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Clinic-Based Testing for Rectal and Pharyngeal Neisseria gonorrhoeae and Chlamydia trachomatis Infections by Community-Based Organizations --- Five Cities, United States, 2007

CDC recommends screening of at-risk men who have sex with men (MSM) at least annually for urethral and rectal gonorrhea and chlamydia, and for pharyngeal gonorrhea (*1*). Although the standard method for diagnosis is culture, nucleic acid amplification (NAA) testing is generally more sensitive and favored by most experts (*2*). NAA tests have not been cleared by the Food and Drug Administration (FDA) for the diagnosis of extragenital chlamydia or gonorrhea and may not be marketed for that purpose. However, under U.S. law, laboratories may offer NAA testing for diagnosis of extragenital chlamydia or gonorrhea after internal validation of the method by a verification study.* To determine sexually transmitted disease (STD) testing practices among community-based organizations serving MSM, CDC and the San Francisco Department of Public Health gathered data on rectal and pharyngeal gonorrhea and chlamydia testing at screening sites managed by six gay-focused community-based organizations in five U.S. cities during 2007. This report summarizes the results of the study, which found that three organizations collected samples for NAA testing and three for culture. In total, approximately 30,000 tests were performed; 5.4% of rectal gonorrhea, 8.9% of rectal chlamydia, 5.3% of pharyngeal gonorrhea, and 1.6% of pharyngeal chlamydia tests were positive. These results demonstrate that gay-focused community-based organizations can detect large numbers of gonorrhea and chlamydia cases and might reach MSM not being tested elsewhere. Public health officials could consider providing support to certain community-based organizations to facilitate testing and treatment of gonorrhea and chlamydia.

Gay-focused community-based organizations provide medical and social services and are guided and staffed by paid or unpaid community residents with various skill levels, including some who might have medical, nursing, or counseling backgrounds (*4*). Funding and other resources are provided by private and public sources. Many gay-focused community-based organizations in cities with large MSM, lesbian, and bisexual populations offer alternative venues to traditional public STD clinics and private physicians by providing onsite STD screening and treatment services. Gay-focused community-based organizations typically do not require health insurance for access, are located in neighborhoods with many MSM, and provide culturally competent services for a historically stigmatized population.

For this survey, gay-focused community-based organizations were defined as nongovernmental organizations that stated in published materials that they principally serve MSM. During April 2008, the 10 U.S. cities with the highest estimated number of gay, lesbian, or bisexual residents were identified (*5*). Gay-focused community-based organizations in each city that provide rectal and pharyngeal gonorrhea and chlamydia testing to MSM were identified through community leaders and Internet searches. Organizations were excluded if they did not provide rectal or pharyngeal gonorrhea or chlamydia testing services, or were unable to provide data on types of test used, number of tests performed, or percentage of positive tests during 2007.

Among 11 gay-focused community-based organizations identified in the 10 cities, 10 provided rectal or pharyngeal gonorrhea or chlamydia testing services. Among those 10 organizations, data were available from six in five cities, including Howard Brown Health Center (Chicago, Illinois), Callen-Lorde Community Health Center (New York, New York), AIDS Health Foundation (Los Angeles, California), Los Angeles Gay and Lesbian Center (Los Angeles, California), Magnet (San Francisco, California), and Gay City Health Project (Seattle, Washington). Data for 2007 were collected during April--July 2008. Overall, staff from six organizations collected samples for 6,499 rectal gonorrhea tests and 5,258 rectal chlamydia tests; staff from five organizations collected 14,189 samples for pharyngeal gonorrhea tests; and staff from four organizations collected samples for 3,410 pharyngeal chlamydia tests (Table). Medical oversight at each organization assured proper specimen collection, transport, results disclosure, treatment, and partner notification. Organizations that used NAA testing generally had higher rates of positivity than those that used culture. Pharyngeal and rectal test positivity generally was high compared with urethral testing.

Four of the six organizations sent the specimens to public health laboratories for testing; costs for that testing were funded by local public health jurisdictions. The other two organizations used commercial laboratories for testing; costs for that testing were funded by patient insurance or self-pay. All laboratories had completed verification studies demonstrating adequate NAA testing performance in extragenital specimens.

