



December 2007: VOLUME 1, NUMBER 6

Clinical Topics in Sexually Transmitted Infections

In this Issue...

Sexually transmitted infections (STIs) continue to cause major morbidity throughout the world, including increased acquisition and transmission of the human immunodeficiency virus (HIV). Since 2006, when the Centers for Disease Control and Prevention (CDC) last updated their STI guidelines, there have been several new developments.

In this issue, we highlight current reports on major advances in the field: a vaccine against the most common human papilloma virus (HPV) strains that cause anogenital cancer and warts, the troubling loss of the fluoroquinolone class as first line agents for the treatment of gonorrhea, the resurgence of lymphogranuloma venereum (LGV) among men who have sex with men (MSM), and the continued misuse of diagnostic testing for herpes simplex virus (HSV).

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1.0 hours Physicians

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November 28, 2009

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Course Directors

John G. Bartlett, MD

Professor of Medicine
Department of Medicine
The Johns Hopkins University
School of Medicine
Baltimore, MD

Paul G. Auwaerter, MD

Associate Professor of Medicine
Clinical Director
Division of Infectious Diseases
The Johns Hopkins University
School of Medicine
Baltimore, MD

Sara E. Cosgrove, MD, MS

Assistant Professor of Medicine
Division of Infectious Diseases
Director
Antibiotic Management Program
Associate Hospital Epidemiologist
The Johns Hopkins University
School of Medicine
Baltimore, MD

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GUEST AUTHOR OF THE MONTH



Commentary & Reviews:

Khalil Ghanem, MD
Assistant Professor of
Medicine
Associate Fellowship Program
Director
Division of Infectious Diseases
Johns Hopkins University
School of Medicine
Baltimore, MD

Guest Faculty Disclosures

Khalil Ghanem, MD has disclosed that he serves on the Speakers' Bureau for Merck & Co.

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LEARNING OBJECTIVES

At the conclusion of this activity, participants should be able to:

- Describe the utility of the quadrivalent HPV vaccine and identify its target population
- Discuss the rise of fluoroquinolone-resistant *Neisseria gonorrhoeae* and its therapeutic implications
- Describe the clinical characteristics of lymphogranuloma venereum
- Identify the appropriate testing strategy for HSV

COMMENTARY

Worldwide, HPV is the most prevalent STI and is responsible for genital warts and anogenital cancers. HPV types 6 and 11 cause 90% of genital warts, and types 16 and 18 cause 70% of cervical cancers. In 2006, the FDA approved a quadrivalent HPV vaccine (HPV types 6, 11, 16, and 18) for use in women aged 9 to 26 years for the prevention of genital warts and anogenital cancers caused by these four types. The vaccine contains non-infectious virus-like particles which induce a robust humoral immune response. The papers by the FUTURE II investigators and by Joura et al (reviewed herein) summarize the efficacy of this vaccine in preventing high-grade cervical, vaginal, and vulvar lesions caused by HPV types 16 and 18. The vaccine appears to prevent nearly 100% of high grade lesions due to these types. It has also been shown to prevent 99% of genital warts.¹ This vaccine, however, has no therapeutic benefits: a woman infected with HPV 16 prior to vaccination will have the same risk of developing HPV-16 related dysplasia as an unvaccinated woman. She will, however, be protected from infection with HPV types 6, 11, and 18 if she were not previously exposed. A bivalent vaccine only containing types 16 and 18 has shown similar efficacy, and is currently under FDA review for licensure. The use of either vaccine will not replace the need for routine screening using the Papanicolaou (Pap) smear.

There are approximately 350,000 cases of gonorrhea reported annually in the U.S. The treatment and control of gonorrhea has been hindered by the ability of the organism to develop drug resistance. Penicillin resistance developed shortly after its introduction, and tetracycline resistance soon followed. Fluoroquinolones have been used as a mainstay of gonorrhea therapy since the early 1990s, but resistance to fluoroquinolones appeared shortly thereafter, and rates of resistance increased significantly in the Far East, the Middle East, and parts of Africa.²

