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# Screening for Chlamydial and Gonococcal Infections: A Systematic Review Update for the U.S. Preventive Services Task Force

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# Structured Abstract

**Background:** In 2014, the U.S. Preventive Services Task Force (USPSTF) recommended screening for chlamydia and gonorrhea in asymptomatic, sexually active women, aged 24 years or younger and in older women who are at increased risk for infection. There was insufficient evidence to recommend for or against screening in men.

**Purpose:** To update the 2014 systematic review and synthesize evidence for the USPSTF on the effectiveness of screening for chlamydial and gonococcal infection in adults and adolescents, including those who are pregnant.

**Data Sources:** Cochrane Central Register of Controlled Trials (January 2014 through May 2020) and Cochrane Database of Systematic Reviews (January 2014 through May 2020), and MEDLINE (January 2014 through May 2020), and manually reviewed reference lists); with surveillance through May 21, 2021.

**Study Selection:** English-language trials and observational studies on screening effectiveness, accuracy of risk stratification and alternative screening methods, test accuracy, and screening harms.

**Data Extraction:** One investigator abstracted data and a second investigator checked data abstraction for accuracy. Two investigators independently assessed study quality using methods developed by the USPSTF.

**Data Synthesis (Results):** 20 studies met inclusion criteria (N=179,515); seven studies were carried forward from the prior report. Three previously included trials of women found chlamydia screening associated with decreased risk of PID versus no screening, though effects were not statistically significant in two trials. One new, good-quality trial of young women and men in primary care clinics found screening for chlamydia associated with decreased risk of hospital diagnosed primary pelvic inflammatory disease (PID) (Relative Risk [RR] 0.6; 95% Confidence Interval [CI], 0.4 to 1.0), though absolute effects were small (absolute difference -0.137%). Screening was not associated with decreased risk of clinic diagnosed PID (RR 1.1; 95% CI, 0.7 to 1.8) or epididymitis in men (RR 0.9; 95% CI, 0.6 to 1.4). Three studies on the accuracy of risk prediction instruments in asymptomatic persons reported an area under the receiver operating characteristic curve (AUC) that ranged from 0.64 to 0.73. Using age criteria alone (<22 years) to selectively screen women for chlamydial and gonococcal infection demonstrated similar accuracy (AUC 0.687, Standard Deviation [SD] 0.014) compared with more extensive risk criteria. Nine studies of diagnostic accuracy found high specificity across anatomic sites, including urine. Sensitivity was high for chlamydial testing in females for all anatomic sites including endocervical testing (range 89 to 100%) and vaginal testing (range 90 to 100%). Studies found high sensitivity of meatal (100%) urethral (99%) and rectal (92%) testing for chlamydia in males, but evidence was limited to one study each. Evidence on pharyngeal testing was limited to one study of MSM that demonstrated low sensitivity for chlamydial infection (69.2%) and higher sensitivity for gonococcal infection (89.1%). Gonococcal testing in females demonstrated highest sensitivity in vaginal samples (>98%) followed by endocervical (>96%) and urine samples (>89%). The sensitivity of urine testing for gonococcal infection in

males was 93 to 100 percent, while sensitivity ranged from 89 to 100 percent for other sites. Three studies demonstrated that self- and clinician-collected vaginal samples for chlamydia and gonorrhea diagnosis were highly sensitive (90 to 100%); no studies meeting inclusion criteria compared collection methods in males. False-positive and false-negative rates were low for testing across anatomic sites and for self- versus clinician- collection of samples. No studies evaluated screening intervals or accuracy of concurrent testing for other infections. Data was lacking for effects of screening on psychosocial harms or effect on risk behaviors or risk perception.

**Limitations:** English language articles only; methodological limitations in the trials; most studies conducted in higher risk populations or settings; meta-analysis not performed; unable to assess for publication bias; studies lacking for pregnant individuals.

**Conclusions:** Screening for chlamydial infection may reduce the incidence of PID in young women. Risk prediction criteria to identify persons with asymptomatic chlamydial or gonococcal infection are associated with limited accuracy and require further validation. Testing for asymptomatic chlamydial and gonococcal infections is accurate at most anatomic sites, using urine sampling, and using self-collected specimens. Research is needed to determine the effectiveness of screening in men, optimal screening intervals, and adverse effects of screening.

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# Chapter 1. Introduction and Background

## Purpose

This systematic review will be used by the U.S. Preventive Services Task Force (USPSTF) to update its 2014 recommendation on screening for chlamydia and gonorrhea infections in sexually active adolescents and adults, including pregnant women.[1]

In 2014, the USPSTF made two separate recommendations for screening for chlamydia (***B recommendation)*** and gonorrhea (***B recommendation)*** in sexually active women aged 24 years or younger and in older women who are at increased risk for infection. These recommendations were based on evidence that screening for chlamydia reduces risk of complications in women at increased risk; evidence that screening for gonorrhea identifies asymptomatic infections and treatment reduces complications associated with untreated asymptomatic infections; and evidence that age was a strong predictor of chlamydial and gonococcal infections, with the highest infection rates occurring in women under 24 years. The USPSTF concluded that the evidence was insufficient to assess the balance of benefits and harms of screening for chlamydia and gonorrhea in men ***(I statement)*** due to the absence of evidence that screening in men improves clinical outcomes or reduces disease transmission to sexual partners.

Prior to 2014, the USPSTF issued a separate recommendation on chlamydia and gonorrhea screening. The 2007 USPSTF recommendation on chlamydia screening was similar to the 2014 recommendation, except that it was graded an ***A recommendation***.[2] The USPSTF also recommended against screening for chlamydia in women aged 25 years or older not at increased risk and found insufficient evidence to recommend routine screening for chlamydia in men. In 2005, the USPSTF recommended screening for gonorrhea in all sexually active women at increased risk for infection, including pregnant women (***B recommendation)***.[3]

## Condition Background

### Condition Definition

Chlamydia is a sexually transmitted infection (STI) caused by the bacterium *Chlamydia trachomatis*. Most *Chlamydia trachomatis* strains infect the columnar epithelial cells of the genital tract, causing inflammation that may be asymptomatic or present as signs of infection such as erythema, edema, and mucopurulent discharge.[4] Infections of the rectum can cause proctitis, while infections of the oropharynx are typically asymptomatic. Inflammation can damage the epithelium and lead to scar formation. In women, scarring may ultimately lead to fallopian tube damage, which is irreversible, and can lead to infertility years after active infection. If left untreated, chlamydia can lead to the same long-term health effects as gonorrhea, including pelvic inflammatory disease (PID), which can lead to complications such as ectopic pregnancy, infertility, and chronic pelvic pain.[5,6] Infants born to infected mothers may contract chlamydial eye disease or pneumonia.[4,7]

Gonorrhea is a STI caused by the bacterium *Neisseria gonorrhoeae*, a gram-negative intracellular diplococcus that infects the mucosal epithelium of the genital tract.[8,9] Other sites of infection include the conjunctiva, oropharynx, and rectum. Infection often leads to local inflammation and, in women, *N. gonorrhoeae* can ascend the urogenital tract and can also cause PID.[9] Infants born to infected mothers may contract ophthalmia neonatorum in the first four weeks of life.[6,10]

## Prevalence and Burden of Disease/Illness

Chlamydia is the most commonly reported STI in the United States (U.S.). In 2019, there were 1,808,703 cases of chlamydial infection reported to the Centers for Disease Control and Prevention (CDC), corresponding to a rate of 552.8 cases per 100,000 persons.[11] Due to under-reporting, the true incidence of chlamydial cases is difficult to accurately estimate. Since the 1980s, the rate of reported chlamydial infection has been rising. This increase is likely related to a combination of enhanced screening efforts, the use of more sensitive tests, and more complete reporting, although it may also reflect a true increase in incidence. In 2019, the rate of chlamydial infection among U.S. women (698.9 cases per 100,000 females) was nearly double the rate among men (399.9 cases per 100,000 males) with the majority of reported cases occurring among women aged 15 to 24 years (3,728.1 per 100,000). From 2018-19, increased rates were observed in females 15-19 year of age (0.8% increase) and 20-24 years of age (0.2% increase). The rate among males increased 5.3 percent between 2018-2019, possibly due to either increased transmission or improved case identification among men who have sex with men (MSM).[11] Increased rates in men also correspond to the increased availability of urine testing and extragenital screening. Males 15 to 44 years of age comprised 93 percent of male chlamydia cases in 2019.[11] Within these populations, prevalence varies by geography, race/ethnicity, and HIV status.[11]

During 2013 to 2019, rates of reported chlamydia cases increased among all racial and Hispanic/Latino ethnicity groups. Chlamydia incidence varies by race, with rates 5.9 times higher in Black compared with White persons.[11] In 2019, the rate of chlamydial infection reported among Black persons was more than five times the rate among White persons (1,233.2 and 209.7 cases per 100,000 population, respectively) and the rate among Hispanic/Latino persons (387.3 cases per 100,000) was nearly two times the rate among White persons.[11] High rates were also reported for American Indians/Alaska Natives (760.0 per 100,000) and Native Hawaiians/Other Pacific Islanders (733.4 per 100,000), while lower rates were reported among those identifying as Asian (128.4 per 100,000) or multirace (231.0 per 100,000). Data from the 2007 to 2012 National Health and Nutrition Examination Survey also demonstrates disparities.[12]

Gonorrhea is the second most commonly reported STI in the U.S., though it is also underreported. In 2019, 616,392 cases were reported to the CDC, corresponding to a rate of 188.4 cases per 100,000 persons, a 5.7 percent increase during 2018-2019.[11] The rate of increase in gonorrhea cases was 5.9 percent for males during 2018-2019 (211.9 to 224.4 per 100,000) and 5.1 percent increase for females (145.2 to 152.6 cases per 100,000). In 2019, the highest rates of infection were among females aged 20 to 24 years (737.4 cases per 100,000), females 15-19 years (559.5 cases per 100,000), males aged 20 to 24 years (743.5 per 100,000) and males 25-29 years (700.6 per 100,000). Black and Hispanic/Latino persons also had higher rates of

gonococcal infection (581.0 and 118.3 per 100,000 population, respectively) than White persons (73.9 per 100,000 population). In 2019, rates of infection in Black persons were 7.9 times the infection rate in Whites.[11] From 2015 to 2019 the rate of gonorrhea among males increased 62.3 percent (139.7 to 224.4 cases per 100,000), possibly related to increased transmission and/or case ascertainment among MSM.

### Pregnancy

Untreated chlamydial infection in pregnancy is associated with complications including preterm labor, premature rupture of membranes, and low birth weight.[13] Infants born to mothers infected with either chlamydial or gonococcal infection are at risk of neonatal conjunctivitis and in the case of chlamydial infection, neonatal pneumonia.[4,7,14] The risk of vertical transmission of gonorrhea is between 30 and 47 percent in the absence of ocular prophylaxis.[15] Rates of gonococcal ophthalmia neonatorum in the U.S. was an estimated 0.4 cases per 100,000 live births per year from 2013 to 2017.[6] Gonococcal ophthalmia neonatorum can cause corneal scarring, ocular perforation, and blindness as early as 24 hours after birth.[16] The USPSTF addresses ocular prophylaxis for gonococcal ophthalmia neonatorum in a separate recommendation and reaffirmed its recommendation for ocular prophylaxis in 2019 (***A recommendation).***[17]

## Etiology and Natural History

In women, chlamydial infection is usually asymptomatic, but can result in transmission and can lead to cervicitis and urethritis.[5] Untreated chlamydial infections may progress to symptomatic PID, which can subsequently result in infertility, chronic pelvic pain, and ectopic pregnancy.[5,6] However, many women with PID have subtle signs and symptoms, leading to clinically silent spread of infection to the upper genital tract and subsequent subclinical pelvic inflammatory disease.[18,19] Chlamydial infection can also facilitate infection with HIV and may potentiate the risk for cervical cancer.[20,21]

In men, genital chlamydial infection is also likely to be asymptomatic but if symptoms do appear, the most common presentation is urethritis.[22] Other symptoms include non-gonococcal urethritis, epididymitis, and in rare instances, reactive arthritis may occur.[22,23,24] Chlamydial infection in men also facilitates HIV transmission[25,26] and can be an etiologic agent of asymptomatic infection of the rectum.[27]

As with chlamydial infection, women infected with gonorrhea are often asymptomatic, but infection can result in cervicitis and complications including PID, ectopic pregnancy, infertility, and chronic pelvic pain.[6] In men, gonorrhea can lead to symptomatic urethritis, epididymitis, and proctitis.[23,28] The majority of urethral infections among males are symptomatic, leading to timely treatment that prevents serious complications, but not transmission to others.[29] However, the overwhelming majority of extragenital (e.g., pharyngeal, rectal) infections in men are asymptomatic. Rarely, local gonococcal infection may disseminate and cause acute dermatitis tenosynovitis syndrome, monoarticular arthritis, meningitis, or endocarditis.[8,30] Gonococcal infection facilitates HIV transmission in both men and women.[20]

## Risk Factors

Age is a strong risk factor for both chlamydia and gonorrhea. In 2019, the highest age-specific rates of chlamydial infection among women and men occurred in the 20 to 24 year age category (4,109.5 cases per 100,000 females; 1,871.5 cases per 100,000 males), followed by women aged 15 to 19 years (3,333.8 cases per 100,000 females).[11] In 2019, rates of gonococcal infection reported to the CDC were also highest among women and men aged 20 to 24 years (737.4 cases per 100,000 females; 743.5 cases per 100,000 males), followed by women aged 15 to 19 years (559.5 cases per 100,000 population).[11] During 2018 to 2019, the largest increase in gonococcal infection was among individuals aged 40 to 44 years (11.3 percent increase).

Other risk factors associated with chlamydial and gonococcal infection include having multiple sexual partners, having a new sexual partner or a sexual partner infected with an STI, inconsistently using barrier contraceptives, and having a history of previous or coexisting STIs.[11] In a 2018 study of STI clinic attendees, MSM had higher reported prevalence rates of chlamydial and gonococcal infections than other clinic attendees, with median prevalence rates of 16.9 and 20.5 percent.[11] A 2017 survey of MSM attending community clinics in five cities reported that approximately one in eight had an extragenital chlamydial or gonococcal infection.[31] Rectal gonorrhea prevalence was higher in MSM infected with HIV than in those not infected with HIV. Notably, chlamydia and gonorrhea at extragenital (rectal and pharyngeal) anatomic sites are often asymptomatic, and these anatomic sites may act as a reservoir of infection, thus affecting gonococcal antimicrobial resistance, and increased risk for HIV transmission and acquisition. One study suggests 70 to 85 percent of infections would be missed with urethral screening alone.[32] A systematic review of prevalence studies conducted in MSM estimated rectal chlamydia and gonorrhea prevalence among MSM as 9.0% and 6.1%, respectively.[33] Epidemiologic data supports the prevalence of extragenital infection in women, which may also present an opportunity for ongoing transmission.[34-36]

## Rationale for Screening/Screening Strategies

Both chlamydial and gonococcal infections are often asymptomatic in women and can lead to serious complications, including PID and associated sequelae.[11] Pregnant women with these infections are at risk of transmitting them to their infants. The risk of vertical transmission of gonorrhea during pregnancy is between 30 and 47 percent.[15] Specific populations of men, particularly young men and MSM, have a higher burden of infection with chlamydia and may be at higher risk for gonococcal infection, many of which are often asymptomatic.[37] Among MSM, rectal chlamydial and gonococcal infections, especially those that are recurrent, have been associated with increased risk for HIV infection.[38] Screening asymptomatic MSM for infection could help to identify those men at high risk for HIV acquisition and lead to consideration of PrEP.[39]

Identification of asymptomatic individuals with chlamydia or gonorrhea through screening could identify those who would benefit from earlier evaluation and management. Screening could also lead to interventions to decrease transmission, and identify close contacts who might benefit from testing.

