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Novel STI Testing Modalities: Opportunities and Challenges

By Chelsea Boyd

Decreasing the high transmission rates of STIs can prevent unnecessary suffering and simultaneously reduce economic costs and strains on the healthcare system.

Introduction

There are a number of sexually transmitted infections (STIs), many of which are so common that estimates suggest that one in five people in the United States have an STI at any given time.[1] The majority of STIs are caused by either a virus, such as HIV and herpes simplex, or by bacteria, such as chlamydia, gonorrhea, and syphilis.[2]

Chlamydia and gonorrhea account for the majority of bacterial STIs in the United States and are the focus of this policy analysis.[3] Although some people experience symptoms from chlamydia and gonorrhea, both infections are often asymptomatic even when they are causing longer-term health harms.[4] Left untreated, these two STIs can cause pelvic inflammatory disease in women, and can negatively impact fertility both in women and, to a lesser extent, in men.[5] Likewise, untreated gonorrhea can spread to the blood or joints, which can be deadly.[6] While the long-term health effects of untreated chlamydia and gonorrhea are generally more severe for women, people of all genders can experience uncomfortable symptoms, such as abnormal genital discharge and a burning sensation during urination.[7]

Because individuals with these STIs are often asymptomatic, they may not realize they have these infections unless they are routinely tested for them. Thus, routine testing facilitates prompt diagnosis and treatment, which prevents long-term health consequences. Routine testing also helps limit the spread of the infections to others.

In addition to the individual health impact of STIs, these infections are costly to healthcare systems. The direct medical costs of new STIs in 2018 was estimated at $16 billion.[8] Beyond medical costs, lost productivity from both the infections themselves and the time spent seeking and receiving treatment also impacts the economy. A 2024 study estimated that lost productivity costs from chlamydia, gonorrhea, and syphilis in 2018 was equivalent to $795 million.[9] Decreasing the high transmission rates of STIs can prevent unnecessary suffering and simultaneously reduce economic costs and strains on the healthcare system.

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Unfortunately, accessing appropriate testing can be difficult. Going to a sexual health clinic or medical appointment requires time away from other responsibilities, such as work or caretaking, as well as transportation—both of which can be challenging to coordinate.[10] Stigma and embarrassment may also prevent people from pursuing

testing at a healthcare facility, especially if the facility is known for STI testing.[11] Even interacting with a healthcare provider may discourage some people from getting tested because of fear of judgment and embarrassment.[12]

To address this issue, innovative testing modalities have been developed to eliminate some of the barriers that people encounter. This policy analysis describes these alternative modalities for chlamydia and gonorrhea testing and discusses the potential benefits and challenges of expanding their use.

The Basics of Testing for Chlamydia and Gonorrhea

Typically, when a healthcare provider tests a patient for chlamydia or gonorrhea, the test uses laboratory procedures to look for evidence of the bacteria's genetic material in a sample collected from the patient. These tests, known as nucleic acid amplification tests (NAATs), are common in healthcare; however, conducting them requires specialized devices and equipment.[13] Because of this, samples are generally sent to a diagnostic laboratory for analysis, which often means the patient will not receive their results on the same day that they visit their provider.

Although most NAATs are conducted in a laboratory setting, several point-of-care (POC) NAATs are now available for chlamydia and gonorrhea. Providers can administer these POC tests in the office setting and deliver the results to the patient in the same visit. Some of these tests are also Clinical Laboratory Improvement Amendment (CLIA) waived, which means they have a low risk of producing incorrect results.[14] The CLIA waiver is granted by the Food and Drug Administration (FDA) and indicates that a test is easy to use and interpret and can be performed outside of a traditional laboratory setting.[15] The POC tests are either single-use (like a pregnancy test) or require a self-contained device to process the samples.[16]

The type of sample used for the NAAT can vary. For genital sites, a urine sample or a vaginal or cervical swab is typically collected.[17] Because chlamydia and gonorrhea infections can occur in extra-genital sites (i.e. the throat or rectum), swabs may be collected from these locations as well.[18]

Self-Sampling vs. Self-Testing

Although they sound similar, self-sampling and self-testing have different connotations. Self-sampling involves a patient collecting their own sample for testing by either collecting urine or swabbing a potentially affected site. Self-sampling can be completed at home or at a healthcare provider's office, but not all tests are FDA approved for self-sampling at home.[19] Studies have shown that vaginal and extra-genital self-sampling are accepted and often preferred by patients and produce results as accurate as samples collected by a provider.[20]