The CDC updated their sexually transmitted diseases treatment guidelines in 2006.³ In the US at that time, fluoroquinolones were still considered first-line agents for the treatment of gonorrhea - except for infections acquired in California and Hawaii, and infections diagnosed in men who have sex with men (MSM). In 2005, >30% of



gonorrhea infections were treated with fluoroquinolones. As described in the review of the Wang paper, rates of fluoroquinolone resistance have been steadily increasing since 1999. Significant increases in fluoroquinolone-resistant strains were detected in 2005 and 2006, which led the CDC to update their 2006 treatment guidelines. The new recommendation is that fluoroquinolones should no longer be used for the treatment of gonorrhea in the US. Currently, the only first-line agents recommended by CDC are the cephalosporins (for uncomplicated gonorrhea, a single 125 mg dose of intramuscular ceftriaxone or a single oral 400mg dose of cefixime are recommended). For penicillin-allergic patients, the treatment of gonorrhea has become much more complicated, given that the only alternate agent recommended by the CDC, spectinomycin, is difficult to obtain after the US manufacturer ceased production of the drug. A single 2g dose of oral azithromycin has excellent activity against uncomplicated gonorrhea and may be used, but the fear of increasing resistance and its gastrointestinal side effects precluded the CDC from listing it as a second-line agent.

Lymphogranuloma venereum (LGV) is a STI caused by *Chlamydia trachomatis* serovars L1-L3. It is endemic in tropical regions and usually presents as a urogenital syndrome consisting of an ulcer and painful regional lymphadenopathy. The LGV serovars are more invasive than the *C. trachomatis* D-K serovars that are commonly encountered in the US. Around 2002, an outbreak of LGV occurred in the Netherlands among MSM⁴, with cases spreading to other European countries and to North America. The largest case series is summarized in the Ward paper (reviewed herein), which highlights the clinical manifestations of a recent LGV outbreak in the United Kingdom. Unlike the classical urogenital manifestations, the majority of patients in this outbreak have been HIV-infected MSM presenting with proctitis. Symptoms included rectal discharge, pain, bleeding, tenesmus, and constipation. Given that the treatment of LGV requires at least 21 days of doxycycline for LGV (compared to a usual 7 day course for non-LGV *C. trachomatis* D-K infections), it is imperative that clinicians not miss this diagnosis.

HSV-2 infects about 25% of the US population. In many cases it is asymptomatic, and although antivirals are available, there is no known definitive cure since herpesviruses establish lifelong latent infection. Culture has been used to diagnose HSV-2, but sensitivity is very low, especially when lesions are absent. Serological testing has been used to diagnose HSV-1 and HSV-2 infections. Initially, crude antigen-based tests were used, but as described in the Morrow paper, significant cross-reaction between HSV-1 and HSV-2 occurs. More recently, glycoprotein-G based tests have been shown to be more specific in differentiating HSV-1 from HSV-2 antibodies. These tests are commercially available (HerpeSelect™ ELISA 1 and 2; HerpeSelect™ Immunoblot 1 and 2; Biokit HSV-2™ or SureVue HSV-2™), but many clinicians are unaware of their existence, and many laboratories continue to perform crude antigen-based tests despite their limitations. Currently, the recommendation is that only glycoprotein-G based tests should be used for the serodiagnosis of HSV-1 and 2. Despite this advancement in serological HSV testing, the study by Mark and colleagues (reviewed herein) highlights an important limitation of the glycoprotein-G based tests: in low prevalence settings the number of false-positive test increases. Both the limitations and the cost of serological testing have made the question of who to test a controversial one. There are no formal recommendations, despite the attempts by different groups to produce a consensus statement.⁵ Clinicians are reminded that the interpretation of any serological test for HSV depends on the type of test that is used, and should take into account the pre-test probability of infection.

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A NEW QUADRIVALENT HPV VACCINE FOR THE PREVENTION OF ANOGENITAL LESIONS IN WOMEN

Females United to Unilaterally Reduce Endo/Ectocervical Disease (FUTURE) II Study Group. **Quadrivalent vaccine against human papillomavirus to prevent high-grade cervical lesions**. *N Engl J Med*. 2007; 356(19):1915-27.

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Joura EA, Leodolter S, Hernandez-Avila M, et al. **Efficacy of a quadrivalent prophylactic human papillomavirus (types 6, 11, 16, and 18) L1 virus-like-particle vaccine against high-grade vulval and vaginal lesions: a combined analysis of three randomized clinical trials**. *Lancet*. 2007; 369(9574):1693-702.

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The study by the FUTURE II investigators describes one of the two large, multicenter, randomized controlled trials evaluating the efficacy of the quadrivalent (HPV types 16, 18, 6, and 11) HPV vaccine against high grade cervical lesions. This impressive study recruited women (N=12,167) between the ages of 15 and 26 years who had four or fewer lifetime sexual partners; participants were randomized to receive 3 doses of the quadrivalent vaccine at 0, 2, and 6 months, or placebo. The primary endpoints were the development of cervical intraepithelial neoplasia (CIN) 2 or 3, adenocarcinoma *in-situ*, or invasive cancer related to HPV types 16 and 18. The primary analysis was restricted to the women who received all three doses of the vaccine and who did not have virologic evidence of past or current infection with HPV 16 or 18 (N=10,565) through month 7 (i.e. one month following the third dose).