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Editorial Note:

In 2007, chlamydia and gonorrhea were the first and second most commonly reported notifiable diseases in the United States, respectively, with 1,108,374 chlamydia cases (370.2 per 100,000 population) and 355,991 gonorrhea cases (118.9 per 100,000 population) (*6*). Most chlamydia and

gonorrhea testing is performed in traditional medical settings and is indicated for screening, diagnosis, or test-of-cure. During 2007, the six gay-focused community-based organizations in this report collected samples for approximately 30,000 rectal and pharyngeal gonorrhea and chlamydia tests from community members attending each facility and detected approximately 1,600 infections. Tests on samples collected by four of the six organizations surveyed were performed by public health laboratories and funded by local health jurisdictions, illustrating the role that partnerships between government and community-based organizations can play in prevention and control of rectal and pharyngeal gonorrhea and chlamydia.

The percentages of positive NAA tests for rectal and pharyngeal gonorrhea and chlamydia were similar to those reported for NAA testing in a previous study from a publicly funded municipal STD clinic (*7*). As expected, NAA test positivity for rectal gonorrhea and chlamydia infections and pharyngeal gonorrhea was generally higher than culture test positivity (*7*).

Compared with cultures, NAA tests have numerous advantages in detecting gonorrhea and chlamydia. NAA tests might perform better than cultures in nontraditional medical settings, where specimens for culture could be vulnerable to suboptimal handling, compared with more traditional medical clinics. NAA tests are more sensitive than culture for diagnosis of rectal or pharyngeal chlamydia or gonorrhea among MSM, while preserving specificity >99% (7).† Furthermore, NAA tests can detect gonorrhea and chlamydia simultaneously with a single test and can detect infection in self-collected specimens, including rectal and pharyngeal specimens (*3*). NAA test results can be available within 48 hours, whereas most culture results are not available for at least 48 hours. Unlike cultures, NAA tests do not require specialized equipment for specimen collection (e.g., a carbon dioxide-enriched atmosphere for storage and transport for *Neisseria gonorrhoea* cultures).

CDC recommends at least yearly screening for rectal gonorrhea and chlamydia for MSM who have had receptive anal intercourse during the preceding year and for pharyngeal gonorrhea for MSM who have participated in receptive oral intercourse during the preceding year. CDC recommends screening at 3--6 month intervals for MSM who have multiple or anonymous partners, have sex in conjunction with illicit drug use, use methamphetamine, or have sex partners who participate in those activities (*1*). CDC does not recommend routine screening for pharyngeal chlamydia (*1*). Nonurethral gonorrhea and chlamydia frequently are asymptomatic and often can be present in the absence of urethral gonorrhea or chlamydia, reinforcing the need to screen persons at the relevant exposed anatomic sites (*4*).

Currently, a low percentage of sexually active MSM at risk for STDs are screened at the minimum frequency recommended by CDC, at least for gonorrhea. In a 2003--2005 national study, 36% of MSM reported being tested for gonorrhea at any anatomic site in the previous year (*8*). Screening for pharyngeal and rectal gonorrhea among MSM is less common than for urethral gonorrhea, impeding efforts to control gonorrhea transmission among MSM (*9*).

The findings in this report are subject to at least four limitations. First, data on indication for testing (e.g., diagnostic screening or test of cure) were available only from the Gay City Health Project, which tested only asymptomatic persons using culture; all other community-based organizations tested symptomatic and asymptomatic persons, resulting in a higher prevalence than what is found in reports limited to screening in asymptomatic persons. Second, the unknown, underlying prevalence of infections, which might have varied in the populations tested using NAA tests compared with cultures, was not considered. Third, information regarding the sex of persons tested at the community-based organizations and of the sex partners was not available, so that results could not be limited exclusively to MSM. Finally, this study described the use of only one type of NAA test; other NAA tests might perform differently.