## Intervention/Treatment

The CDC recommends seven days of doxycycline as treatment for chlamydial infections in non-pregnant adolescents and adults as a first line regimen.[29,40] Alternative regimens include a single dose of azithromycin or levofloxacin for seven days, but treatment failure among men is noted to be higher for azithromycin compared with doxycycline[41] and questions remain about the effectiveness of azithromycin for treating rectal infections in both men and women.[29] For patients in whom compliance or loss to followup is a concern, direct observation of a single dose of azithromycin is recommended. In recent years, treatment of gonococcal infection has been complicated by increasing drug resistance to *N. gonorrhoeae*. Consequently, the CDC now recommends a single 500mg intramuscular dose of ceftriaxone for uncomplicated urogenital, anorectal, and pharyngeal gonorrhea for persons weighing less than 150kg, and 1g ceftriaxone for those weighing over 150kg.[29,42] Treatment for chlamydial coinfection with oral doxycycline (100mg twice daily for 7 days) should occur when chlamydial infection cannot be excluded.[42]

The CDC recommends that all sex partners of patients with either gonococcal or chlamydial infection exposed in the preceding 60 days undergo evaluation and treatment for infection.[29] In the case of a sex partner that cannot be linked to care, expedited partner therapy (EPT) given by the patient is suggested.[29] EPT is the clinical practice of treating sex partners of persons who receive gonorrhea or chlamydia diagnoses by providing medications or prescriptions to the patient, unless prohibited by law, and is recommended for heterosexual partners for both infections. Patients provide partners with these therapies without the examination of the partner by a health-care provider. Rescreening all patients diagnosed with chlamydial or gonococcal infection three months after treatment is recommended due to risk of re-infection, regardless of whether the index patient believes that sex partners were successfully treated.[29]

### Pregnancy

The CDC recommends using azithromycin as the treatment of choice for pregnant women infected with chlamydia. The CDC also recommends repeat testing to document eradication of chlamydial infection four weeks post-treatment.[29] Prevention of chlamydial neonatal pneumonia requires treating maternal chlamydial infection during pregnancy via prenatal detection and treatment. Gonorrhea is treated with a single 500mg intramuscular dose of ceftriaxone.[42] The risk of neonatal ophthalmia due to maternal gonococcal infection can be reduced with routine topical prophylaxis at delivery. Pregnant women diagnosed with either infection should have repeat testing three months after treatment (or at the third trimester or within three months of delivery).[29]

## Current Clinical Practice/Recommendations of Other Groups

Screening for *Neisseria gonorrhoeae* and *Chlamydia trachomatis* is usually performed by testing urine or urogenital swab specimens from the endocervix, vagina, or male urethra.[43] Extragenital testing allows for test samples obtained from other sites, including the oropharynx and rectum, and has been cleared by the FDA.[43,44] Rectal swabs can be used to detect infection in persons who engage in receptive anal intercourse, and self-collected vaginal swabs are also available. Nucleic acid amplification test (NAAT) is the preferred diagnostic test for chlamydia because of

its high sensitivity and specificity and its use on specimens obtained noninvasively (using vaginal or urine specimens).[45] The CDC and the USPSTF both support the use of NAAT to detect chlamydial and gonococcal infections and NAAT is FDA-approved for this purpose.[29,46]

The CDC recommends the use of NAAT to diagnose genitourinary gonococcal infection because NAAT permits testing on the widest variety of specimens, including endocervical, vaginal, rectal, oral, and male urethral swabs, as well as urine samples. NAATs are also FDA-approved for this purpose.[29] *Neisseria gonorrhoeae* can be diagnosed from a culture or Gram stain of the male urethra showing intracellular Gram-negative diplococci. However, a negative Gram stain does not rule out gonococcal infection, due to lower sensitivity than NAAT in asymptomatic males.[47]

The CDC screening recommendations for screening for chlamydia and gonorrhea in young women align with the USPSTF.[29] The CDC recommends screening for all women age 24 years and younger, and targeted screening in women age 25 and older who are at increased risk of infection. The CDC also recommends screening MSM for both chlamydia and gonorrhea at least annually at sites of sexual contact regardless of condom use.[29] Furthermore, the CDC recommends screening women up to age 35 years for chlamydia and gonorrhea at intake in juvenile and adult correctional facilities, as well as screening men up to age 30 years for chlamydia and gonorrhea at intake into jails.[29] Recommendations from other medical organizations (**Table 1)** are consistent with the CDC or USPSTF recommendations.[29,48-55] The CDC also makes a recommendation to consider screening young men in high prevalence clinical settings or in populations with a high burden of infection (MSM).[29]

The CDC recommends screening all pregnant women up to age 25 years, and older women at increased risk for chlamydial and gonococcal infection at their first prenatal visit.[29] Third trimester screening for chlamydial and gonococcal infections is recommended for women who are at high risk for re-infection to prevent postnatal complications and infection of the neonate.

Despite current screening recommendations to screen high-risk persons for chlamydial and gonococcal infection, screening rates are suboptimal. In a review of the healthcare claims of patients presenting for general medical or gynecological examinations, rates of documentation for testing were minimal, regardless of high-risk sexual behavior status. Among patients claiming high-risk sexual behaviors, 21 to 60 percent were tested for chlamydial infection and 21 to 56 percent were tested for gonococcal infection.[56]

# Chapter 2. Methods

## Key Questions and Analytic Framework

Using methods developed by the USPSTF[57] the Evidence-based Practice Center (EPC) developed the scope and Key Questions in collaboration with the USPSTF and Agency for Healthcare Research and Quality (AHRQ). Investigators created an analytic framework with the key questions and the patient populations, interventions, outcomes, and adverse effects reviewed **(Figure 1)**.

Key differences between this report and the prior reviews are using one framework for all populations; evaluating accuracy of risk stratification and screening strategies for identifying persons at increased risk; diagnostic accuracy of anatomic site-specific testing and collection methods. We did not re-review the diagnostic accuracy of specific assays or tests, which the prior review found to be highly accurate.[58] This report addresses four Key Questions on the effectiveness of screening for chlamydial and gonococcal infections. The populations addressed were asymptomatic adults and adolescents, including those who are pregnant.

### Key Questions

1. In asymptomatic, sexually active adults and adolescents, including those who are pregnant, what is the effectiveness of screening for chlamydial and gonococcal infections in reducing complications of infection and transmission or acquisition of disease, including gonorrhea, chlamydia, and HIV?
2. What is the accuracy of risk stratification methods or alternative screening strategies for identifying persons at increased risk of chlamydial and gonococcal infections (such as younger persons or men who have sex with men)? Screening strategies include testing for concurrent infections, including HIV, or using different screening intervals.
3. What is the diagnostic accuracy of anatomic site-specific testing and collection methods for identifying persons with chlamydial and gonococcal infections?
4. What are the harms of screening for chlamydial and gonococcal infections (such as labeling, anxiety, false-positive/alarm results, false-negative results/reassurance, or change in risk behaviors or risk perception)?

Key Question 1 focuses on the effectiveness of screening on clinical outcomes including complications of infection, transmission, or acquisition of disease. Key Question 2 evaluates the accuracy of risk stratification methods or alternative screening strategies for increased risk populations, including testing for concurrent sexually transmitted infections or using different screening intervals. Key Question 3 examines the diagnostic accuracy of anatomic site-specific testing and collection methods, including self-collected swabs. Key Question 4 addresses the harms of screening. The USPSTF previously determined that treatment is effective; therefore, there was no Key Question on the effectiveness of treatment.

## Contextual Questions

The USPSTF also requested Contextual Questions to help inform the report. Contextual Questions are not reviewed using systematic review methodology.

1. What is the prevalence rate of chlamydial or gonococcal infections (and concurrent HIV infection) in partners of patients who test positive for chlamydial or gonococcal infections?
2. What is the effectiveness of partner services (such as traditional partner services or expedited partner therapy) in reducing rates of reinfection or acquisition of chlamydial and gonococcal infections in the index patient?

# Search Strategies

We searched the Cochrane Database of Systematic Reviews (January 2014 through May 2020), Cochrane Central Register of Controlled Trials, PsycINFO, Ovid MEDLINE In-Process & Other Non-Indexed Citations (January 2014 through May 2020), and Ovid MEDLINE (January 2014 through May 2020) for relevant English-language studies and systematic reviews. Search strategies are available in **Appendix A1.** Electronic searches were supplemented by review of reference lists of relevant articles and studies meeting inclusion criteria. We also carried forward studies in the prior USPSTF report[58] that met inclusion criteria for this update. Ongoing surveillance was conducted to identify major studies published since May 2020 that may affect the conclusions or understanding of the evidence and the related USPSTF recommendation. The last surveillance was conducted on May 21, 2021, and identified no studies affecting review conclusions.

# Study Selection

Two reviewers independently evaluated each study to determine inclusion based on predetermined eligibility criteria developed for each Key Question (**Appendix A2**). After an initial dual review of citations and abstracts, investigators retrieved full-text articles of potentially relevant material. Two reviewers conducted full-text review of articles; discrepancies were resolved through consensus or with input from a third reviewer. The selection of studies is summarized in the literature flow diagram (**Appendix A3**). **Appendix A4** lists included studies and **Appendix A5** lists studies excluded at the full-text level with reasons for exclusion.

The target population was asymptomatic, sexually active adults and adolescents, including those who are pregnant. For screening effectiveness and harms, we included randomized controlled trials (RCT) and controlled observational studies of screening versus no screening in asymptomatic individuals that evaluated health outcomes. Outcomes for KQ1 included reduced complications of chlamydial or gonococcal infections and reduced transmission or acquisition of disease, including gonorrhea, chlamydia, and HIV; and for pregnant individuals, reduced adverse maternal, fetal, or infant outcomes. Studies on risk stratification methods and screening strategies for chlamydia and gonorrhea that reported measures of diagnostic accuracy or discrimination

were included for KQ2. For KQ3, we included studies on the diagnostic accuracy (including measures of discrimination) of testing at various anatomic sites or using different collection methods (self- versus clinician- collected). Studies that did not report diagnostic accuracy but provided data to calculate them were also included. For studies of diagnostic accuracy, samples were reported as collected from male or female anatomic sites. This differs from the remainder of the included studies that reported outcomes according to populations of men and women. For KQ4, false alarm rates (the proportion of patients with a positive test who do not have the disease) and false reassurance rates (the proportion of patients with a negative test who actually have the disease) were calculated from the positive predictive value and negative predictive value, respectively, when population prevalence was reported.[59] False positive and false negative results were also reported. For KQ4, uncontrolled observational studies were also included for the adverse effects of screening.

## Data Abstraction and Quality Rating

We constructed evidence tables summarizing the data from each study. One investigator abstracted details about the study design, patient population, setting, interventions, analysis, followup, and results. A second investigator reviewed data abstraction for accuracy. Two investigators independently applied predefined criteria developed by the USPSTF (**Appendix A6**) to rate the quality of individual controlled trials, systematic reviews, and observational studies and rate them as "good," "fair," or "poor," depending on the extent of methodological shortcomings.[57] We modified the cohort criteria for cross-sectional studies. Discrepancies were resolved through consensus. In accordance with USPSTF procedures, we excluded studies rated poor quality due to important methodological shortcomings that severely undermine their reliability.[57]

## Data Synthesis

We assessed the aggregate internal validity (quality) of the body of evidence for each KQ ("good", "fair", "poor") using methods developed by the USPSTF, based on the number, quality and size of studies, consistency of results between studies, and directness of evidence in the Summary of Evidence.[57] We determined aggregate internal validity using the totality of evidence (new studies identified for the update plus studies carried forward from the prior USPSTF report).[60] Statistical meta-analysis was not performed because of methodological limitations of the studies and heterogeneity in study designs, interventions, populations, and other factors.

## Expert Review and Public Comment

A draft research plan for this topic was posted on the USPSTF website for public comment from February 7, 2019 to March 6, 2019, and was revised in response to public comments prior to finalization. Revisions included clarification of the populations and risk behaviors addressed, the reference standard for diagnostic accuracy, and terminology regarding anatomic site-specific testing.

The draft report was reviewed by content experts (**Appendix A7**), USPSTF members, Agency for Healthcare Research and Quality (AHRQ) Medical Officers, and collaborative partners. Reviewer comments were presented to the USPSTF during its deliberations and have been incorporated into the final report. Additionally, a draft version of this report was posted for public comment from March 2, 2021 to March 29, 2021. In response, we revised some of the background, references, and discussion. No substantive changes were necessary.

# Chapter 3. Results

## Included Studies

Our literature search resulted in 2,356 unique citations. A total of 20 studies (reported in 20 publications) met inclusion criteria. Thirteen studies[61-73] were newly identified for this review and seven[74-80] were carried forward from the previous USPSTF report. Seven studies from the prior review were not carried forward because they evaluated key questions or outcomes not addressed in this review (e.g., effectiveness of screening strategies, accuracy of diagnostic testing assays, NAAT testing).[81-87]

## Key Question 1. In Sexually Active, Asymptomatic Adolescents and Adults, Including Those Who Are Pregnant, What Is the Effectiveness of Screening for Chlamydial or Gonococcal Infections in Reducing Complications of Infection and Transmission or Acquisition of Disease, Including Gonorrhea, Chlamydia, and HIV?

### Summary

- The prior USPSTF review included three trials of women at increased risk for chlamydia that found screening associated with reduced risk of PID versus no screening. While risk of PID was reduced with screening in all 3 trials, results were statistically significant in only one.
- One large new trial of men and women in primary care clinics found screening associated with a statistically significant reduction in risk of hospital diagnosed PID versus usual care, though absolute effects were small. Screening was not associated with reduced risk of clinic diagnosed PID in young women or epididymitis in young men.
- No study evaluated the effectiveness of screening for gonorrhea versus no screening.
- There were no studies reporting disease acquisition or transmission or clinical outcomes other than PID or epididymitis; there were no studies of pregnant populations.

### Evidence

#### Chlamydia

Four randomized trials evaluated the effectiveness of screening for chlamydial infection for reducing complications of infection (**Table 2; Appendix B Tables 1 and 2**).[67,74,75,78] Three of the trials[74,75,78] were also included in the prior USPSTF review.[58] One trial was conducted in the United States,[78] two in Europe,[74,75] and one in rural Australia.[67] Sample sizes ranged from 1,700 to 63,338 (total N = 70,174). Three trials enrolled women,[74,75,78] and one trial enrolled both women and men.[67] One trial was conducted exclusively in adolescents (high school students,

mean age not reported).[75] The other trials enrolled adolescents and adults (16 to 34 years) from a rural primary care setting,[67] university setting,[74] and from a population of higher risk women.[78] Three trials compared screening versus usual care: one multi-faceted screening program,[67] one home sampling,[75] and one clinic-based testing.[78] One trial compared immediate versus deferred screening.[74] Three trials used self-collected vaginal[67,74,75] or male urine testing,[67] and one study used clinician-collected endocervical samples.[78] Two trials were rated good- quality[67,74] and two trials were rated fair- quality (**Appendix B Table 3**).[75,78] Methodological limitations of the fair-quality trials included unclear details regarding randomization methods and high loss to follow-up.