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Testing using a self-collected sample generally occurs through one of two processes: traditional and direct-to-consumer. In the more traditional process, a patient visits a healthcare provider either in-person or via a telehealth appointment; the provider assesses the patient's symptoms and needs and orders the relevant tests; and the patient collects the sample or samples necessary to complete the test.[21] If the sample is collected at home, the patient will usually either mail the sample to a laboratory or deliver the sample to a healthcare facility.[22] Alternatively, some services now offer direct-to-consumer chlamydia and gonorrhea testing. These businesses or organizations facilitate ordering through a website, app, or phone call and ship the necessary sample-collection materials to the person who orders the test.[23] The person then collects their sample and mails it to a laboratory for processing. Results are often provided

through electronic communication methods, a secure online platform, or over the phone.[24] In 2023, the FDA approved the first over-the-counter chlamydia and gonorrhea test.[25] It uses a self-collected sample that is mailed to a laboratory for processing.[26]

Self-testing, on the other hand, implies that the patient collects their own sample and completes and interprets the test themselves. The most ubiquitous self-test are pregnancy tests and at-home COVID-19 tests. Currently, there are no FDA-approved self-tests for chlamydia or gonorrhea.[27] Although self-testing for chlamydia and gonorrhea has the potential to help increase diagnoses and decrease barriers to testing (e.g., stigma, access to facilities, embarrassment), it also presents some challenges.[28] One challenge is that both chlamydia and gonorrhea are infections that require mandatory reporting of cases to applicable health departments and the Centers for Disease Control and Prevention (CDC).[29] If people receive their results at home and do not seek treatment, there is no way to document their case, which can hinder public health monitoring.[30] Nevertheless, including proper educational materials that help people determine what to do if their results are positive can ensure that people seek treatment and minimize the potential for undocumented cases.

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Opportunities and Challenges With Novel STI Testing Modalities

Novel testing modalities, including self-collected samples, direct-to-consumer tests, and over-the-counter tests, have the potential to lower barriers to STI testing, which might help more people become aware of their STI status and decrease transmission to others.

Opportunities With Novel STI Testing Modalities

There are several benefits to using novel STI testing modalities including decreasing the strain on the healthcare system, increases in testing through self-collection programs, and increased telehealth utilization.

Traditional STI testing requires a healthcare provider to meet with a patient and collect the required samples to run the tests. Although the collection procedures are not complicated, they do take time, which is a limited resource for most healthcare providers and systems. Because the United States is facing provider shortages, finding ways to decrease the strain on the healthcare system can benefit patients and providers.[31] Self-collected samples, whether collected at home or in a clinic, not only save patients time, but can also increase efficiency within the healthcare system.

For example, an evaluation of a program that offered sample self-collection at a university health clinic found that the two most commonly cited reasons for opting for self-collection were "ease of testing" and "no appointment needed."[32] Furthermore, the students who collected their own samples overwhelmingly reported satisfaction with the program and the ease of the collection processes, with 80 percent saying they would use the service again, and 82 percent saying they would recommend it to friends.[33] From a population-health standpoint, the study found that the university health clinic conducted more STI tests in the year that the self-collection program was introduced compared to two years prior, which suggests that the self-collection program contributed to the increase in testing.[34]

Another benefit of self-collected samples is that they expand the types of facilities that can offer chlamydia and gonorrhea testing, especially for women.[35] Because provider-collected samples require a pelvic exam, this limits the types of facilities that can offer

these testing services.[36] Some examples of locations that could begin offering chlamydia and gonorrhea testing under a self-collected sample model include pharmacies, military bases, correctional facilities, substance use treatment centers, and harm reduction service centers.[37]

Telehealth services can also utilize these new chlamydia and gonorrhea testing options, providing additional efficiency for patients and providers. In this care setting, visits can be conducted in real-time or asynchronously, such as through a messaging system. Both methods allow a patient to discuss their symptoms with the provider who can order the appropriate tests. Sample collection materials are then mailed to the patient who collects the sample themselves and either delivers it to the clinic or mails it to a lab. Although the time required to mail collection materials and samples may delay diagnosis and treatment, the convenience of testing at home can be an added benefit.

