane immune-chromatographic assay for the detection of *Treponema pallidum* antibodies in human whole blood, serum, and plasma. The test, which acts as a screening test, will primarily be performed in a CLIA-waived setting using fingerstick samples of whole blood only, with results being available as quickly as 12 minutes. Clinicians should follow up all positive tests with further syphilis serological laboratory testing and clinical evaluation before final diagnosis, company material advises.[4]

According to the National Coalition of STD Directors, such a CLIA-waived test will be useful in several critical settings such as STD clinics, as part of partner outreach and notification services, for screening in high-risk settings including jails and emergency departments, and in outreach settings serving disproportionately impacted populations, such as gay men and other men who have sex with men.

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New HPV vaccine covers 9 types of HPV

Get ready to include a new human papillomavirus (HPV) vaccine at your facility. The Food and Drug Administration (FDA) has approved Gardasil 9 from Kenilworth, NJ-based Merck Sharp & Dohme Corp., a subsidiary of Merck & Co.

The new vaccine covers nine HPV types: HPV 6 and HPV 11, the two low-risk types that cause most cases of genital warts, as well as seven high-risk types: HPV 16, 18, 31, 33, 45, 52, and 58. The new vaccine is administered as three shots, with the initial dose followed by shots given two and six months later. *(*Contraceptive Technology Update *reported on the vaccine. See, "Potential HPV vaccine shows promise: What could it mean for young women?" January 2014, p. 1.)*

The Gardasil 9 vaccine helps prevent infection against the same four types of HPV as the Gardasil quadrivalent vaccine, as well as five other high risk types: 31, 33, 45, 52, and 58. The vaccine has the potential to prevent approximately 90% of cervical, vulvar, vaginal, and anal cancers. It is approved for use in females ages 9 through 26 and males ages 9 through 15.

"The development and approval of the nine-valent HPV vaccine is a major advancement in preventing the transmission of HPV," said **William Smith**, executive director of the

EXECUTIVE SUMMARY

The Food and Drug Administration has approved a new human papillomavirus vaccine: Gardasil 9 from Merck Sharp & Dohme Corp. The new vaccine covers nine HPV types: HPV 6 and HPV 11, the two low-risk types that cause most cases of genital warts, as well as seven high-risk types: HPV 16, 18, 31, 33, 45, 52, and 58.

- Gardasil 9 is administered as three shots, with the initial dose followed by additional shots given two and six months later.
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National Coalition of STD Directors in a statement. "With this vaccine, virtually eradicating cervical, anal, and other genital cancers as well as genital warts within a generation is possible if actual scale up in vaccination occurs."

Gardasil 9 joins two other approved HPV vaccines: Gardasil, the quadrivalent vaccine, and Cervarix, a bivalent vaccine manufactured by Philadelphia-based GlaxoSmithKline that protects against HPV types 16 and 18 in females. At press time, the 9-valent vaccine was scheduled for release in February 2015. The federal Advisory Committee on Immunization Practices (ACIP) was set to vote on recommendations for the vaccine and coverage under the Vaccines for Children program at its February 2015 meeting. Managed care coverage typically follows ACIP recommendations.

Review the results

To test the new vaccine, researchers conducted a randomized, controlled clinical study in the United States and abroad in some 14,000 females ages 16-26 who tested negative for vaccine HPV types at the start of the study. Women enrolled in the study received Gardasil or Gardasil 9.

Study findings indicate the nonovalent vaccine was 97% effective in preventing cervical, vulvar, and vaginal cancers caused by the five additional HPV types: 31, 33, 45, 52, and 58. Researchers also found that Gardasil 9 is as effective as Gardasil for the prevention of diseases caused by the four shared HPV types (6, 11, 16, and 18) based on similar antibody responses in participants in clinical studies.[1] Due to the low incidence of anal cancer caused by the five additional HPV types, the prevention of anal cancer is based on Gardasil's demonstrated effectiveness of 78%, as well as additional data on antibodies in males and females who received Gardasil 9.[2]

Safety data indicate the most commonly reported adverse reactions as injection site pain, swelling, redness, and headaches. As with any vaccine, patients might faint after getting a vaccination, with fainting more common in teens than in young children or adults, according to the Centers for Disease Control and Prevention.[3] To keep patients from getting hurt from fainting, a 15-minute waiting period for people of all ages is recommended after any vaccination.

Impact of new vaccine?

HPV vaccines have been on the market in the United States since 2006, when the original Gardasil was approved. The approval of Cervarix followed in 2009.

Despite efforts to promote vaccine uptake, recent national data indicate the number of girls and boys ages 13-17 receiving HPV vaccination is unacceptably low, despite a slight increase in vaccination coverage since 2012.[4] While the data suggest about 57% of teen girls and 35% of teen boys received one or more doses of HPV vaccine, nearly 86% of adolescents had received one dose of the tetanus, diphtheria, and pertussis vaccine.[4] *(To read more on this topic, see the* CTU *article, "HPV vaccine continues to be underutilized," October 2014, p. 117.)*

Anita Nelson, MD, professor in the Obstetrics and Gynecology Department at the David Geffen School of Medicine at the University of California in Los Angeles, says the availability of the new and improved vaccine will give clinicians something new to say to patients and, she hopes, will reinvigorate professional enthusiasm for the vaccine. Patients who have been vaccinated should not return for the new vaccine; the incremental benefit is not worth the cost, she states.

The Centers for Disease Control and Prevention has developed the "You Are The Key" website (http://1.usa.gov/1eGPIdM) with resources to assist healthcare professionals in strengthening their recommendation for HPV vaccine. *(Need a resource for talking with parents about vaccination for HPV? Download free talking points at http://1.usa.gov/1phjRrM.)*

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