The three trials included in the prior USPSTF review reported results that favored screening for chlamydial infection versus no screening for reducing risk of PID, though only one trial reported a statistically significant difference. A good-quality RCT, the Prevention of Pelvic Infection (POPI), included 2,529 sexually active symptomatic (35%) or asymptomatic (65%) young women from universities and colleges in the United Kingdom (U.K., mean age 21 years; range: 16-27 years).[74] Among all participants, screening was associated with reduced risk of PID, though the difference was not statistically significant (relative risk [RR] 0.65; 95% confidence interval [CI], 0.34 to 1.22). However, 79 percent (30/38) of PID cases occurred in women who had tested negative at baseline. As described in the prior USPSTF review, among the subgroup of participants who reported no symptoms during the 6 months before the study (i.e., pelvic pain, dyspareunia, abnormal vaginal bleeding or discharge), the reduction in risk was larger, but also not statistically significant (0.6% [5/787] vs. 1.6% [14/861], RR 0.39; 95% CI, 0.14 to 1.08) (Sarah Kerry, personal communication). A fair-quality RCT of 2,607 women with increased risk for chlamydia in Washington state reported a statistically significant reduction in PID in the screened versus usual care group after 1 year of followup (0.89% [9/1,009] vs. 2.07% [33/1,598], RR 0.44; 95% CI, 0.20 to 0.90).[78] A fair-quality RCT of 1,761 female high school students in Denmark found one-time home-based screening to be associated with lower risk of chlamydia compared with usual care (opportunistic physician-based screening) after 1 year (2.9% [13/443] vs. 6.6% [32/487], RR 0.45; 95% CI, 0.24 to 0.84) and PID (2.1% [9/443] vs. 4.2% [20/487], RR 0.50; 95% CI, 0.23 to 1.08).[75] Since few participants were screened in the usual care group, they were considered to be similar to an unscreened comparison group.

A new, good-quality cluster-randomized trial (the ACCEPt trial) of screening for chlamydia evaluated screening effectiveness in 180,355 young men and women aged 16 to 29 (mean age not reported) in 130 rural Australian primary care clinics.[67] Participants were eligible for at least one chlamydia test per year, regardless of symptoms or contact history. Clusters were randomized to a multifaceted screening intervention tailored to the clinic (computer alert to test eligible patients, incentive payment for testing, patient recall and reminder system, education for general practitioners and nurses, patient information, partner notification, and feedback on testing performance) versus usual practice for chlamydial testing and management (mean follow-up 3.1 years). Demographics were reported for 63,338 clinic patients; approximately 49 percent (30,759/63,338) were women, 35 percent were 16 to 19 years old (22,212/63,338), 32 percent were 20 to 24 years old (20,319/63,338), and 33 percent were 25 to 29 years old (20,807/63,338).

Screening was associated with a statistically significant reduction in risk of a hospital diagnosed primary PID (RR 0.6; 95% CI, 0.4 to 1.0), but the absolute difference was small (0.24%

[57/23,527] vs. 0.38% [88/23,219]). There was no difference in the risk of a repeat chlamydia infection within six weeks to six months of a positive test (odds ratio [OR] 3.1; 95% CI, 0.7 to 13.8), or for PID diagnosed in clinics (0.45% [293/65,519] vs. 0.39% [237/60,384]; RR 1.1; 95% CI, 0.7 to 1.8). In men, there was no difference between screening versus usual care in risk of epididymitis diagnosed in clinics (0.26% [106/41,168] vs. 0.27% [106/38,717]; RR 0.9; 95% CI, 0.6 to 1.4).

**Gonorrhea**

As in prior USPSTF reviews, no study evaluated the effectiveness of screening for gonorrhea versus no screening.

# Key Question 2. What Is the Accuracy of Risk Stratification Methods or Alternative Screening Strategies for Identifying Persons at Increased Risk for Chlamydial or Gonococcal Infections (Such as Younger Persons or Men Who Have Sex With Men)?

## Summary

- The 2014 USPSTF review did not evaluate the diagnostic accuracy of risk criteria for chlamydial or gonococcal infections.
- In asymptomatic patients, two studies of the "Vancouver" risk tool and one study of a 3-item risk score for identifying persons with chlamydial or gonococcal infections reported AUCs that ranged from 0.64 to 0.73.
- One study of women attending family planning or STI clinics (not necessarily asymptomatic) found age ≤22 years was associated with similar discrimination for chlamydial and gonococcal infections (AUC 0.69) compared with multi-item screening criteria (AUC 0.72 to 0.73).
- Two studies of women in other settings (IUD insertion, surgical abortion) found risk prediction tools for chlamydial and gonococcal infections associated with poor accuracy.
- One study conducted in a narrowly-defined, high risk patient population used a survey that strongly correlated increasing numbers of oral sex partners in the preceding 3 month period with rates of pharyngeal gonorrhea.
- No study compared screening intervals or alternative screening strategies, such as testing for concurrent infection with HIV.

## Evidence

The 2014 USPSTF review did not evaluate the accuracy of risk stratification methods or alternative screening strategies for chlamydial or gonococcal infections.[60] For this report, seven studies evaluated strategies for identifying persons at increased risk for chlamydial or gonococcal infections using different criteria to select patients for testing **(Table 3; Appendix B Tables 4**

**and 5**).[62-64,66,68-70] Enrollment ranged from 245 to 35,818 (total N = 93,137). Two studies enrolled only women,[69,70] and five included both men and women.[62-64,66,68] Participants were asymptomatic in 3 studies,[62-64] symptom status was not reported in three studies,[66,68,69] and one study included both asymptomatic (52%) and symptomatic (47%) populations.[70] Three studies were conducted in Canada,[62-64] three in the U.S.,[66,68,70] and one in Europe.[69] Settings included family planning clinics,[70] STI or sexual health clinics,[62-64,68,70] university or community clinics,[66] and a pregnancy termination clinic.[69] Six studies were cross-sectional[62-64,66,69,70] and one was a case-control study.[68] All studies were rated fair- quality (**Appendix B Table 6**). Methodological limitations included inadequate selection of patients and measurement of exposures or outcomes, including retrospective data collection; some studies reported between-group differences between intervention and control groups, rather than groups being similar at baseline.

Two cross-sectional studies conducted in Vancouver, British Columbia, evaluated the "Vancouver" risk estimation tool, an instrument for identifying asymptomatic women and heterosexual men at increased risk for chlamydial or gonococcal infection[62,63] Factors in the model included age, sex, race, number of partners, and other known STI risk factors. In the original study evaluating this tool, discrimination in a validation cohort of 14,956 asymptomatic patients attending STI clinics in Vancouver was fair (AUC 0.64; 95% CI, 0.61 to 0.67). A risk score cutoff of ≥6 points identified 83 percent of cases in the validation cohort, while screening 68 percent of the population.[62] A followup study[63] in 10,425 asymptomatic women and heterosexual men in seven sexual health clinics throughout British Columbia (prevalence 5.3%) reported similar discrimination (AUC 0.69; 95% CI, 0.67 to 0.71). A cutoff of ≥8 points detected 86 percent of cases while screening 63 percent of the population and a cutoff of ≥6 identified 95 percent of infections while screening 78 percent of the population.[63]

A cross-sectional study of 35,818 asymptomatic men and women attending clinics for STI testing in Canada evaluated discrimination of a clinical risk score based on 3 criteria (age, indicators of risk, and injection drug use) and criteria derived from population based screening guidelines based on 6 criteria (age, number of sexual partners, injection drug use by patient or partner, transactional sex, prior infection).[64] The clinical risk score was associated with higher discrimination (AUC 0.73; 95% CI, 0.71 to 0.74) than presence of any guideline risk factors (AUC 0.55; 95% CI, 0.54 to 0.56) or number of guideline risk factors (AUC 0.64; 95% CI, 0.63 to 0.66), though none of the criteria were associated with high discrimination.

A cross-sectional study of 6,672 women attending family planning and STI clinics in the United States compared nine sets of selective screening criteria for chlamydial infection.[70] In the family planning clinics (n=4,471) 69 percent of women were asymptomatic, while nearly 80 percent of women in STI clinics (n=2201) reported genitourinary symptoms.[70] Criteria were from the CDC and various states or provinces: Seattle (3 versions), California (2 versions), Wisconsin, and Ontario, in addition to age criteria (≤ 22 years) (see **Appendix C**). Points were assigned for age 24 or younger, Black, nulliparous, 2 or more sex partners in the past year, and vaginal douche in the past year; while the Seattle-2 version also included unmarried status, and cervical ectopy. Among the nine multi-item criteria, the highest AUC values were for two versions of state specific criteria (Seattle 2 AUC 0.726, standard deviation [SD] 0.014, sensitivity 83 to 84%, specificity 35 to 51%; Seattle-3 AUC 0.723, SD 0.015, sensitivity 92%, specificity 19 to 31%). Age alone (≤ 22 years) performed nearly as well as multiple item criteria, with similar sensitivity

(74-77%) and specificity (51-56%), and AUC 0.687 (SD 0.014). Using an age cutoff of 22 or younger, nearly 80 percent of cases were identified while testing 50 percent of the population.

Two studies evaluated the accuracy of screening criteria in other settings. A cross-sectional study of 5,087 women age 14 to 45 years attending clinic for IUD insertion compared three screening criteria for chlamydial and gonococcal infections based on: age alone; age and having multiple partners; or age, having multiple partners, and other risk markers (history of STI, inconsistent condom use).[66] The risk-based criteria had the highest sensitivity, but very low specificity (sensitivity 99%, specificity 7.6%); age (sensitivity 80.7%; specificity 48.1%) and age plus partner (sensitivity 84.7%; specificity 44.8%) performed similarly. A fair- quality, cross-sectional study evaluated a model using data from women who underwent surgical abortion in France (326 women in the validation set).[69] The model assigned points for having 1 or no children (43 points); not using contraception (34 points); and gestational age of abortion more than 10 weeks (23 points). At a cutoff of 40 points, sensitivity was 100 percent and specificity 26.9 percent; and at a cutoff 60 points, sensitivity was 83.3 percent and specificity 58.8 percent.

A fair- quality case-control study evaluated the proportion of gonorrhea cases missed by testing only for urogenital gonorrhea. It was conducted among 12 STI clinics in Los Angeles County in 245 consecutive men or women aged 15 to 29 years presenting for chlamydia or gonorrhea testing with a history of oral intercourse in last the 3 months with a partner of the opposite sex.[68] The study population was largely Hispanic/Latino or Black and symptom status was not reported. Among those with gonorrhea, 28 percent had pharyngeal gonorrhea only. Compared to those without pharyngeal gonorrhea, a higher proportion of those with pharyngeal gonorrhea reported being men who had sex with women and men (25% versus 3%), to have swallowed ejaculate or vaginal fluid in last 3 months (28.6% versus 14.9%), or to have a recently incarcerated sex partner (35.3% versus 19.4%). In a multivariate model, there was a strong association between higher number of oral sex partners in the last 3 months (adjusted odds ratio [aOR] 5.7; 95% CI, 1.3 to 25.6) and the presence of concurrent urogenital gonorrhea (aOR 6.2; 95% CI, 2.6-14.3) and risk of pharyngeal gonorrhea, after adjusting for age, sex, and number of sex partners.[68]

# Key Question 3. What Is the Diagnostic Accuracy of Anatomic Site-Specific Testing and Collection Methods for Identifying Persons With Chlamydial or Gonococcal Infections?

## Summary

- The 2014 USPSTF review included four studies of site-specific testing for chlamydia in females that reported sensitivities that ranged from 86 to 96 percent for endocervical testing, 89 to 100 percent for vaginal testing, and 72 to 98 percent for urine testing. Specificity was high across anatomic sites, ranging from 98 to 100 percent.
- Five studies of diagnostic accuracy of site- specific testing for chlamydial infection, including three studies in the prior USPSTF review, reported sensitivities that ranged from 89

to 100 percent for endocervical testing and 90 to 100 percent for vaginal testing, excluding one outlier study reporting lower sensitivities. Specificities were 99 to 100 percent for endocervical testing and 95 to 100 percent for vaginal testing, and 96 to 100 percent for urine testing.
- The sensitivity of meatal (100%), urethral (99%) and rectal (92%) testing for chlamydia in males was high, but evidence was limited to one study each. Specificities were not reported and data were not provided to calculate specificity for all sites.
- The sensitivity of pharyngeal testing for chlamydia was 69.2% in one study of men who have sex with men; specificity was not reported.
- Three studies of diagnostic accuracy of site- specific testing for gonococcal infections in females reported sensitivities of 98 percent to 100 percent for vaginal samples, 96 percent and 98 percent for endocervical samples, and 89 percent and 100 percent for urine samples. Specificity was high at all sites (95% to 100%).
- Three studies of diagnostic accuracy of gonococcal infections in males reported sensitivities of 93 to 100 percent for urine testing; sensitivity ranged from 89 to 100 percent at other sites.
- The sensitivity of pharyngeal testing for gonorrhea was 89 percent in one study of men who have sex with men; specificity was not reported.
- Three studies of self- and clinician-collected vaginal samples for chlamydia diagnosis and one study of self- and clinician-collected vaginal samples for gonorrhea diagnosis found both collection methods to be highly sensitive (90 to 100%, excluding one outlier study). There were no studies comparing self- versus clinician-collected samples in males.

## Evidence

The prior 2014 USPSTF review[58] included 10 fair-quality studies on the accuracy of NAATs compared with culture or expanded reference standards in asymptomatic individuals in high prevalence settings. Six studies included in the prior review were excluded from this review, because they compared performance characteristics between different types of assays (assay versus assay). Four studies in the prior review compared the accuracy of testing at different anatomic sites and were carried forward for this review (**Table 4**; **Appendix B Tables 7, 8 and 9**).[76,77,79,80] In these studies, anatomic site-specific testing for chlamydial infection in females indicated sensitivity ranging from 89 to 96 percent for endocervical testing,[76,77] 89 to 100 percent for vaginal testing,[76,77] and 72 to 98 percent for urine testing.[76] One outlier study[79] reported lower sensitivities than the other studies (51.9%, 55.6%, 51.9%, and 44.4% for endocervical, clinician-collected vaginal, self-collected vaginal, and urine testing, respectively). Specificity ranged from 98 to 100 percent across all sites.[76,77,79] For gonorrhea, the sensitivity of testing in females was 90 percent (specificity 100%) for endocervical testing and 98 percent for vaginal testing (specificity 100%)[80] The prior review also found self- and clinician-collected vaginal samples for chlamydia testing equally sensitive (ranging from 98% to 100%) and specific (>99%) in two studies,[76,77] although one other study found self-collected vaginal samples had lower sensitivity (55%).[79] Self-collected vaginal specimens were highly sensitive and specific for gonorrhea (98% and 100%).[80] The 2014 report did not identify studies on the diagnostic accuracy of site-specific testing or collection methods in males.