Importantly, telehealth tests, direct-to-consumer testing (where patients order tests from a company or lab without provider guidance), and over-the-counter tests can all reduce barriers that discourage people from routine STI testing. Because none of these modalities require visiting a provider's office, it may be easier to fit testing around existing schedules and responsibilities. These modalities also enhance access for people with limited access to transportation or who live in remote or underserved areas. Moreover, testing modalities that do not force individuals to interact with a healthcare provider or visit a location associated with sexual health care can alleviate the fear of judgment or stigma associated with STI testing and increase a patient's comfort in prioritizing this important health behavior.[38] Finally, the ability to receive STI testing more conveniently and discretely may increase testing frequency and coverage, which could, in turn, improve identification and treatment rates, thereby minimizing opportunities for the infections to spread to other people.

Challenges With Novel STI Testing Modalities

Although there are clear benefits to exploring the wider implementation of programs that utilize novel testing modalities, there are also some challenges to keep in mind, including confidentiality issues, high pricing, and treatment coordination. One challenge with direct-to-consumer tests that send tests and results via mail is that confidentiality can be a challenge for people who live in shared households, even if the packaging is discrete.[39] Delivering direct-to-consumer test results via a secure website would be one way to address concerns regarding confidentiality of results, and this approach would likely be reassuring for many, as a survey of college students found that the ability to receive results through a secure website was an important factor in their willingness to adopt testing modalities that required self-sample collection.[40] Nevertheless, this option may not be as accessible for people who are less comfortable with technology or people without consistent internet access, so having an alternative means of accessing results, either through the mail or via telephone, would allow people to select the option best suited to their needs.

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Another challenge with some testing modalities, particularly over-the-counter and direct-to-consumer testing, is cost. The FDA-approved, over-the-counter test for chlamydia and gonorrhea sells for $99 at the time of writing, which is notably higher than the $20 to $30 that most studies have found consumers are willing to pay.[41] While the over-the-counter test is eligible for flexible spending account (FSA) and health savings account (HAS) funds, not all individuals have access to these types of accounts. Similarly, insurance may not cover these types of tests because they are not ordered by a healthcare provider.[42] Likewise, the cost of direct-to-consumer tests

vary considerably. A 2021 position statement from The American Sexually Transmitted Diseases Association stated that direct-to-consumer chlamydia and gonorrhea tests ranged from $49 to more than $189, and packages that test for multiple infections cost upwards of $400.[43] Because these types of tests rely on the consumer to select the appropriate tests without guidance from a provider, the consumer may order incorrect or unnecessary tests, which can further increase costs.[44]

Another potential challenge associated with over-the-counter and some direct-to-consumer testing is treatment coordination after a positive test, given that there is no interaction with a healthcare provider to purchase the tests. Some tests provide next steps for treatment coordination via telehealth after a positive test result, but this is not true for every test.[45] From a logistics standpoint, chlamydia is generally treated with oral antibiotics, so a healthcare provider could write a prescription after a telehealth visit without the need to visit a medical office.[46] However, the recommended treatment for gonorrhea requires an injection of antibiotics, which requires an office visit for administration, increasing the complexity of treatment coordination.[47] Finally, if a patient seeks treatment, healthcare providers will not always accept the results of an over-the-counter or direct-to-consumer test without confirmatory testing.[48] If confirmatory testing is required, the patient and health system will incur added costs and extra time before treatment.[49]

Although self-collecting samples for STI tests produces results that are concordant to provider-collected samples, this is only the case if individuals can easily understand the collection instructions. Thus, providing adequate sample-collection and delivery instructions to consumers will help ensure that labs receive usable samples and results are as accurate as possible.[50] For over-the-counter and direct-to-consumer tests where a patient does not interact with a healthcare provider before collecting their sample, clear instructions should be included with the collection materials, and patients can be directed to additional online resources or a customer service line should the provided materials not suffice.

Conclusion

If the United States wants to decrease infection rates of chlamydia and gonorrhea, identifying and treating undiagnosed cases is vital. Self-sample collection is one way to expand testing options and provide consumers with a more private, less stigmatizing way of testing for chlamydia and gonorrhea. Combining sample self-collection with telehealth and direct-to-consumer testing can also minimize the logistical barriers and stigma associated with office visits. The benefits of sample self-collection also extend to the healthcare system, utilizing healthcare providers' time more efficiently and providing more opportunities to identify undocumented cases. To reach the goal of decreasing cases and transmission of chlamydia and gonorrhea, we must encourage continued innovation in test development, analysis, and implementation of novel modalities for care delivery. Through innovation and increased competition, it is possible to expand access to convenient, low-cost, low-barrier STI testing modalities, which will benefit individual health and decrease costs and burdens on health systems.

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About the Author
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