After a mean follow-up time of 3 years, overall vaccine efficacy based on the primary analysis was 98%. Over 99% of a subset of women included in an immunogenicity subgroup analysis seroconverted following the third dose of the vaccine. After two years of follow-up, most women (>95%) had detectable antibody levels to three types of HPV found in the vaccine. A lower percentage of women (32%) had undetectable levels to type 18, but all of these women were still protected against disease caused by type 18. The investigators also conducted a population efficacy analysis that included all women who were randomized and who received at least 1 dose of the vaccine irrespective of their baseline HPV status (this analysis provides short-term information on how efficacious this vaccine will be in a 'real' population, where some women may have already been infected with HPV). The population efficacy against HPV 16- and 18-related lesions after 4 years of follow-up was 44%. Vaccine side-effects included fever (10%), pain (83%), swelling (25%), and erythema (25%) at the injection site. The vaccine did not appear to have any therapeutic benefit in women who were previously infected with the four types contained in the vaccine. To date, no serious side effects have been definitively



linked to the vaccine. As this is a relatively new vaccine, long-term monitoring for side effects is ongoing.

Journa et al analyzed data from the FUTURE II as well as two other large clinical trials^{1,2} to determine the efficacy of the vaccine against vulvar and vaginal intraepithelial neoplasia grades 2 and 3 associated with HPV 16 and 18 in 18,174 women. The methods were identical to the ones described above. For the primary analysis, the vaccine was 100% effective at preventing vaginal and vulvar lesions. In the intention-to-treat analysis, it was 71% effective. The intention to treat analysis is similar to the population efficacy analysis described above; it includes women who may have been previously infected with HPV prior to vaccination as well as women who may not have completed all three doses of the vaccine. This analysis provides a better estimate of how this vaccine will perform in a 'real-life' setting.

These studies indicate that this vaccine is highly effective at preventing cervical, vaginal, and vulvar high-grade lesions associated with HPV-types 16 and 18 as well as low grade lesions and warts caused by types 6, 11, 16, and 18. They also highlight the importance of trying to vaccinate women before their first sexual exposure to maximize vaccine efficacy. Finally, given the lower population efficacy, it is important to continue routine Papanicolaou (Pap) smear testing in all women irrespective of their vaccination status.

Currently, the quadrivalent vaccine is approved for use in girls/women ages 9 to 26 years. The vaccine requires refrigeration. The three doses are given intramuscularly at 0, 2, and 6 months. Ideally, it is preferable to try and give all doses within one year, but if a patient presents at a later time, the recommendation is to pick up where you left off, i.e. the whole vaccine series need not be reinitiated. The vaccine is labeled category B in pregnancy; it is not recommended that the vaccine be given to pregnant women because the relative immunosuppression associated with pregnancy may limit the efficacy of the vaccine. Duration of protection is unknown, but after four years of follow-up, the vaccine-type antibody levels are still high. There are ongoing studies to evaluate the efficacy of the vaccine in mid-adult women (up to the age of 45 years), HIV-infected women, and men.

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2. Villa LL, Costa RLR, Petta CA, et al. [Prophylactic quadrivalent human papillomavirus \(types 6, 11, 16 and 18\) LI virus-like particle vaccine in young women: a randomized double-blind placebo-controlled multicenter phase II efficacy trial](#). *Lancet Oncol*. 2005; 6: 271-278.

THE RISE OF FLUOROQUINOLONE-RESISTANT GONORRHEA AND THE LOSS OF A FIRST-LINE THERAPEUTIC CLASS

Wang SA, Harvey AB, Conner SM, et al. **Antimicrobial resistance for *Neisseria gonorrhoeae* in the United States, 1988 to 2003: the spread of fluoroquinolone resistance**. *Ann Intern Med*. 2007; 147(2):81-8.

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Centers for Disease Control and Prevention. **Update to CDC's sexually transmitted diseases treatment guidelines, 2006: fluoroquinolones no longer recommended for treatment of gonococcal infections**. *MMWR Morb Mortal Wkly Rep*. 2007; 13; 56 (14):332-6.