The current review compared the accuracy of screening tests obtained from different anatomic sites or from urine samples, or obtained using different collection methods (self-collected versus

clinician- collected). Nine studies[61,65,71-73,76,77,79,80] evaluated the diagnostic accuracy of anatomic site-specific testing and six studies[65,71,76,77,79,80] compared collection methods for identifying chlamydial or gonococcal infections (**Table 4**; **Appendix B Tables 7, 8 and 9**).[61,65,71-73,76,77,79,80]

All of the studies were conducted in the U.S.,[65,71,76,79] U.K.,[61,72,73,77,80] or Canada.[76] Sample sizes ranged from 133 to 3,974 (Total N = 16,204). Six studies enrolled only females,[65,72,76,77,79,80] two studies enrolled only males,[61,73] (including one study that enrolled MSM),[73] and one study[71] enrolled both male and female participants. One study was conducted exclusively in an adolescent population (mean age 16 years).[65] Five studies enrolled a mix of adolescents and adults (mean age 19 to 37 years).[71,73,77,79,80] Two studies did not report mean age but reported age ranges between 16 and 25 years,[72,76] and age was not reported in one study.[61] In four studies that reported race, the proportion of Black participants ranged from 9 to 96 percent[65,71,77,80] Race was not reported in the other five studies. One study[79] reported that participants were asymptomatic for chlamydia or gonorrhea at baseline, and four did not report symptom status.[61,65,72,76] Three studies included a mix of asymptomatic and symptomatic participants, but stratified results according to presence or absence of symptoms.[71,77,80] In the remaining study of MSM attending a sexual health/HIV clinic, the proportion of participants with symptoms at baseline was 28 percent.[73] Prevalence of infection ranged from 1.5 to 26.6 percent for chlamydial infection and 1.5 to 11.7 percent for gonococcal infection. All studies were rated fair-quality (**Appendix B Table 10)**. Methodological limitations included unclear methods of enrolling patients for study inclusion and unclear description of whether index test results were interpreted independently of the reference standard.

### Accuracy of Anatomic Site Tests

*Chlamydia*

**Female population.** Three new studies[65,71,72] and three studies[76,77,79] from the prior review evaluated the accuracy of anatomic site-specific testing for chlamydia in females (**Table 5; Figure 2**).[65,71,72,76,77,79] Prevalence of chlamydia ranged from 6 to 27 percent (**Table 4**). Accuracy of site-specific testing was high across all anatomic sites (sensitivity range 84 to 100%; specificity range 95 to 100%), other than one outlier study[79] that reported consistently lower sensitivity among all sites tested (range 44% to 56%). While this study was conducted in a high prevalence population of university students age 16 to 25 years (chlamydia prevalence 21.6 %), reasons for lower sensitivity are unclear but might be related to the use of a single test to identify chlamydial infection at a time when NAAT testing was not routinely employed.

The sensitivity and specificity of endocervical and vaginal testing was consistent in five of six studies.[65,71,72,76,77] For endocervical testing, sensitivity ranged from 89 to 100 and specificity ranged from 99 to 100 percent. Vaginal testing from both patient and clinician- collected samples showed similar sensitivities, ranging from 90 to 100 percent; specificity was also high (range 95% to 100%). The sixth study reported lower but similar sensitivity at both anatomic sites (endocervical 52% and vaginal 56%) but specificity remained high (100% for both sites).[79] Urethral testing was also highly sensitive, based on one study that used three different NAATs, ranging from 88 to 97 percent (specificity range 98-100 percent).[76] The sensitivity of urine

testing was more variable than anatomic site testing in five studies (range 44 to 100%; median 85%), with specificities ranging from 96 to 100 percent.[65,71,72,76,79]

**Male population.** Three studies reported on the diagnostic accuracy of anatomic site-specific testing for chlamydial infection in males **(Table 6; Figure 3)**.[61,71,73] Urine testing was highly sensitive in all three studies (89 to 100%). Meatal (92%),[61] urethral (99%),[73] and rectal (92%)[73] testing were also highly sensitive, while pharyngeal testing was associated with lower sensitivity (69%),[73] all based on one study each.

*Gonorrhea*

**Female population.** Three studies reported the sensitivity and specificity of site-specific testing for gonorrhea in females (**Table 7; Figure 4**).[65,71,80] Prevalence of gonorrhea infection was 2.5[80] and 2.6[71] percent in two of the studies and 12 percent in the other.[65] Reference standards were either clinician-collected samples or urine testing. Across sites, sensitivity and specificity ranged from 90 to 100 percent and 97 to 100 percent, respectively. Vaginal samples (both self- and clinician-collected) were associated with a sensitivity of 98 percent in one trial and 100 percent in three trials (specificity range 99 to 100%). In comparison, endocervical samples (sensitivity 90% and 98%) and urine samples (91% and 100%) were slightly less sensitive. Specificity was also high, ranging from 97 to 100 percent.

**Male population.** Three studies compared site-specific testing for gonorrhea in males (**Table 8; Figure 5**).[61,71,73] Gonorrhea infection prevalence was low in two of the studies (1.5 and 4.2%)[61,71] and was high in the third study (27%).[73] Urine testing was evaluated in two studies, with sensitivities of 93 percent and 100 percent; corresponding specificities were high (99.8 and 99.3%).[61,73] The diagnostic accuracy of other sites, based on one study each, was 89 percent sensitivity for pharyngeal testing,[73] 93 percent for rectal testing,[73] 98 percent for urethral testing[73] and 100 percent for meatal testing.[61]

**Accuracy of Clinician and Self-Collected Tests**

*Chlamydia*

**Female population.** Two new studies[62,65] and two studies[71,76,79] from the prior review compared the accuracy of clinician- and self-collected vaginal samples for diagnosis of chlamydial infection in females (**Table 5; Figure 2**), including one study that utilized three different NAATs.[76] Sensitivity was similarly high for both collection methods. Clinician-collected sample sensitivity was 90 to 100 percent in two studies,[71,76] and 56 percent in the other study.[79] Self-collected samples were also highly sensitive for chlamydia diagnosis, ranging from 90 to 98 percent in two studies[71,76] and was 52 percent in the remaining study.[79] The outlier study reporting lower sensitivities, also included in the 2014 USPSTF report, only reported results from study participants with complete sets of results from nine different testing strategies, and required two positive NAATs from two separate specimens as a reference standard. This method presumably reduced the number of false positive tests, although the overall prevalence of chlamydia infection was high (22%).[79] There were no studies comparing clinician- and self-collected testing at other anatomic sites.

**Male population.** No studies meeting inclusion criteria reported on the accuracy of clinician- versus self-collected testing for chlamydia in males.

*Gonorrhea*

**Female population.** One study compared clinician- and self-collected vaginal samples for diagnosis of gonorrhea infection **(Table 7)**.[71] In this study, the accuracy of self-collected samples was nearly identical to those collected by clinicians; sensitivities were 100 percent for both sites, and specificities were 100 and 99.7 percent, respectively. There was no evidence comparing clinician- and self-collected testing for other anatomic sites.

**Male population.** There were no studies meeting inclusion criteria on the accuracy of clinician- versus self-collected testing for gonorrhea in males.

# Key Question 4. What Are the Harms of Screening for Chlamydial or Gonococcal Infections (Such as Labeling, Anxiety, False-Positive/Alarm Results, False-Negative Results/Reassurance, or Changes in Risk Behaviors or Risk Perception)?

## Summary

- The 2014 USPSTF review included four diagnostic accuracy studies of site-specific testing or collection methods that reported false-positive rates for gonorrhea and chlamydia of 3 percent or lower and false-negative rates ranging from 0 to 9 percent for gonorrhea and 0 to 14 percent for chlamydia across all NAATs and specimen types. False alarm rates (1 – positive predictive value) ranged from 0 to 16 percent and false reassurance rates (1 – negative predictive value) ranged from 0 to 2 percent in three studies, with one outlier study reported higher false reassurance rates (11 to 13%).
- False positive rates for chlamydia ranged from 0 to 2 percent in six studies (2 new studies) across all sites. False negative rates ranged from 0 to 28 percent in five studies; a sixth study reported higher false negative rates (44% to 56%).
- False positive rates for self-collected and clinician-collected tests ranged from 0 to 1.2 percent for chlamydia based on 3 studies in females (1 new study), and was 0 percent (for self-collected samples) and 0.3 percent (for clinician-collected samples) for gonorrhea in females based on one study. False positive rates ranged from 0 to 12 percent for chlamydia and gonorrhea self- and clinician-collected tests, excluding one outlier study.
- Evidence on false positive and false negative rates in males, according to anatomic site, was limited to two new studies for chlamydia and gonorrhea. False positive rates were consistently low (<1%), while false negative rates ranged from (0 to 8%).
- No studies reported on harms of collection methods for chlamydia or gonorrhea in males.
- No studies evaluated psychosocial harms, such as anxiety, related to screening or effects of screening on risk behaviors or risk perception.

## Evidence

The 2014 USPSTF review included four diagnostic accuracy studies of site-specific testing or collection methods that reported false-positive rates (1 – specificity) for gonorrhea and chlamydia as 3 percent or lower and false-negative rates (1 – sensitivity) that ranged from 0 to 9 percent for gonorrhea and 0 to 14 percent for chlamydia across all NAATs and specimen types. In these studies, false alarm rates (1 – positive predictive value) for chlamydia and gonorrhea ranged from 0 to 16 percent,[76,77,79,80] and false reassurance rates (1 – negative predictive value) ranged from 0 to 2 percent in three studies; one outlier study (see Key Question 3) reported lower sensitivity across anatomic sites reported higher false reassurance rates (11 to 13%).[79] The false alarm rate refers to the proportion of persons with a positive test who do not have an infection and the false reassurance rate refers to the proportion of persons with a negative tests who do have an infection.

Of the nine diagnostic accuracy studies included in Key Question 3 (including four studies included in the prior review), eight reported rates of false positive and false negative rates (and corresponding false alarm and false reassurance rates) for anatomic site- specific testing and six studies reported these rates for collection methods (**Tables 9, 10, 11, and 12**).[61,65,71,72,76,77,79,80] Harms of chlamydia testing were reported in six studies of females[65,71,72,76,77,79] and two studies of males;[61,71] harms of gonorrhea testing were reported in three studies of females[65,71,80] and two studies of males.[61,71] In these studies, the prevalence of chlamydial infection ranged from 8 to 27 percent in females and 11 percent in males. The prevalence of gonococcal infection was 2 to 12 percent in females and 2 to 4 percent in males. As in prior USPSTF reviews, no study evaluated psychosocial harms (e.g., anxiety) related to screening and no study evaluated effects of screening on changes in risk behaviors or risk perceptions.

### Site-specific Testing

Across all anatomic sites, the false positive rates for chlamydia testing in females ranged from 0 to 2 percent in six studies and corresponding false alarm rates ranged from 0 to 16 percent (**Table 9**; **Appendix B Tables 7, 8 and 9**).[65,71,72,76,77] By anatomic site, false positive rates were 0 to 0.7 percent for endocervical testing (false alarm rates 0 to 9%), 0 to 1.2 percent for vaginal testing (false alarm rates 0 to 12%), 0.2 to 1.7 percent for urethral testing (false alarm rates 2 to 11%) and 0 to 2 percent for urine testing (false alarm rates 0 to 16%). False negative rates ranged from 0 to 28 percent across sites in five of the studies (corresponding false reassurance rates ranged from 0 to 5%). One outlier study included in the prior report (see Key Question 3) reported higher false negative (range 44 to 56%) and false reassurance (range 11 to 13%) rates across anatomic sites;[79] this study evaluated a high-prevalence population (22% chlamydia prevalence). Evidence of harms in males was limited to two studies that found false positive rates of 0.4 percent for meatal (false alarm rate 4%) and 0.3 to 0.7 percent for urine (false alarm rates 3 to 6%) testing, with false reassurance rates of <1 percent (**Table 10**; **Appendix B Tables 7, 8 and 9**).[61,71]

For gonorrhea testing, evidence was limited to three studies in females[65,71,80] and two in males.[61,71] (**Tables 11 and 12**; **Appendix B Tables 7, 8 and 9**). In females, false positive rates were <1 percent across sites (corresponding false alarm rates ranged from 0 to 20%); false

negative rates ranged from 0 to 10 percent (false reassurance rates 0 to 5%).[65,71,80] In males, false positive rates were similarly low (<1% across sites). False alarm rates were 7 to 30 percent, but false reassurance rates were very low (0 to 0.2%).[61,71]

### Collection Methods

One new study[71] and two studies from the prior report[76,79] reported false negative rates for clinician- and self-collected vaginal samples for diagnosis of chlamydial infection in females (**Table 9; Appendix B Tables 7, 8 and 9**). Clinician-collected vaginal sample testing was associated with false positive rates ranging from 0 to 1.2 percent and corresponding false alarm rates that ranged from 0 to 8 percent. Rates were similar for self-collected samples (false positive rates 0 to 1%; false alarm rate range 0 to 12%). False negative and false reassurance rates were low for both collection methods in two studies (range 0 to 12% and 0 to 5%, respectively).[71,76] The third, outlier study found higher false negative (44% for clinician- and 48% for self-collected specimens) and false reassurance rates (11% for clinician- and 12% for self-collected).[79] One study directly compared the accuracy of clinician versus self-collected vaginal samples for gonorrhea in females and found a 0.3 percent false positive rate (false alarm rate 14%) with clinician-collected samples and 0 percent false positive and false alarm rate for self-collected samples. (**Table 11; Appendix B Tables 7, 8 and 9**).[71] False reassurance rates were 0 percent for both collection methods in this study.

No studies reported the accuracy of clinician- versus self-collected methods for chlamydia or gonorrhea in males.

### Other Harms of Screening

There were no studies of psychosocial harms, such as anxiety, related to testing that met criteria for this or the prior review, and no studies of risk behaviors or risk perception.

# Contextual Questions

## Contextual Question 1. What Is the Prevalence Rate of Chlamydial or Gonococcal Infections (and Concurrent HIV Infection) in Partners of Patients Who Test Positive for Chlamydial or Gonococcal Infections?

Three studies reported prevalence rates in partners of patients who test positive for infection. Two studies reported prevalence rates for chlamydia[88,89] and one study for gonorrhea.[90] Chlamydia rates ranged from 27 to 39 percent in male partners of infected women in a small study[88] that compared home sampling versus conventional contact tracing. The study did not report the percentage of asymptomatic patients, but aimed to assess whether the test rate of partners could be increased by having male contacts of infected women send a urine sample directly from home compared with a urethral swab obtained in a clinical setting. Contact tracing results were reported as the percentage of partners who were examined in each group.

A prospective study of cervical chlamydia positive heterosexual women who were asymptomatic or had mild symptoms were followed to assess concurrent rectal chlamydia also assessed partner prevalence.[89] The prevalence of infections in index cases was similar regardless of whether the partner had rectal chlamydia or not. An observational study conducted in Australia reported the prevalence of antibiotic resistant gonorrhea in partners of infected patients using pharyngeal and rectal swabs for asymptomatic MSM.[90] Thirty-four of 458 partners (7.4%) simultaneously tested from a large prospective cohort were positive for gonorrhea.

