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Preparing for the Chlamydia and Gonorrhea Self-Test

Thomas A. Peterman, MD, MSc, Kristen Kreisel, PhD, Melissa A. Habel, MPH, William S. Pearson, PhD, MHA, Patricia Dittus, PhD, John R. Papp, PhD

Division of STD Prevention, National Center for HIV, Hepatitis, STD, and TB Prevention, Centers for Disease Control and Prevention, Atlanta GA.

Brief summary:

Self-tests for gonorrhea and chlamydia are being developed that will bring opportunities for prevention, but challenges for treatment, partner treatment, and surveillance.

Keywords

Chlamydia; gonorrhea; testing; prevention; treatment; surveillance

Introduction

New technology may soon allow individuals to test themselves for chlamydia (CT) and gonorrhea (GC), the two most commonly reported notifiable infections in the United States.¹ Untreated CT and GC infections in women can lead to serious consequences including pelvic inflammatory disease (PID), tubal factor infertility, ectopic pregnancy, and chronic pelvic pain. A randomized trial of CT screening found it prevented 1 case of symptomatic PID for every 12.5 women with CT that were detected and treated.² Annual screening for both infections is recommended for all sexually active women under age 25, and for older women at increased risk (USPSTF Grade B).³ Yet, only about 40% of the estimated 3.7 million incident infections in 2008 were diagnosed and reported.^{4, 5} A recent review of clinical preventive services found CT and GC screening were underutilized despite providing substantial opportunities to improve population health.⁶ Rates of reported CT and GC have increased in recent years⁷ and budgets have been cut for many health departments, leading to decreasing STD services.⁸ These new self-tests might help this discouraging situation, but they will also bring new issues for treatment, prevention, and surveillance. In this paper, we discuss likely characteristics of these new tests and areas where research is needed to prepare for them.

Corresponding Author: Thomas A. Peterman, Mailstop E02, CDC, 1600 Clifton Rd, Atlanta GA 30333, Fax 404-639-8610; Phone 404-639-6102; tap1@cdc.gov.

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Tests

Laboratory tests have evolved from culture dependent to independent platforms that utilize less-invasive specimen types. This has allowed greater access to testing due to the ease of specimen collection and transport. However, the detection of sexually transmitted infections (STIs) has been largely limited to tests performed by skilled technicians in laboratories.⁹ These tests are marketed in the United States following a rigorous review process prescribed by the Food and Drug Administration (FDA) to ensure accurate performance characteristics. Strict guidance for specimen collection, transport of specimens, test procedures, and reporting of results are detailed in the product insert of each test. There are no STI tests that have been cleared by the FDA for self-testing. There are websites that allow persons to self-collect a specimen and mail it to a laboratory for testing.¹⁰ The cost and validity of these tests are quite variable, and home-collection of specimens has not been approved by the FDA.

Bridging gaps in STI testing through the development and deployment of self-tests has the potential to increase screening but must be carefully implemented. Potential problems include poor test accuracy and low predictive value. The performance of laboratory-based tests currently used to detect CT and GC are exceptionally high with sensitivities over 95% and specificities over 99.5%.⁹ The positive predictive value of a test is a function of test specificity and prevalence of infection within the test population and may be poor when the prevalence is low. The performance of future self-tests must be comparable to laboratory tests to minimize false positives and false negatives. Nevertheless, people will need to understand that tests are not perfect.

Laboratory-based nucleic acid amplification tests (NAATs) recommended by the CDC identify CT and GC in clinical specimens by amplifying target-specific nucleic acids for detection.⁹ There are various methods used but all rely on specific target amplification. Diagnostic test research has focused on microfluidic design of NAATs to maintain performance of laboratory tests yet allow for potential adaptation to self-tests. Targeting a specific gene sequence for amplification and detection requires a device that can perform these functions. Some approaches have used small stand-alone units to power amplification and detect the result but these are likely impractical for self-tests. More promising are test cartridges that can be attached to smartphones for power and detection of amplified products. A smartphone app might also directly report the positive test to the state or local health department and assist in linking patients to a provider for treatment though such a link might discourage testing among persons who want to remain anonymous.

Treatment: who, when, where?

Laboratory-based NAATs are very sensitive and specific, however it takes a few days to get results so presumptive treatment is recommended for persons with urethritis or cervicitis. Presumptive treatment is also recommended for all partners who have had sex with an infected person in the preceding 60 days because they may have incubating infections.¹¹ New self-tests are likely to have lower specificities than NAATs, but the likelihood of infection among persons with a positive self-test would still be higher than in some

situations for which empiric treatment is recommended. Thus, treating patients who report that they have a positive self-test, without doing confirmatory testing, seems reasonable.