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 NEWSLETTER ARCHIVE

Wang et al recently conducted a 15-year retrospective review of the Gonococcal Isolate Surveillance Project (GISP) database and reported on the antimicrobial resistance trends of *Neisseria gonorrhoeae* in the United States. GISP was established in 1986; this network of 25-30 US-based STD clinics collects the first 25 male gonococcal isolates each month and submits these to a regional laboratory for antimicrobial susceptibility testing. The CDC relies on this information to make therapeutic recommendations.

In this report, based on 82,064 isolates collected from 37 US cities, the investigators found the following trends:

- Ciprofloxacin resistance increased from 0% in 1990 to 4.1% in 2003
- Only 3 isolates had decreased susceptibility to ceftriaxone
- Azithromycin resistance was low: 0% in 1992, 0.7% in 1996, and 0.4% in 2003
- Only 5 spectinomycin resistant isolates were identified, all pre-1995

By 2006, approximately 13% of all GISP isolates were resistant to fluoroquinolones. Based on these data, the CDC issued an update to the 2006 STD Treatment Guidelines. In this update, they no longer recommend the use of fluoroquinolones for the treatment of gonorrhea (and related diseases such as pelvic inflammatory disease). The only remaining first-line treatment options are cephalosporins: intramuscular ceftriaxone and oral cefixime. Alternate agents include other cephalosporins (ceftizoxime, cefoxitin + probenecid, or cefotaxime). For penicillin-allergic patients, the only recommended alternate regimen is intramuscular spectinomycin. Clinicians should note, however, that spectinomycin has reduced activity against oropharyngeal gonorrhea, and is difficult to find in the US, since the manufacturer has discontinued production of the drug. The report mentions that a single 2g dose of azithromycin, although not recommended due to fears of increasing resistance and gastrointestinal intolerance, is effective and may be considered in penicillin-allergic patients.

These studies highlight the emergence and rapid spread of fluoroquinolone-resistant *N. gonorrhoeae*, as well as the ensuing difficulty in treating this infection. Single-dose fluoroquinolones have been the mainstay of therapy since 1993. Their therapeutic loss has limited the options to essentially a single class of antibiotics: the cephalosporins. Penicillin-allergic patients are left with very limited CDC-recommended options.

THE RESURGENCE OF LYMPHOGRANULOMA VENEREUM AMONG GAY MEN

Ward H, Martin I, Macdonald N, et al. **Lymphogranuloma venereum in the United Kingdom.** *Clin Infect Dis.* 2007 Jan 1; 44(1):26-32.

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Ward and colleagues report on the largest case series of LGV, which, since 2005, has emerged as a significant cause of proctitis among MSM in the United Kingdom. Similar outbreaks had been reported in the Netherlands and North America. LGV is caused by *C. trachomatis* serogroups L1, L2, and L3. In 2004, an enhanced surveillance system for LGV was set up which consisted of a reference laboratory diagnostic service and reporting system. Clinicians were encouraged to test all MSM who presented with an inguinal syndrome or proctitis. If the presence of *C. trachomatis* was confirmed by the local laboratory, specimens were forwarded to a reference laboratory for genotyping.



Between October 2004 and February 2006, 327 cases of LGV were confirmed with the following demographics:

Male Sex	95%
Median Age	38 years
Symptomatic	87%
Anorectal Symptoms Only (rectal discharge, pain, bleeding, tenesmus, or constipation)	228
Urogenital Symptoms Only (genital, ulcer/abscess, urethral discharge, dysuria, inguinal lymphadenopathy)	12
Combination of Symptoms (anorectal and urogenital)	34
HIV Co-Infection	76%
Concomitant Infection (with another sexually transmitted infection)	39%

Several patients were mistakenly treated for inflammatory bowel disease. The majority of infections were thought to have been acquired in the United Kingdom.

Until recently, LGV had only been thought of as a "tropical disease", rarely occurring outside of the developing world. Unlike the classically described manifestations that are urogenitally-based (primary ulcers followed by painful lymphadenopathy, also known as buboes), the majority of cases reported in the recent outbreak have been associated with predominantly anorectal symptoms among MSM who are also likely to be HIV infected. Diagnosis is based on clinical suspicion and the exclusion of other etiologies of proctitis, along with *C. trachomatis* testing (if available). Lymph node specimen aspirates may also be tested for *C. trachomatis* by culture (not always available), direct immunofluorescence, or nucleic acid detection. (Clinicians should note that nucleic acid amplification tests for *C. trachomatis* are not FDA-cleared for testing rectal specimens.) Additional procedures (e.g. genotyping) are required for differentiating LGV from non-LGV *C. trachomatis* strains, but these are not widely available. In the absence of specific LGV diagnostic testing, if a patient presents with the typical syndrome, it is appropriate to treat for LGV. The primary CDC-recommended treatment regimen is oral doxycycline 100mg twice a day for 21 days.