## Contextual Question 2. What Is the Effectiveness of Partner Services (Such as Traditional Partner Services or Expedited Partner Therapy)?

Three studies addressed partner services, including expedited partner therapy, in reducing rates of reinfection or acquisition of chlamydial or gonococcal infections in the index patient.[91-93] Types of partner services addressed in the studies included partner notification, a process by which sexual partners of patients diagnosed with a sexually transmitted infection are informed or notified of their exposure and the need to receive treatment; expedited partner therapy (EPT), in which there is facilitated access to antibiotic treatment or a prescription for medication by the index patient to their partner(s) without the need for a medical exam or evaluation of the partner; and expedited partner notification, when a clinician provides the index patient with antibiotics or a prescription to give to the sex partner.

A systematic review commissioned by the Cochrane collaborative reviewed the effect of strategies of partner notification in persons with sexually transmitted infections.[93] Expedited partner therapy was compared with simple patient referral (control) with regard to effects on rates of re-infection of the index patient. When combining trials of STI causing urethritis or cervicitis, expedited partner therapy was associated with decreased risk of re-infection of the index patient versus simple patient referral, but was not associated with decreased risk versus enhanced patient referral, in which additional support was given to enhance outcomes. In three trials, expedited partner therapy and enhanced patient referral were associated with similar levels of repeat infection (RR 0.96; 95% CI, 0.60 to 1.53).

Another systematic review evaluated different methods of partner notification on rates of reinfection of the index patient.[91] There were four randomized controlled trials of partner notification interventions that compared the effectiveness of expedited partner notification with simple patient referral that included verbal advice from the partner (attention-control) on the rate of index patient reinfection with gonorrhea or chlamydia. Expedited partner notification was defined as a doctor providing the index patient with antibiotics or a prescription to give to the sex partner for preventing index reinfection. Effects of expedited partner notification versus simple patient referral appeared smaller in trials that included only women with chlamydia (RR 0.90, 95% CI, 0.60 to 1.35) than in trials that included patients with either gonorrhea or chlamydia (RR 0.61, 95% CI, 0.39 to 0.94).

A pilot RCT of partner notification models in community settings evaluated the effect of accelerated partner therapy (APT), the U.K adaptation of EPT, for partner notification.[92] APT conforms to U.K. prescribing regulations but is otherwise identical to EPT. One hundred ninety-nine women reported 339 male partners, of whom 313 were contactable. The primary outcome

was whether each contactable partner was treated within 6 weeks of the index partner's diagnosis. Rates of reinfection or persistence of infection in the index patient was reported as a secondary outcome. APT was offered using three different methods, implemented in three different arms of the intervention, as pharmacy notification (community pharmacist assessment of partners plus routine PN) or hotline (telephone assessment of partners plus standard partner notification) versus standard partner notification alone (control). Only 38/199 (19%) index patients returned a postal urine sample for reinfection or persistence and chlamydia positivity was 15 percent (2/13) in the standard arm, 0 percent in the hotline arm, and 10 percent (1/10) in the pharmacy arm.

# Chapter 4. Discussion

## Summary of Review Findings

The evidence reviewed in this report is summarized in **Table 13**. The USPSTF previously determined that treatment is effective for chlamydial and gonococcal infections. One new trial of screening was generally consistent with prior screening trials that reported decreased risk of PID associated with screening. New evidence on risk prediction tools indicate suboptimal accuracy and require validation in primary care populations in the U.S. Evidence largely confirmed prior findings regarding high accuracy of diagnostic testing at various anatomic sites and home-based testing, with low false-positive and false-alarm rates. Important gaps include lack of studies on psychosocial or other harms related to screening, studies comparing screening intervals or alternative screening strategies, and studies evaluating changes in risk behaviors or risk perception.

Results of four screening trials, including one new trial, found screening for chlamydia associated with decreased risk of PID, though effects were not statistically significant in most trials and the magnitude of benefit was relatively small. No studies reported on the effectiveness of screening in men, other than one study that reported rates of epididymitis,[67] and there were no studies of pregnant individuals for any outcome. One large, new, good- quality trial of young men and women in primary care clinics in rural Australia found screening for chlamydia associated with reduced risk of hospital diagnosed PID in hospital diagnosed patients, although absolute effects were small (absolute difference -13.7 per 100,000 women).[67] In contrast to the three trials included in the prior report, this trial enrolled both men and women in primary care practices. There was no difference in risk of clinic-based PID diagnosis in women, epididymitis in men, or prevalence of chlamydia infection in young men or women. The study did not report data on transmission of infection.

This report included studies on the accuracy of risk criteria that were not addressed in prior USPSTF reviews. Three studies in asymptomatic patients found fair discrimination, but require further validation in diverse clinical and geographic settings. One study in a mixed population of asymptomatic and symptomatic women found similar discrimination of age ≤22 alone versus multi-item risk criteria. In other populations (women presenting for IUD insertion or surgical abortion) risk criteria were not accurate. One study found a high rate of pharyngeal gonorrhea in a population of high risk persons attending STI clinics, with a strong correlation between increasing numbers of oral sex partners in the three month period and rates of pharyngeal gonorrhea. Screening both urogenital and pharyngeal sites in order to increase sensitivity of case detection in certain populations may have implications for extragenital testing in other higher risk populations, especially given data on the association between rectal STI and HIV acquisition in men.[27,94]

Accuracy of diagnostic testing for chlamydia was highly accurate across all genitourinary anatomic sites with vaginal and endocervical testing demonstrating the highest accuracy,[65,71,72,76,77,79] followed by urine testing in females.[65,71,72,76,79] In males, meatal,[61] urethral[73] and urine[61,71] testing yielded similarly high sensitivity, as did rectal testing,[73] based on

one study. Gonococcal testing was also highly accurate across anatomic sites for females with endocervical and vaginal sites demonstrating the highest accuracy,[65,71,80] followed by urine samples.[71] Urine testing for gonococcal infections demonstrated the highest sensitivity in males compared with meatal testing.[61,71] One study of pharyngeal testing, conducted in MSM, demonstrated low sensitivity for chlamydial infection (69.2%) but higher sensitivity for gonococcal infection (89.1%).[73] In females, self- and clinician-collected vaginal samples for chlamydia and gonorrhea diagnosis were both highly sensitive,[71,76,79] but no studies meeting inclusion criteria compared collection methods in males. These results were largely based on asymptomatic patient populations, increasing relevance to screening populations in the U.S.

In addition to diagnostic accuracy, other factors that may inform testing at extragenital sites include higher prevalence of extragenital chlamydial and gonococcal infection in MSM and persons attending STI clinics, as well as persons engaging in sexual contact at those sites. A small observational study of MSM in Australia reported the prevalence of antibiotic resistant gonorrhea in partners of infected patients using pharyngeal and rectal swabs and demonstrated that asymptomatic MSM can transmit antibiotic resistant strains of gonorrhea directly to their partners.[90] In the U.S., prevalence data indicates that MSM are disproportionately affected by STIs, including HIV.[31] In a report of prevalence data from STI and HIV clinic attendees, approximately one in eight men had an extragenital chlamydial or gonococcal infection.[31] Given the reported rates of antibiotic resistant strains of gonococcal infection for MSM,[95] considerations to expand the range of specimen types for screening has the potential to increase identification of infected individuals, especially for asymptomatic MSM in whom nearly 90 percent of all gonorrhea infections are in non-genital sites.[96]

There are few harms to screening for infection based on findings from this review, including low rates of false positive or false negative findings, false alarm rates, and false reassurance rates. However, no studies provided data about other potential adverse effects of screening for any population groups, including anxiety, changes in risk behaviors or risk perception. Further research is needed to determine the effectiveness of screening in multiple populations and on various clinical outcomes; trials of gonorrhea screening, including screening high risk groups; effective screening strategies and intervals; and harms of screening.

## Limitations

We restricted inclusion to English language studies and did not include studies published only as abstracts or modeling studies of screening versus no screening; however, we did not identify non-English language studies in our searches or unpublished studies that met inclusion criteria. The inclusion criteria for this review included settings and tests relevant to current U.S. practice and did not re-evaluate the accuracy of NAAT testing. Studies that evaluated that accuracy of rectal or extragenital NAAT prior to their FDA clearance were also not included, which may limit some data informing the performance of certain tests. Therefore, some studies included in the prior USPSTF review were excluded, reducing the potential evidence base. However, this approach improved the relevance of the evidence to the USPSTF screening recommendation. There was variation in the quality and applicability of studies. A number of studies were conducted in STI clinics or other high-risk clinical settings or in persons at higher risk for

infection, which may reduce applicability to primary care settings or persons at lower risk. Evidence on men was limited and there were no studies of pregnant individuals. Screening trials focused on PID and epididymitis as the main outcome, but other health outcomes such as infertility, chronic pelvic pain and ectopic pregnancy are also relevant, but may be more challenging to correlate. Detection of PID and epididymitis in one trial may have been limited by relatively low screening rates (17% to 25%).[67] Differences in assay sensitivity may have contributed to differential impact on PID prevention. There were no screening studies that reported disease acquisition or transmission. Meta-analysis was not performed due to relatively small number of studies and heterogeneity in populations, settings, comparisons, and outcomes. We were not able to do formal graphical or statistical assessments for publication bias due to small numbers of studies.

## Emerging Issues/Next Steps

Despite many years of relatively consistent screening recommendations, rates of chlamydial and gonococcal infections continue to rise. This trend is likely due in part to changes in risk behaviors, though it may also be due other factors. Screening tests for chlamydial and gonococcal infection are accurate regardless of anatomic site or collection method. Further understanding of the clinical significance of asymptomatic infections at extragenital sites and the effectiveness of screening at those sites is needed. Additional screening studies that evaluate extragenital testing may also inform strategies for screening in various settings and among target groups. There were no studies of alternative screening strategies, including testing for concurrent infection, including HIV, and no studies that addressed screening intervals. Further evaluation of expanded screening strategies may provide opportunities to further evaluate testing, especially among those at increased risk.

## Relevance for Priority Populations

Evaluating the effectiveness of testing and risk criteria among priority populations has the potential to increase identification of infected individuals. Evidence on this topic has previously focused on women, with evidence lacking for men in general, and MSM in particular. Since the prior review, additional studies among MSM have emerged that demonstrate disproportionate risk for this group despite the overwhelming lack of screening studies in this population.[31] For this review, two studies included populations of MSM in the study population (2 to 7%)[68,73] and no studies included transgender or non-binary populations. While most studies were primarily conducted in heterosexual populations, several groups continue to experience increased risk for sexually transmitted infections including MSM, gender minority and transgender populations, but data are limited.[97,98] Two studies were exclusively of men,[61,73] of which one diagnostic accuracy study evaluated anatomic site- specific testing exclusively in MSM.[73] Two studies were exclusively of adolescents (under age 19)[65,75] and 17 studies included for this review included adolescents in the study population.[62-70,72-74,76-80] Two studies were primarily in Black and Hispanic/Latino populations which, based on population data, have a higher prevalence of chlamydial infection, but studies in other populations with high prevalence of infection (e.g., American Indians/Alaska Natives) are lacking.[65,68] While findings of this review may be

applicable across age categories, additional evidence is needed to inform clinical practice for men, including MSM, populations with higher prevalence of infection, rural populations, and in pregnant individuals, for whom no studies were identified.

## Future Research

Research is lacking on the effectiveness of screening for gonorrhea in all population groups and for chlamydia in men, pregnant individuals, and women without risk factors. Studies that evaluate risk assessment criteria require further validation in settings applicable to U.S. primary care practice. Future studies could compare the effectiveness of screening versus no screening in populations at different levels of risk, using specimens from different anatomical sites, screening that includes testing for concurrent STIs including HIV, and screening at different intervals. Studies could evaluate the impact of access to screening for high-risk and known underserved populations. No studies provided data about potential adverse effects of screening other than those related to test performance for any asymptomatic population group. Studies are also needed to evaluate the effect of screening on risk behavior and risk perception. No study addressed screening in pregnant individuals.

## Conclusions

Screening for chlamydial infection may reduce the incidence of PID in young women. Risk prediction criteria to identify persons with asymptomatic chlamydial or gonococcal infection are associated with limited accuracy and require further validation. Testing for asymptomatic chlamydial and gonococcal infections is accurate at most anatomic sites, using urine sampling, and using self-collected specimens. Research is needed to determine the effectiveness of screening in men, optimal screening intervals, and adverse effects of screening.

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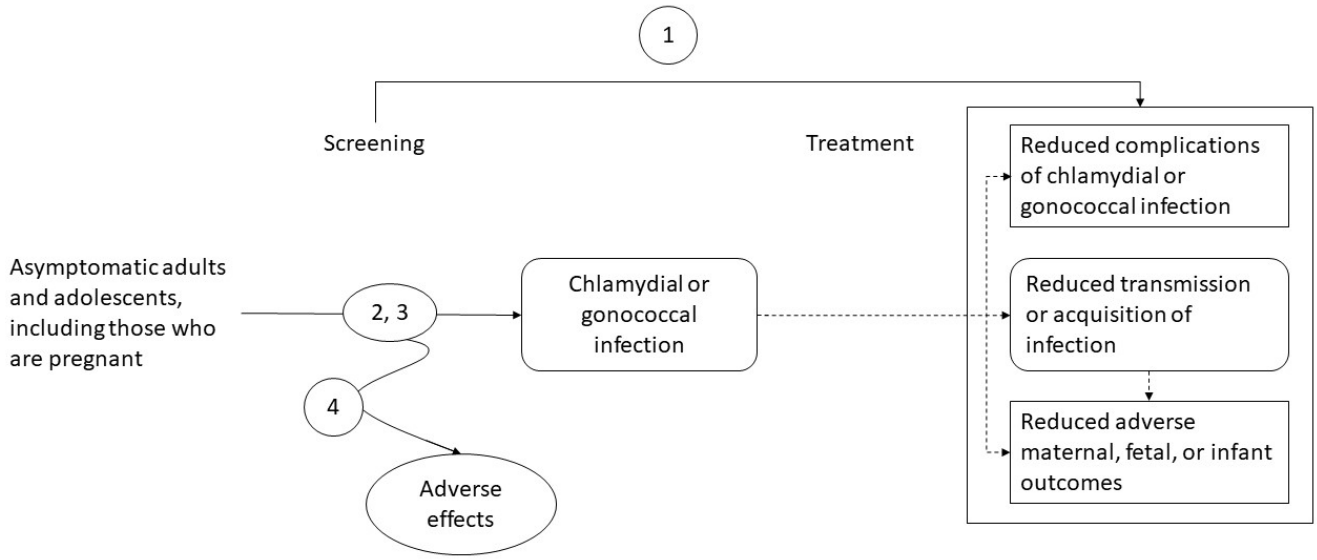
**Figure 1. Analytic Framework**