Treating partners may be another challenge. Patients may want a higher level of certainty before notifying their partners than they require before treating themselves. Notifying a partner after a false-positive test could unnecessarily strain a relationship,^{12–14} however, not notifying an infected partner may result in re-exposure and re-infection of the index patient.^{15, 16} Partner notification could be based on the index patient's history of a positive self-test, a confirmatory rapid test of the patient at the clinician's office, or could await the result of a confirmatory NAAT (though this would require abstaining from sex with the partner in the interim). Confirmatory testing delays treatment, increases costs, and the increase in specificity brings a decrease in sensitivity. Approaches to treatment and partner treatment will require careful consideration.

Assuring the availability of low-cost and convenient treatment will be another issue, especially for persons who have asymptomatic infections that are easily ignored. Convenient walk-in clinics are increasingly used as a source of care for STD.¹⁷ Providers in these and other settings will need to develop protocols for managing patients who present to their clinics after a positive self-test, and consider a range of approaches from just treating the reported infection to offering a full sexual health evaluation.

Prevention

Screening young women for CT has been shown to prevent PID.² If screening and treatment reaches high enough levels, it could also lower the prevalence of infection in the population.¹⁸ Will self-tests lead to widespread testing? Some self-tests have been widely used while others have not. Self-tests for pregnancy were introduced in the late 1970's and now millions are sold every year.¹⁹ Self-tests for HIV were approved by the FDA in 2012, but the current cost (about \$40) exceeds what most individuals are willing to pay (about \$17), especially when many clinics offer free or reduced price testing using a more accurate test.²⁰ Although self-tests are not yet available for other sexually transmitted infections, in some areas persons can collect a specimen at home, mail it to a lab for testing, and receive their results within several days. A randomized controlled trial in Texas found screening rates were higher for men who could mail in a urine specimen (72%) compared to men who had to visit a clinic for screening (48%).²¹ A well-established program in Maryland and Washington DC that offers free mail-in testing for CT, GC, and trichomonas tested 858 specimens during 6 months in 2012.²² A survey of young adults found 93% thought self-tests were a "good idea", 73% thought people their age would use the tests, and they expected to pay an average of \$23 per test.²³ How many will actually purchase and use a real self-test remains to be seen. Research will be needed to develop methods for promoting the use of self-tests.

Saving surveillance

Gonorrhea has been a reportable condition since 1941 and chlamydia has been a reportable condition in all states since 2000. In 2015, GC (395,216) and CT (1,526,658) comprised 76% of all reported nationally notifiable infectious conditions.¹ Surveillance is based

primarily on laboratories reporting all positive tests. Self-tests may complicate the ability to monitor trends in GC and CT because self-tests would bypass this established reporting system. If patients seek care following a positive self-test and their provider sends another specimen to a lab for testing, those results would be captured. However, if self-test results are not confirmed by providers, or even if results are confirmed by other point-of-care tests performed in a clinician's office, they may not be captured. Providers could report all cases they treat, as is mandated in most jurisdictions, however, provider reporting is often incomplete.²⁴ Diagnoses might be inferred based on monitoring electronic records of medications prescribed, but the medications used to treat these infections are also used for many other infections.^{25, 26} Perhaps electronic medical records could be used to directly identify diagnosed infections, but this technology is currently feasible in only a few areas. At this point, the way forward for surveillance is unclear. It would be advantageous to identify new approaches for surveillance now rather than wait until after the tests are widely used. This would allow comparison of reports from both before and after self-tests are introduced and help measure the impact on surveillance.

Conclusion

Self-tests for CT and GC have the potential to greatly expand testing. If self-tests lead to widespread screening and treatment, they could potentially decrease rates of PID and lower the prevalence of CT and GC. Although persons interested in a screening test may find that self-tests provide a major advantage by avoiding the need to visit a clinic, it is not so clear that young women are actively seeking a screening test. Currently, most screening is performed as recommended by clinicians in the context of a clinic visit for another reason.²⁶ Self-tests could be a major advance in the clinical setting because they will allow clinicians to diagnose and treat an infection at a single visit. Further research is needed to identify ways to increase demand for screening outside of the clinical setting and to reduce the patient cost for an over-the-counter test. There are other barriers to overcome. Providers will need to establish protocols for treating patients and their partners. New surveillance techniques will be needed if treatment is based on testing done outside of laboratories. Self-tests are new tools that will soon be available. We should be prepared to use them.

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