

Late-Breaker Oral Abstract: Performance of Nucleic Acid Amplification Tests (NAATs) for Chlamydial and Gonococcal Infections of the Oropharynx and Rectum in MSM

DNA Testing Method Can Identify Twice as Many Throat and Rectal Gonorrhea and Chlamydia Infections as Traditional Bacterial Culture

A new study shows that a more efficient STD screening method – called a nucleic acid amplification test (NAAT) – can detect at least twice as many oropharyngeal (throat) and rectal gonorrhea and chlamydia infections as a bacterial culture test, the standard means of diagnosing gonorrhea and chlamydia infections in extra-genital sites.

Culture testing requires that bacteria be grown in a controlled laboratory setting before the infection can be identified. Because NAATs can detect bacterial DNA directly from a patient sample, they are generally more accurate, easier to use, and provide results faster than culture tests.

Diagnosing and treating infections at all exposed anatomic sites (i.e., genitals, throat, rectum) is essential for preventing the spread of STDs. To date, three NAATs are cleared by the Food and Drug Administration (FDA) to screen for both chlamydia and gonorrhea infections in the urogenital tract. These tests have replaced traditional bacterial culture for those infections in many medical settings. However, none of these NAATs has been cleared by the FDA to screen for infections in the throat or rectum, which are relatively common among men who have sex with men (MSM). FDA clearance of NAATs for use at extra-genital sites would require submission of additional data to verify their effectiveness.

To assess whether NAATs already approved for urogenital use are effective in identifying chlamydia and gonorrhea infections in the throat and rectum, researchers from the University of California, San Francisco (UCSF) and the San Francisco Department of Public Health, led by UCSF's Julius Schachter, tested oropharyngeal and rectal swab specimens from 1,110 MSM attending San Francisco's public STD clinic between October 2005 and May 2007. Forty percent of the men had no symptoms for either disease. All collected samples were tested with a traditional culture test, as well as two different NAATs currently FDA-approved for urogenital use.

Among the MSM participating in the study, the tests indicated that chlamydia prevalence was 0.8 percent in the throat and 6.1 percent in the rectum; gonorrhea prevalence was 8.3 percent in the throat and 8.2 percent in the rectum. Dr. Schachter and colleagues found that both NAATs identified a significantly larger number of chlamydia and gonorrhea infections in the throat and rectum than traditional bacterial culture tests. NAATs were statistically similar in identifying the majority of all chlamydia and gonorrhea infections in the throat and rectum (range: 63%-100%), while culture tests identified significantly fewer proportions of infections in extra-genital sites (range: 27%-44%). Both NAATs also had greater sensitivity (the ability to correctly identify those who are infected) than traditional culture tests, and comparable specificity (the ability to correctly identify those who are not infected).

The authors note that FDA clearance of NAATs to screen for chlamydia and gonorrhea infections in the throat and rectum would clear the way for their widespread use in medical settings, identify more infections, and help stop the continued spread of these diseases – particularly among MSM.

CDC is working with the FDA and test manufacturers to gather, analyze, and coordinate the submission of relevant data to the agency. In the interim, laboratories may use NAATs to test for chlamydia and gonorrhea in the throat or rectum, provided they first perform in-house studies to verify the accuracy of their testing methods in accordance with established federal regulations. The San Francisco Department of Public Health, for example, has performed such a study and now uses NAATs in its laboratory to screen for chlamydia and gonorrhea at all three anatomic sites. CDC encourages dialogue among public health professionals to determine whether their local patient populations are at risk for chlamydia and gonorrhea infections at extra-genital sites, and advises local health departments to work with laboratory directors to ensure the development of diagnostic capacity for such testing if it is needed.