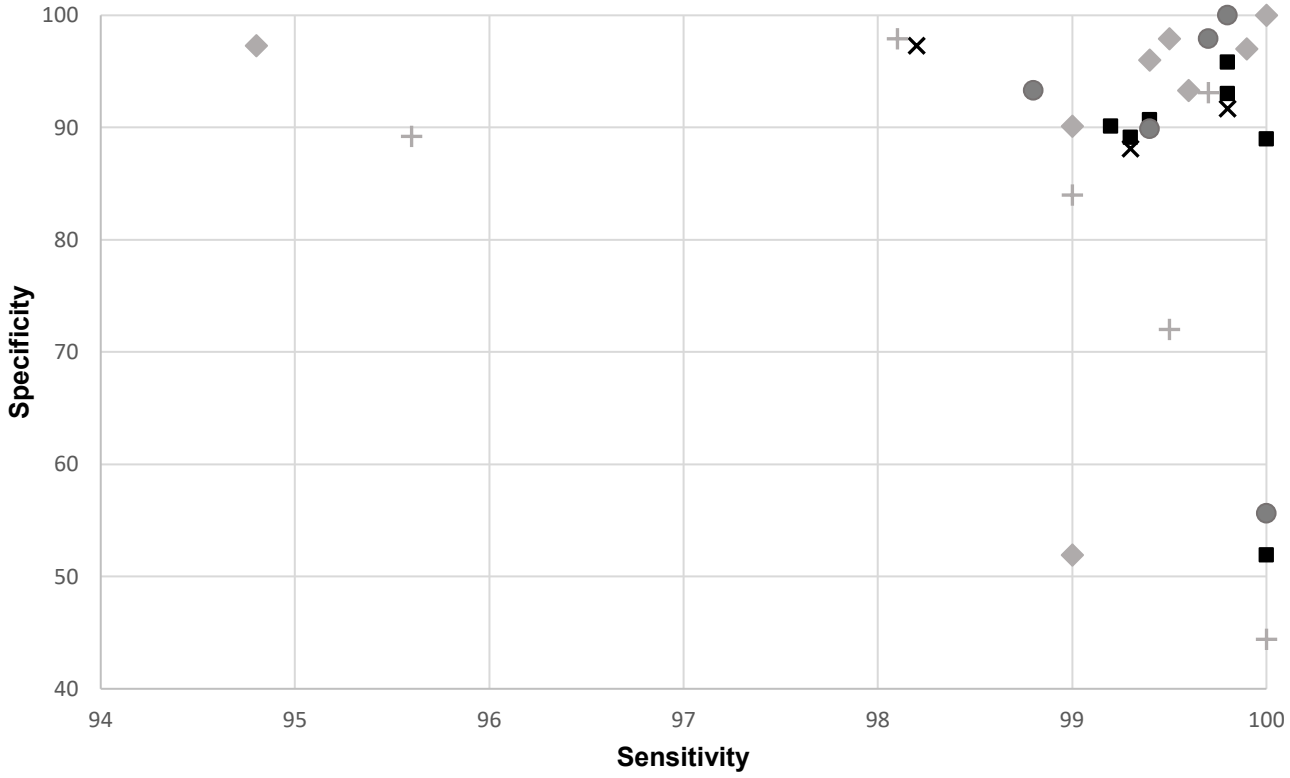



Note: Numbers in the figure correspond to the Key Question number.

**Key Questions**

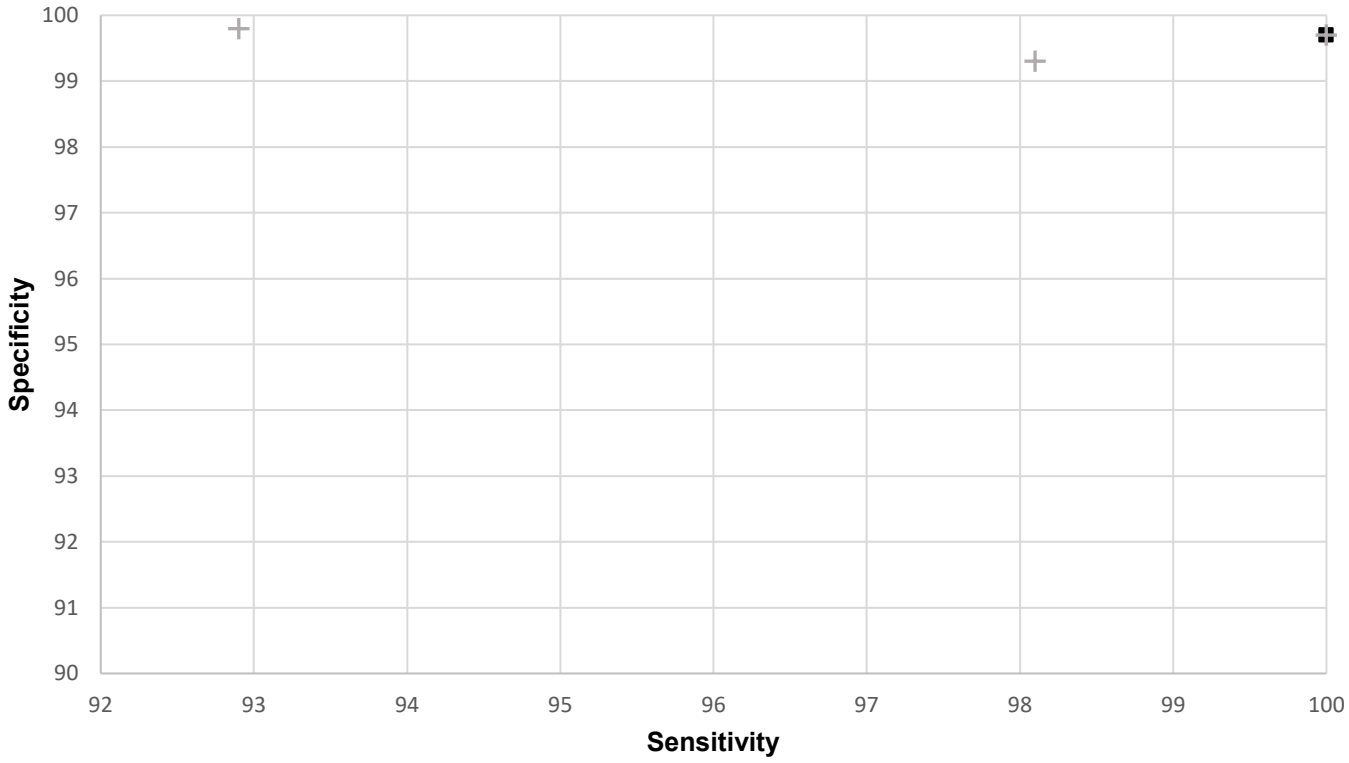
1. In asymptomatic, sexually active adults and adolescents, including those who are pregnant, what is the effectiveness of screening for chlamydial and gonococcal infections in reducing complications of infection and transmission or acquisition of disease, including gonorrhea, chlamydia, and HIV?
2. What is the accuracy of risk stratification methods or alternative screening strategies for identifying persons at increased risk of chlamydial and gonococcal infections (such as younger persons or men who have sex with men)? Screening strategies include testing for concurrent infections, including HIV, or using different screening intervals.
3. What is the diagnostic accuracy of anatomic site-specific testing and collection methods for identifying persons with chlamydial and gonococcal infections?
4. What are the harms of screening for chlamydial and gonococcal infections (such as labeling, anxiety, false-positive/alarm results, false-negative results/reassurance, or change in risk behaviors or risk perception)?

**Figure 2. Diagnostic Accuracy of Site-Specific Testing for Female Chlamydial Infection**




**Legend**
- ■ Endocervix
- ◆ Vagina, self-collected
- ● Vagina, clinician-collected
- × Urethra
- \+ Urine

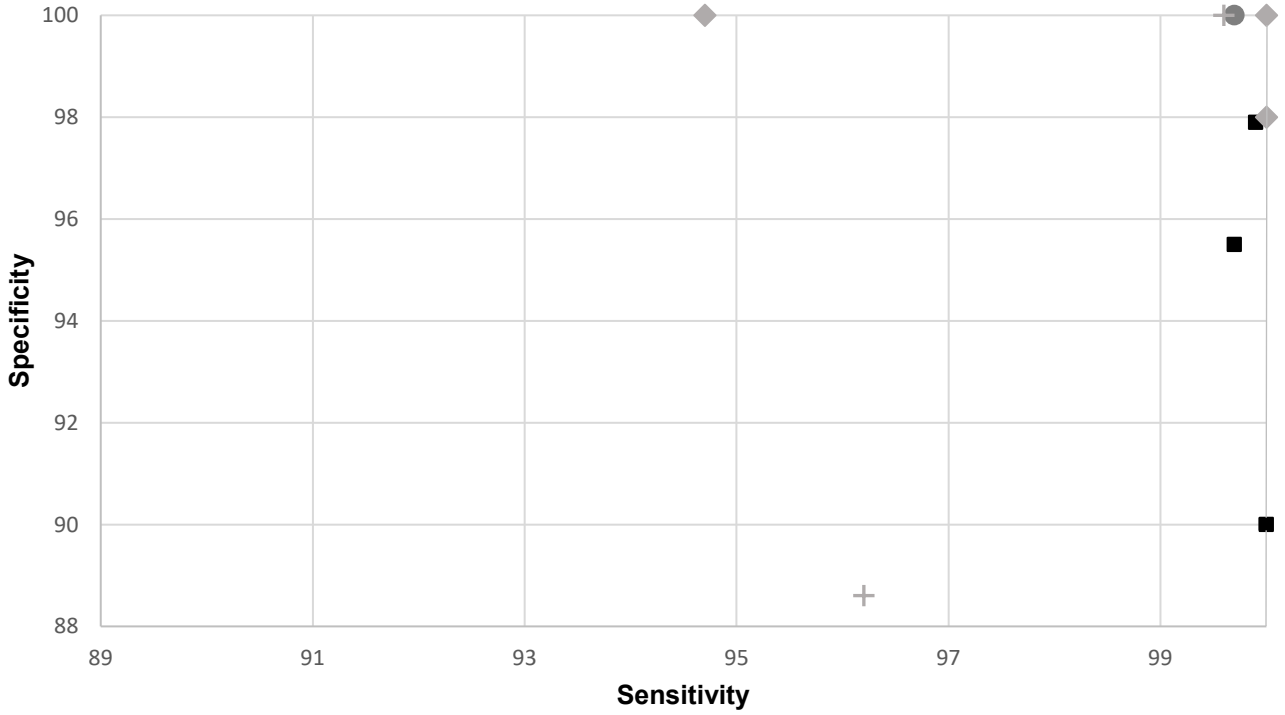
**Figure 3. Diagnostic Accuracy of Site-Specific Testing for Male Chlamydial Infection***




**Legend**
■ Meatal
+ Urine

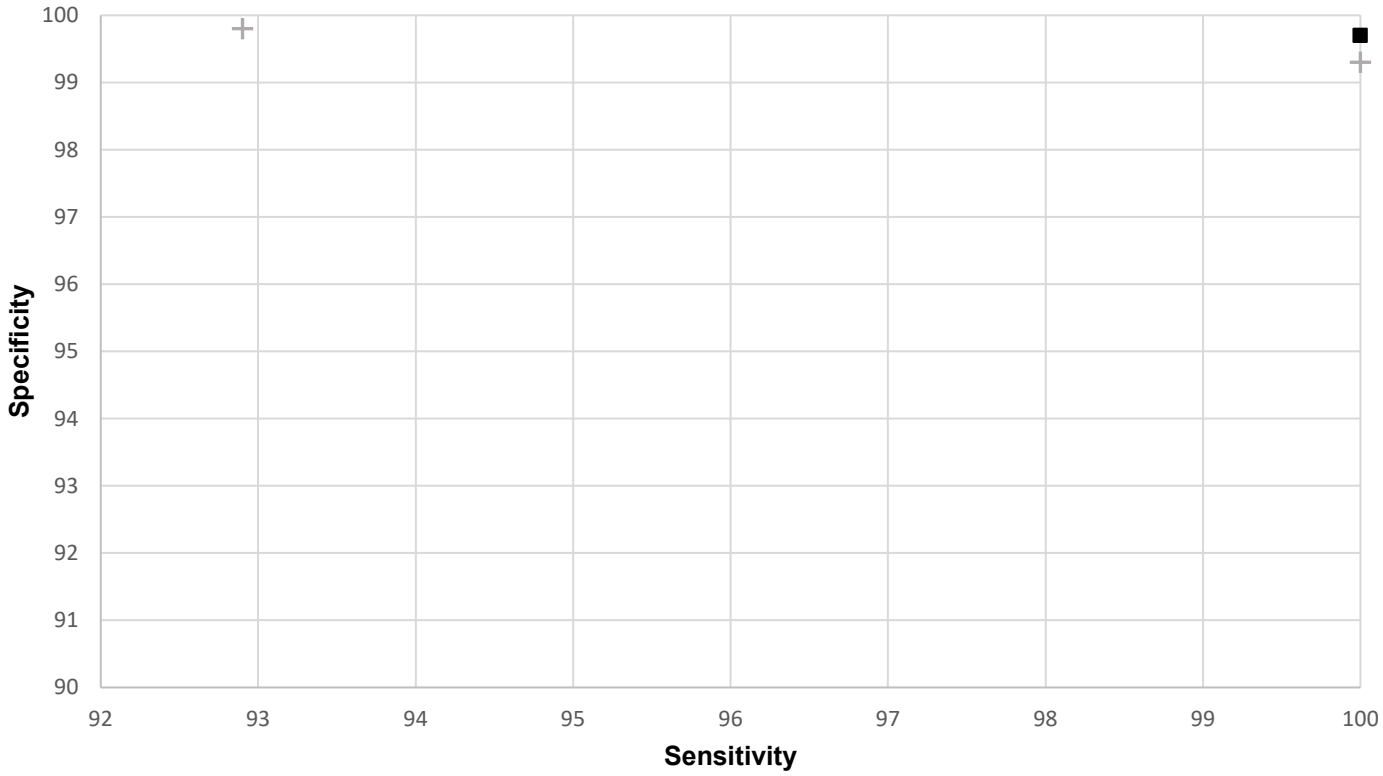
*Results from one study[79] are not included in Figure 3 as the study did not report specificity or include data to calculate specificity

**Figure 4. Diagnostic Accuracy of Site-Specific Testing for Female Gonococcal Infection**




**Legend**
- Endocervix
- Vagina, self-collected
- Vagina, clinician-collected
- Urine

**Figure 5. Diagnostic Accuracy of Site-Specific Testing for Male Gonoccocal Infection***




**Legend**
■ Meatal
+ Urine

*Results from one study[79] are not included in Figure 5 as the study did not report specificity or include data to calculate specificity