HSV SEROLOGICAL TESTING: ITS USE AND MISUSE

Morrow RA, Brown ZA. **Common use of inaccurate antibody assays to identify infection status with herpes simplex virus type 2.** *Am J Obstet Gynecol.* 2005 Aug; 193(2):361-2.

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Mark HD, Nanda JP, Roberts J, Rompalo A, Melendez JH, Zenilman J. **Performance of focus ELISA tests for HSV-1 and HSV-2 antibodies among university students with no history of genital herpes.** *Sex Transm Dis.* 2007 Sep; 34(9):681-5.

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Morrow reports the results of HSV-type specific testing at 172 laboratories that participate in the College of American Pathologists' test proficiency program. In this study, each lab received a serum sample known to be positive for HSV-1 IgG and negative for HSV-2 IgG antibodies.

Nearly all the laboratories (98%) detected the HSV-1 antibodies, while more than half the laboratories erroneously detected the presence of HSV-2 antibodies. Ninety-four laboratories reported the type of test used to detect HSV-2. Among the laboratories that used a glycoprotein-G based test, 100% accurately reported the lack of HSV-2 antibodies; when earlier generation HSV serological tests that contained crude antigen mixtures were used, up to 84% detected the presence of HSV-2 antibodies. The poor performance in this survey is thought to be due to the cross-reactivity of HSV-1 and HSV-2 antigens when non-glycoprotein-G based tests are used.

Mark and colleagues report the results of a study that used glycoprotein-G based testing to determine the HSV-1 and HSV-2 serostatus of 100 university students (64% female; mean age 24.5 years) who reported no history of genital herpes. The overall seroprevalence of HSV-2 was 3.4% by Western Blot. The sensitivity of the glycoprotein-G based ELISA was 100%, the specificity was 94.1%, and the positive predictive value was 37.5%. Low positive predictive value results reflect frequent false positive results.

The study by Morrow highlights the fact that serological testing for HSV-1 and HSV-2 should only be performed using the more specific glycoprotein-G based tests, and that crude-antigen based testing should no longer be performed. The study by Mark indicates a high rate of false positive test results when glycoprotein-G based serological testing is performed in a population where the prevalence of HSV-2 is low. The more specific Western Blot test is not commercially available: in the US, a single laboratory in Seattle, Washington performs this test. If the pre-test probability for HSV-2 infection is low (e.g., patient asymptomatic, low-risk), it is probably best not to test. Interpretation of HSV serologies should take into account both the type of test used and the pre-test probability of infection.

Scenario	Suggested HSV-2 Testing Strategy
A patient presents with a history of recurrent genital lesions of unclear etiology. He is currently asymptomatic.	HSV-2 G-glycoprotein-based test may be performed: a negative result would rule out HSV-2 as a cause of the recurrent genital lesions.
A young couple presents for evaluation. The male partner has a history of recurrent genital ulcers. The female partner does not. Daily antiviral therapy for the male partner is being considered to prevent transmission to the female partner.	Both the male and female partners should be tested for HSV-2 using a G-glycoprotein-based test. This test will help determine whether HSV-2 is the cause of recurrent ulcers in the male partner and will help determine whether the female partner is HSV-2 negative.
A 20 year-old asymptomatic patient with two lifetime sex partners who has never had a STI and who denies a history of genital lesions or ulcers wants to be checked for "all venereal diseases".	Although a HSV-2 G-glycoprotein-based test may be performed, a positive test should be interpreted cautiously given the relatively low pre-test probability of HSV-2 infection.

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At the conclusion of this activity, participants should be able to:

- Describe the utility of the quadrivalent HPV vaccine and identify its target population
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- Identify the appropriate testing strategy for HSV

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- **John G. Bartlett, MD** has disclosed that he has served on the HIV Advisory Board for GlaxoSmithKline, Abbott, Bristol-Myers Squibb, Pfizer and Tibotec. He is also on the Policy Board for Johnson & Johnson.
- **Paul G. Auwaerter, MD** has disclosed that he has served as a consultant for Novartis, Pfizer, Ortho-McNeil, Schering-Plough, and Genzyme. He is on the Speakers' Bureau for Schering-Plough and has also disclosed that he is a Stock Shareholder for Johnson & Johnson.
- **Sara E. Cosgrove, MD, MS** has disclosed that she has received grants or research support from Merck and served on the Advisory Boards for Ortho-McNeil, Cadence Pharmaceuticals, and Theravance/Astellas.

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