Two large commercial laboratory service vendors, Laboratory Corporation of America and Quest Diagnostics, recently have verified and begun offering NAA tests for diagnosis of rectal and pharyngeal gonorrhea and chlamydia. As more laboratories verify NAA tests to detect gonorrhea and chlamydia, community-based organizations increasingly can be effective partners in the STD prevention efforts to control rectal and pharyngeal gonorrhea and chlamydia, and possibly reduce HIV transmission in MSM. More widespread use of NAA tests likely would allow the detection of infections that might be missed by culture, either because of the relatively lower sensitivity of culture or because persons collecting samples might lack the experience necessary to ensure proper collection and handling. Manufacturers of NAA tests can pursue FDA clearance of those tests for the diagnosis of rectal and pharyngeal gonorrhea and chlamydia by gathering and submitting to FDA sufficient data on test performance for those indications. In the interim, CDC and the Association of Public Health Laboratories can help support increases in NAA testing by providing technical assistance and specimens to laboratories for use in verification studies (*2*).

Rectal and pharyngeal gonorrhea and chlamydia among MSM remain a public health concern. The feasibility and utility of integrating testing for extragenital gonorrhea and chlamydia into existing services at gay-focused community based organizations likely will depend on many factors (e.g., funding availability, staff training, and regional disease burden). Local health jurisdictions might increase chlamydia and gonorrhea testing among MSM by providing financial and technical support to gay-focused community-based organizations and collaborating with them on activities related to the prevention and control of rectal and pharyngeal gonorrhea and chlamydia.

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* Verification studies permit the use of tests for an indication that does not have formal clearance by FDA. Verification studies can be performed at a single laboratory or in collaboration with a second laboratory. The second laboratory might be able to provide a panel of previously tested positive and negative specimens for comparative purposes. A typical verification protocol involves testing of at least 20 positive and 20 negative specimens compared to the reference standard or to results obtained from a second laboratory. The test performance (i.e., sensitivity and specificity) should be equivalent or better than the reference standard or to those obtained by the second laboratory (*3*).

† Studies have shown sensitivity of 63%--100% for NAA tests, depending on the type of test used, anatomic site sampled, and the organism assayed, versus 27%--41% for culture (*5*).

TABLE. Number of tests performed by gay-focused community-based organizations,* by test type, laboratory, and funding source, to detect rectal and pharyngeal Neisseria gonorrhoeae and Chlamydia trachomatis infections --- five U.S. cities,† 2007

Tests performed, by organization (city)	Rectal						Pharyngeal					
	N. gonorrhoeae infections			C. trachomatis infections			N. gonorrhoeae infections			C. trachomatis infections		
	No. tests	No. positive	(%)	No. tests	No. positive	(%)	No. tests	No. positive	(%)	No. tests	No. positive	(%)
NAA§ tests only												
Los Angeles Gay and Lesbian Center (Los Angeles)**	1,845	206	(11.2)	1,841	248	(13.5)	7,214	471	(6.5)	---¶		
AIDS Healthcare Foundation (Los Angeles)**	670	30	(4.5)	658	66	(10.0)	1,410	60	(4.3)	---		
Magnet (San Francisco)**	2,307	107	(4.6)	2,307	151	(6.5)	3,397	194	(5.7)	3,397	54	(1.6)
Culture only												
Howard Brown Health Center (Chicago)††	40	3	(7.5)	34	0	(0)	41	0	(0)	13	0	(0)
Callen-Lorde (New York City)††	1,176	5	(0.4)	---			1,456	4	(0.3)	---		
Gay City Health Project (Seattle)**	461	2	(0.4)	418	3	(0.7)	671	30	(4.5)	---		
Total	6,499	353	(5.4)	5,258	468	(8.9)	14,189	759	(5.3)	3,410	54	(1.6)

* Includes nongovernmental organizations providing sexually transmitted diseases clinics and testing, primarily for men who have sex with men, but might include persons identified as lesbian or bisexual.

† Chicago, Illinois; Los Angeles, California; New York, New York; San Francisco, California; and Seattle, Washington.

§ Nucleic acid amplification. All NAA tests were APTIMA Combo 2 assays (Gen-Probe, Inc., San Diego, California).

¶ Did not test for *C. trachomatis*.

** Testing funded by local health jurisdiction and conducted at local public health laboratory.

†† Testing funded by insurance or patient out-of-pocket expenses and conducted at commercial laboratory.

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