**Table 1. Screening Recommendations of Other Groups**

| Organization, year | Recommendations |
|---|---|
| Centers for Disease Control and Prevention, 2015[29] | Recommends annual screening for chlamydial and gonococcal infections in all sexually active women younger than 25 and in older women with specific risk factors (a new sex partner or multiple sex partners), per USPSTF. The CDC also recommends screening MSM at least annually, and recommends more frequent screening of MSM with multiple or anonymous partners. Clinical settings with a high prevalence of chlamydia should consider screening sexually active young men. Furthermore, CDC recommends screening women younger than 35 at intake in juvenile and adult correctional facilities and screening men up to age 30 at intake into jails. |
| American College of Obstetricians and Gynecologists, 2016[48] | Recommends annual screening for *C. trachomatis* in all sexually active females aged 25 or younger and in older women with risk factors. Recommends chlamydial screening in all pregnant women in early pregnancy and repeat testing in the third trimester for women with risk factors. Recommends screening for gonorrhea in women younger than 25 years and for women 25 years and older with risk factors, and in pregnant females 25 years or younger or for those living in an area where gonorrhea is common. |
| American Medical Association, 2009[49] | Follow CDC recommendations. |
| American Academy of Pediatricians, 2011[50] | Follow CDC recommendations |
| American Academy of Family Physicians, 2016[51] | Follow USPSTF recommendations. |
| American College of Physicians, 2015[52] | Follows USPSTF screening recommendations for chlamydial infections. |
| Public Health Agency of Canada[53-55] | Recommends annual screening for *C. trachomatis* and *N. Gonorrhoeae* in all sexually active persons under the age of 25 with retesting after 3 months in infected patients or based on continued risk factors. Risk-based screening is recommended for those 25 years and older. Recommends screening for chlamydia and gonorrhea at the first prenatal visit and again during pregnancy based on risk factors. |

Abbreviations: ACOG = American College of Obstetricians and Gynecologists; CDC = Centers for Disease Control and Prevention; MSM= men who have sex with men

**Table 2. Randomized Controlled Trials of Screening for Chlamydia to Reduce Adverse Outcomes**

| Author, Year | Population (*n*) | Interventions | Duration | Attrition | Outcomes | Quality |
|---|---|---|---|---|---|---|
| Hocking *et al.*, 2018[67] | Sexually active males and females age 16-29 years in 130 primary care clinics in Australia (n=63,338) | Multifaceted screening program vs. usual care (control) | Mean 3.1 years | Not reported | Incidence of PID in clinic‡:<br>Screened: 0.45% (293/65,519)<br>Control: 0.39% (237/60,384)<br>RR 1.1 (95% CI 0.7 to 1.8)<br>Incidence of PID in hospitals:<br>Screened: 0.24% (57/23,527)<br>Control: 0.38% (88/23,219)<br>RR 0.6 (95% CI 0.4 to 1.0)<br>Incidence of epididymitis§:<br>Screened: 0.26% (106/41,168)<br>Control: 0.27% (106/38,717)<br>RR 0.9 (95% CI 0.6 to 1.4) | Good |
| Oakeshott *et al.*, 2010†[74] | Sexually active females age ≤27 years recruited from universities and colleges in the U.K. (n=2,529) | Immediate screening vs. deferred screening after 1 year (control) | 1 year | Screened: 5%<br>Control: 7% | Incidence of PID in asymptomatic women (n=1648):<br>Screened: 0.6% (5/787)<br>Control: 1.6% (14/861)<br>RR 0.39 (95% CI 0.14 to 1.08)<br>Incidence of PID in all women:<br>Screened: 1.3% (15/1191)<br>Control: 1.9% (23/1186)<br>RR 0.65 (95% CI 0.34 to 1.22) | Good |
| Ostergaard *et al.*, 2000†[75] | Female students recruited from high schools in one county in Denmark (n=1,700) | Home screening vs. usual care opportunistic screening in a clinic (control) | 1 year | Screened: 49%<br>Control: 42% | Incidence of new chlamydia infections in all females:<br>Screened: 2.9% (13/443)<br>Control: 6.6% (32/487)<br>RR 0.45 (95% CI 0.24 to 0.84)<br>*p*= 0.026<br>Incidence of PID in all females:<br>Screened: 2.1% (9/443)<br>Control: 4.2% (20/487)<br>RR 0.50 (95% CI 0.23 to 1.08)<br>*p*= 0.045 | Fair |

**Table 2. Randomized Controlled Trials of Screening for Chlamydia to Reduce Adverse Outcomes**

| Author, Year | Population (*n*) | Interventions | Duration | Attrition | Outcomes | Quality |
|---|---|---|---|---|---|---|
| Scholes *et al.*, 1996†[78] | Women age 18 to 34 years recruited from a health maintenance organization in the U.S. selected by risk criteria (n=2,607) | Clinic screening vs. usual care (control) | 1 year | 24% of participants did not return final questionnaire | Incidence of PID in all women:<br>Screened: 8 per 10,000 women-years (9 cases)<br>Control: 18 per 10,000 women-years (33 cases)<br>RR 0.44 (95% CI 0.20 to 0.90) | Fair |

*Only includes participants with followup who were independently tested outside of study protocol.
†Included in prior USPSTF evidence review
‡Denominator is the number of females aged 16-33 years with at least one consultation during the intervention period
§Denominator is the number of men aged 16-29 with at least one consultation during the intervention period

**Abbreviations:** CI = confidence interval; PID = pelvic inflammatory disease; RR = relative risk; vs. = versus; U.K. = United Kingdom; U.S. = United States

**Table 3. Studies Evaluating Strategies for Identifying Persons Who Are at Increased Risk for Chlamydial or Gonococcal Infections**

| Author, year | Strategy | Infection | Sex | Study design | Population, N | Results | Quality rating |
|---|---|---|---|---|---|---|---|
| Falasinnu *et al.*, 2014[62] | Risk estimation model | GC, CT | M, F | Cross-sectional | Asymptomatic men and women, attending clinic for STI testing; Canada (n=25,393) | Derivation population (n=10,437): AUC=0.75; 95% CI, 0.72 to 0.80<br>Validation population (n=14,956): AUC=0.64; 95% CI, 0.61 to 0.67 | Fair |
| Falasinnu *et al.*, 2016[63] | Risk estimation model | GC, CT | M, F | Cross-sectional | Asymptomatic men and women, attending clinic for STI testing; Canada (n=20,862) | Derivation population (n=10,437):AUC= 0.74 (95% CI 0.70 to 0.77)<br>Validation population (n=10,425): AUC=0.69 (95% CI 0.67 to 0.71) | Fair |
| Falasinnu *et al.*, 2016[64] | Population guideline vs. guideline + number of risk factors vs. clinical risk score[a] | STI | M, F | Cross-sectional | Asymptomatic men and women, attending clinic for STI testing; Canada (n=35,818) | Guideline (any vs. no risk factors): AUC 0.55 (95% CI 0.54 to 0.56)<br>Guideline (numbers of risk factors): AUC 0.64 (95% CI 0.63 to 0.66)<br>Risk score model: AUC 0.73 (95% CI 0.71 to 0.74) | Fair |
| Grentzer *et al.*, 2015[66] | Age vs. age + partner vs. risk-based screening[b] | GC, CT | F | Cross-sectional | Women age 14 to 45 years attending clinic for IUD insertion; U.S. (n=5087) | *Sensitivity; specificity; NPV; PPV; %*<br>Age: 80.7; 48.1; 98.8; 4.5<br>Age + partner: 84.7; 44.8; 99.0; 4.5<br>Risk: 99.3; 7.6; 99.7; 3.2 | Fair |
| Javanbakht *et al.*, 2018[68] | Risk estimation | GC | M, F | Case-Control | Men and women age 15 to 29 years reporting giving oral sex to partner of opposite sex in past 90 days; U.S. (n=245) | Risk of pharyngeal gonorrhea:<br>Number of oral sex partners in 3 months: aOR 5.7; 95% CI 1.3 to 25.6 aOR 5.7; 95% CI 1.3 to 25.6<br>Presence of concurrent urogenital gonorrhea: aOR 6.2; 95% CI 2.6-14.3 | Fair |
| Lavoue *et al.*, 2014[69] | Model to predict infection[c] | CT | F | Cross-sectional | Women with surgical abortion and CT test; France (n=652 derivation, n=326 validation) | *Sensitivity, %; specificity, %*<br>Cutoff 40: 100; 26.9<br>Cutoff 60: 83.3; 58.8 | Fair |
| Miller, *et al.,* 2000[70] | Compares 9 sets of screening criteria[d] | CT | F | Cross-sectional | Women in family planning clinics; U.S. (n=4754) | *Criteria; AUC (SD); sensitivity, %; specificity, %*<br>CDC: NA, 85, 38<br>Seattle-1: 0.599 (0.017); 56; 54<br>Wisconsin: 0.604 (0.023); 50; 66<br>Ontario: 0.630 (0.017); 76; 41<br>California-1: 0.633 (0.016); 94; 20<br>Age ≤ 22: 0.687 (0.014); 77; 51<br>California-2: 0.701 (0.015); 97; 9<br>Seattle-3: 0.723 (0.015); 92; 31 | Fair |

**Table 3. Studies Evaluating Strategies for Identifying Persons Who Are at Increased Risk for Chlamydial or Gonococcal Infections**

| Author, year | Strategy | Infection | Sex | Study design | Population, N | Results | Quality rating |
|---|---|---|---|---|---|---|---|
| | | | | | | Seattle-2: 0.726 (0.014); 84; 51 | |

Abbreviations: aOR = adjusted odds ratio; AUC = area under the receiver operating characteristic curve; CDC = Centers for Disease Control and Prevention; CI = confidence interval; CT = chlamydia; F = female; GC = gonorrhea; IUD = intrauterine device; M = male; NA = not applicable; NPV = negative predictive value; OR = odds ratio; PID = pelvic inflammatory disease; PPV = positive predictive value; RCT = randomized controlled trial; RR = relative risk; SD = standard deviation; STD = sexually transmitted disease; STI = sexually transmitted infection; U.K. = United Kingdom; U.S. = United States.

[a]Population guideline from the Public Health Agency of Canada (any vs. no risk factors including age <30, 2 or more sexual partners, injection drug use, sexual contact with injection drug user, sexual contact with commercial sex workers, previous STD); guideline (numbers of risk factors including age <30, 2 or more sexual partners, injection drug use, sexual contact with injection drug user, sexual contact with commercial sex workers, previous STD); clinical risk score model (age, race/ethnicity [white/nonwhite], number of sexual partners [0, 1-2, 3 or more], previous CT or GC diagnosis [yes/no], condom use [always, not always]; injection drug use [yes/no]).
[b]Age-based (≤25 years); age + partner-based (≤25 years + multiple partners); risk-based (≤25 years, multiple partners, history of STI, inconsistent condom use).
[c]Model includes: 0 or 1 child (43 points); not using contraception (34 points); gestational age of abortion >10 weeks (23 points). Low-risk of CT infection = 0-40 points; intermediate-risk = 40-60; high-risk = 60-100.
[d]Screening criteria listed in publication (Miller, 2000[69]).

**Table 4. Characteristics of Diagnostic Accuracy Studies**

| Study, year | Assessment | Country, Setting | Eligibility Criteria | Population | Sample size, Proportion with condition | Study Quality |
|---|---|---|---|---|---|---|
| Berry *et al.*, 2017[61] | Site-specific testing | U.K.<br>Sexual health clinic | Men attending sexual health clinic for sexual health screening | Age (mean): NR<br>100% male sex<br>Race: NR<br>Symptomatic: NR | 1517<br>CT: 10.5%<br>NG: 4.2% | Fair |
| Fang *et al.*, 2008[65] | Site-specific testing | U.S.<br>Adolescent clinic | Sexually active adolescent women, age 12 to 18 years | Age (median): 16 years<br>100% female sex<br>Race: 96% black<br>Symptomatic: NR | 342†<br>CT: 26.6%<br>NG: 11.7% | Fair |
| Nye *et al.*, 2019[71] | Site-specific testing<br><br>Collection method | U.S.<br>Family planning, obstetric/ gynecology, or STI clinic | Eligible for screening per clinical site's standard practice, age ≥14 years | Age (mean): 29 years<br>88% female sex<br>Race: 45% black, 46% white<br>Symptomatic: 38% | 3749‡<br>CT: 6.8% (6.2% women, 11.3% men)<br>NG: 1.5% (1.6% women, 1.5% male | Fair |
| Schachter *et al.*, 2003[76]* | Site-specific testing<br><br>Collection method | U.S. and Canada<br>Family planning, obstetric/ gynecology, or STI clinic | Women attending family planning, obstetrics/ gynecology, or STI clinics for routine care or birth control, Age 16 to 25 years | Age (mean): NR, range 16 to 25 years<br>100% female sex<br>Race NR<br>Symptomatic: NR | 2,517<br>CT: 9.6% | Fair |
| Schoeman *et al.*, 2012[77]* | Site-specific testing | U.K.<br>Sexual health clinic | Women, Age ≥16 years | Age (mean): 25 years<br>100% female sex<br>Race: 80% white, 9% black, 7% mixed, 4% other<br>Symptomatic: 34% | 3974<br>CT: 10.3% | Fair |
| Shrier *et al.*, 2004[79]* | Site-specific testing<br><br>Collection method | U.S.;<br>University medical clinic for adolescents and young adults | Sexually experienced women attending clinic for routine gynecologic care, age 16 to 25 years | Age (mean): 19 years<br>100% female sex<br>Race: NR<br>Symptomatic: 0% | 139<br>CT: 21.6% | Fair |
| Skidmore *et al.*, 2008[72] | Site-specific testing | U.K.<br>Genitourinary medicine clinic | Women attending genitourinary clinic, age 18 to 24 years | Age (mean): NR; range 18 to 24 years<br>100% female sex<br>Race: NR<br>Symptomatic: NR | 267<br>CT: 9.3% | Fair |
| Stewart *et al.*, 2012[80]* | Site-specific testing | U.K.<br>Sexual health clinic | Women attending sexual health clinic, age ≥16 years | Age (mean): 25 years<br>100% female sex<br>Race: 80% white, 9% black, 7% mixed, 4% other<br>Symptomatic: 28% | 3973 (2,234‡)<br>NG: 2.5% (1.8%‡) | Fair |

**Table 4. Characteristics of Diagnostic Accuracy Studies**

| Study, year | Assessment | Country, Setting | Eligibility Criteria | Population | Sample size, Proportion with condition | Study Quality |
|---|---|---|---|---|---|---|
| Sultan *et al.*, 2016[73] | Site-specific testing | U.K.<br>Sexual health/ HIV clinic | Men who have sex with men, age ≥18 years | Age (median): 37 years<br>100% male sex<br>Race: NR<br>Symptomatic: 28% | 1064<br>CT: 15%<br>NG: 27% | Fair |

Abbreviations: CT = Chlamydia trachomatis; NG = Neisseria gonorrhoeae; NR = not reported
* Study included in prior USPSTF review
† Participants were tested multiple times over a 5-year period. The total number of chlamydia tests administered was 1,080; the total number of gonorrhea tests was 1,079.
‡ Asymptomatic population only

**Table 5. Diagnostic Accuracy of Anatomic Site-Specific Testing for Chlamydial Infection in Females**

| Author, year Sample size | Test | Reference standard | Endocervix, clinician-collected n=number tested | Vagina, clinician-collected n=number tested | Vagina, self-collected n=number tested | Urethra n=number tested | Urine n=number tested |
|---|---|---|---|---|---|---|---|
| Schachter *et al*., 2003[76] n=2,517 (n=609 tested using Amplicor PCR) | Amplicor CT/NG PCR | LCx Probe System, Amplicor PCR or Amplified CT Assay, clinician-collected cervical swab or urine sample | n=600<br>Sensitivity: 90.7 (95% CI 81.7-96.2)<br>Specificity: 99.4 (95% CI 98.3-99.9) | n=579<br>Sensitivity: 93.3 (95% CI 85.1-97.8)<br>Specificity: 98.8 (95% CI 98.4-99.7) | n=568<br>Sensitivity: 90.1 (95% CI 81.7-96.2)<br>Specificity: 99.0 (95% CI 97.7-99.7) | n=602<br>Sensitivity: 97.3 (95% CI 90.7-99.8)<br>Specificity: 98.2 (95% CI 96.8-99.2) | n=577<br>Sensitivity: 84.0 (95% CI 73.7-91.5)<br>Specificity: 99.0 (95% CI 97.7-99.7) |
| Schachter *et al*., 2003[76] n=2,517 (n=1,408 tested using Amplified CT) | Amplified CT Assay | LCx Probe System, Amplicor PCR or Amplified CT Assay, clinician-collected cervical swab or urine sample | n=1,408<br>Sensitivity: 89.1 (95% CI 82.0-95.0)<br>Specificity: 99.3 (95% CI 98.7-99.7) | n=1,408<br>Sensitivity: 89.9 (95% CI 83.1-94.7)<br>Specificity: 99.4 (95%CI 98.8-99.7) | n=1,408<br>Sensitivity: 93.3 (95% CI 87.2-97.1)<br>Specificity: 99.6 (95% CI 99.1-99.9) | n=1,407<br>Sensitivity: 88.1 (95% CI 81.1-93.4)<br>Specificity: 99.3 (95% CI 98.7-99.7) | n=1,387<br>Sensitivity: 72.0 (95% CI 63.3-80.1)<br>Specificity: 99.5 (95% CI 99.0-99.8) |
| Schoeman *et al*., 2012[77] n=2,233* | Aptima Combo-2 | Aptima CT, clinician-collected endocervical swab | n=2,233<br>Sensitivity: 89.0 (95% CI 84.0-93.0)<br>Specificity: 100.0 (95% CI 99.8-100) | - | n=2,233<br>Sensitivity: 97.0 (95% CI 94.0-99.0)<br>Specificity: 99.9 (95% CI 99.7-100) | - | - |
| Fang *et al*., 2008[65] n=342 (1,080 tests) | BD ProbeTec ET | BD ProbeTec ET, clinician-collected endocervical swab and urine sample | n=1,076<br>Sensitivity: 90.1 (95% CI 82.9-95.9)<br>Specificity: 99.2 (95% CI 98.9-99.9) | - | n=1,034<br>Sensitivity: 98.2 (95% CI 93.6-99.8)<br>Specificity: 99.5 (95% CI 98.7-99.8) | - | n=1,042<br>Sensitivity: 89.2 (95% CI 81.8-94.3)<br>Specificity: 99.5 (95% CI 98.8-99.8) |
| Shrier *et al*., 2004[79] n=139 | Cobas Amplicor PCR | Cobas Amplicor and Abbot LCx assay, clinician-collected urethral, vaginal and endocervical swab | n=126<br>Sensitivity: 51.9 (95% CI 32.0-71.3)<br>Specificity: 100.0 (95% CI 96.5-100) | n=126<br>Sensitivity: 55.6 (95% CI 36.4-73.1)<br>Specificity: 100.0 (95% CI 96.5-100) | n=126<br>Sensitivity: 51.9 (95% CI 32.0-71.3)<br>Specificity: 99.0 (95% CI 95.0-100) | - | n=126<br>Sensitivity: 44.4 (95% CI 26.9-63.6)<br>Specificity: 100.0 (95% CI 96.5-100) |
| Nye *et al*., 2019[71] n=3,289* | Cobas CT/NG 2.0 | Aptima Combo 2 Assay and BD ProbeTec CTQ/GCQ, clinician-collected endocervical (women) or urethral (men) swab, and/or urine sample | n=3,174<br>Sensitivity: 93.0 (95% CI 88.5-95.5)<br>Specificity: 99.8 (95% CI 99.6-99.9) | n=2,241<br>Sensitivity: 97.9 (95% CI 94.0-99.3)<br>Specificity: 99.7 (95% CI 99.4-99.9) | n=996<br>Sensitivity: 96.0 (95% CI 86.5-98.9)<br>Specificity: 99.4 (95% CI 98.6-99.7) | - | n=3,190<br>Sensitivity: 93.1 (95% CI 88.7-95.8)<br>Specificity: 99.7 (95% CI 99.4-99.8) |

**Table 5. Diagnostic Accuracy of Anatomic Site-Specific Testing for Chlamydial Infection in Females**

| Author, year<br>Sample size | Test | Reference standard | Endocervix, clinician-collected<br>n=number tested | Vagina, clinician-collected<br>n=number tested | Vagina, self-collected<br>n=number tested | Urethra<br>n=number tested | Urine<br>n=number tested |
|---|---|---|---|---|---|---|---|
| Skidmore *et al*., 2008[72] | Cobas Taqman 48 CT | Cobas Taqman 48 CT, clinician-collected endocervical swab | - | - | n=255<br>Sensitivity: 100.0 (95% CI 85.2-100)<br>Specificity: 100.0 (95% CI 98.4-100) | - | - |
| Schachter *et al*., 2003[76]<br>n=2,517 (n=500 tested using LCx Probe System) | LCx Probe System LCR | LCx Probe System, Amplicor PCR or Amplified CT Assay, clinician-collected cervical swab or urine sample | n=498<br>Sensitivity: 95.8 (95% CI 85.8-99.5)<br>Specificity: 99.8 (95% CI 98.8-100) | n=497<br>Sensitivity: 100.0 (95% CI 92.6-100)<br>Specificity: 99.8 (95% CI 98.8-100) | n=500<br>Sensitivity: 97.9 (95% CI 88.9-99.9)<br>Specificity: 99.5 (95% CI 98.4-99.9) | n=500<br>Sensitivity: 91.7 (95% CI 80.0-97.7)<br>Specificity: 99.8 (95% CI 98.8-100) | n=499<br>Sensitivity: 97.9 (95% CI 88.9-99.9)<br>Specificity: 98.1 (95% CI 96.3-99.1) |

*Asymptomatic population

**Table 6. Diagnostic Accuracy of Anatomic Site-Specific Testing for Chlamydial Infection in Males**

| Author, year Sample size | Test | Reference standard | Meatal, self-collected n=number tested | Urine n=number tested | Urethra n=number tested | Rectum n=number tested | Pharynx n=number tested |
|---|---|---|---|---|---|---|---|
| Sultan *et al*., 2016[73] n=1,064 | Aptima Combo-2 | Standard of care testing at each anatomical site | - | n=NR Sensitivity: 89.0-95.0, depending on volume of urine Specificity: not calculable | n=NR Sensitivity: 98.6 (95% CI 92.6-100) Specificity: not calculable | n=NR Sensitivity: 92.1 (95% CI 85-96.5) Specificity: not calculable | n=NR Sensitivity: 69.2 (95% CI 38.6-90.9) Specificity: not calculable |
| Berry *et al*., 2017[61] n=1,517 | BD ProbeTec ET | Abbott Real-Time CT/NG, urine sample | n=1,517 Sensitivity: 92.0 (95% CI 86.1-95.9) Specificity: 99.7 (95% CI 99.2-99.9) | n=1,517 Sensitivity: 100.0 (95% CI 97.3-100) Specificity: 99.7 (95% CI99.3-99.9) | - | - | - |
| Nye *et al*., 2019[71] n=460* | Cobas CT/NG 2.0 | Aptima Combo 2 Assay and BD ProbeTec CTQ/GCQ, clinician-collected urethral swab, and/or urine sample | - | n=460 Sensitivity: 98.1 (95% CI 89.9-99.7) Specificity: 99.3 (95% CI 97.9-99.7) | - | - | - |

*Asymptomatic population

**Table 7. Diagnostic Accuracy of Anatomic Site-Specific Testing for Gonococcal Infection in Females**

| Author, year<br>Sample size | Test | Reference standard | Endocervix<br>n=number tested | Vagina, clinician-collected<br>n=number tested | Vagina, self-collected<br>n=number tested | Urine<br>n=number tested |
|---|---|---|---|---|---|---|
| Stewart *et al*., 2012[80]<br>n=2,234* | Aptima Combo-2 | Aptima Combo-2, clinician-collected urethral and endocervical swab | n=2,234<br>Sensitivity: 90.0 (95% CI 77.0-96.0)<br>Specificity: 100.0 (95% CI 99.8-100) | - | n=2,234<br>Sensitivity: 98.0 (95% CI 87.0-100)<br>Specificity: 100.0 (95% CI 99.8-100) | - |
| Fang *et al*., 2008[65]<br>n=342 (1,079 tests) | BD ProbeTec ET | BD ProbeTec ET, clinician-collected endocervical swab and urine sample | n=1,076<br>Sensitivity: 95.5 (95% CI 84.5-99.4)<br>Specificity: 100.0 (95% CI 99.6-100) | - | n=1,030<br>Sensitivity: 100.0 (95% CI 92.0-100)<br>Specificity: 99.4 (95% CI 98.7-99.8) | n=1,040<br>Sensitivity: 90.7 (95% CI 77.9-97.4)<br>Specificity: 96.9 (95% CI 99.4-100) |
| Nye *et al*., 2019[71]<br>n=3,289* | Cobas CT/NG 2.0 | Aptima Combo 2 Assay and BD ProbeTec CTQ/GCQ, clinician-collected endocervical (women) and/or urine sample | n=3,174<br>Sensitivity: 97.9 (95% CI 88.9-99.6)<br>Specificity: 99.9 (95% CI 99.7-100) | n=2,240<br>Sensitivity: 100.0 (95% CI 90.6-100)<br>Specificity: 99.7 (99.4-99.9) | n=996<br>Sensitivity: 100.0 (95% CI 70.1-100)<br>Specificity: 100.0 (95% CI 99.6-100) | n=3,190<br>Sensitivity: 100 (95% CI 92.6-100)<br>Specificity: 99.6 (95% CI 99.3-99.8) |

*Asymptomatic population

**Table 8. Diagnostic Accuracy of Anatomic Site-Specific Testing for Gonococcal Infection in Males**

| Author, year<br>Sample size | Test | Reference standard | Meatal, self-collected<br>n=number tested | Urine<br>n=number tested | Urethra<br>n=number tested | Rectum | Pharynx |
|---|---|---|---|---|---|---|---|
| Sultan *et al*., 2016[73]<br>n=1,064 | Aptima Combo-2 | Standard of care testing at each anatomical site | - | n=NR<br>Sensitivity: 91.0-93.0, depending on volume of urine (95% CI NR)<br>Specificity: not calculable | n=NR<br>Sensitivity: 97.9 (95% CI 93.9-99.6)<br>Specificity: not calculable | n=NR<br>Sensitivity: 93.4 (95% CI 88.5-96.7)<br>Specificity: not calculable | n=NR<br>Sensitivity: 89.1 (95% CI 83.1-93.5)<br>Specificity: not calculable |
| Berry *et al*., 2017[61]<br>n=1,517 | BD ProbeTec ET | Abbott Real-Time CT/NG, urine sample | n=1517<br>Sensitivity: 100.0 (95% CI 91.6-100)<br>Specificity: 99.7 (95% CI 99.2-99.9) | n=1517<br>Sensitivity: 92.9 (95% CI 80.5-98.5)<br>Specificity: 99.8 (95% CI 99.4-99.7) | - | - | - |
| Nye *et al*., 2019[71]<br>n=460 | Cobas CT/NG 2.0 | Aptima Combo 2 Assay and BD ProbeTec CTQ/GCQ, clinician-collected urethral swab, and/or urine sample | - | n=460<br>Sensitivity: 100.0 (95% CI 64.6-100)<br>Specificity: 99.3 (95% CI 98.1-99.8) | - | - | - |

*Asymptomatic population

**Table 9. False Positive, False Alarm, False Negative, and False Reassurance Rates of Testing for Chlamydial Infection in Females**

| Anatomic site | Number of studies | Prevalence | False positive rate range (1-specificity) | False alarm rate range (1-PPV) | False negative rate range (1-sensitivity) | False reassurance rate range (1-NPV) |
|---|---|---|---|---|---|---|
| **Endocervix** | 6 studies[65,71,72,76,77,79] | 6.2-26.6% | 0%-0.7% | 0%-8.6% | 4.2%-48.1% (excluding outlier: 4.2%-11.9%) | 0.4%-11.6% (excluding outlier: 0.4% to 1.5%) |
| **Urethra** | 1 study*[76] | 8.6% | 0.2%-1.7% | 2.2%-11% | 2.7%-11.9% | 0.4%-1.1% |
| **Urine** | 5 studies[65,71,72,76,79] | 6.2-26.6% | 0%-2.0% | 0%-16.1% (excluding outlier: 0%-7.5%) | 2.1%-55.6% (excluding outlier: 2.1%-27.7%) | 0.2%-13.2% (excluding outlier: 0.2%-5.1%) |
| **Vagina, clinician-collected** | 3 studies[71,76,79] | 6.2%-21.6% | 0%-1.2% | 0%-7.9% | 0%-44.4% (excluding outlier: 0%-11.9%) | 0%-10.8% (excluding outlier: 0%-1.0%) |
| **Vagina, self-collected** | 6 studies[65,71,72,76,77,79] | 6.2-26.6% | 0%-1.0% | 0%-12.0% | 0%-48.1% (excluding outlier: 0%-9.3%) | 0%-11.7% (excluding outlier: 0%-4.8%) |

*This study[76] included results from three different tests
Abbreviations: NPV=negative predictive value; PPV=positive predictive value

**Table 10. False Positive, False Alarm, False Negative, and False Reassurance Rates of Testing for Chlamydial Infection in Males**

| Anatomic site | Number of studies | Prevalence | False positive rate range (1-specificity) | False alarm rate range (1-PPV) | False negative rate range (1-sensitivity) | False reassurance rate range (1-NPV) |
|---|---|---|---|---|---|---|
| **Meatal, self-collected** | 1 study[61] | 10.5% | 0.4% | 3.8% | 8.0% | 0.8% |
| **Urine** | 2 studies[61,71] | 10.5% and 11.3% | 0.3% and 0.7% | 2.8% and 5.6% | 0% and 1.9% | 0% and 0.2% |

Abbreviations: NPV=negative predictive value; PPV=positive predictive value

**Table 11. False Positive, False Alarm, False Negative, and False Reassurance Rates of Testing for Gonococcal Infections in Females**

| Anatomic site | Number of studies | Prevalence | False positive rate range (1-specificity) | False alarm rate range (1-PPV) | False negative rate range (1-sensitivity) | False reassurance rate range (1-NPV) |
|---|---|---|---|---|---|---|
| **Endocervix** | 3 studies[65,71,80] | 1.6%-11.7% | 0%-0.1% | 0%-6.1% | 2.1%-10.0% | 0%-0.2% |
| **Urine** | 1 study[71] | 1.6% | 0.4 | 20.0% | 0 | 0% |
| **Vagina, clinician-collected** | 1 study[71] | 11.7% | 0.3 | 14.0% | 0 | 0% |
| **Vagina, self-collected** | 3 studies[65,71,80] | 1.6%-11.7% | 0%-0.6% | 0%-12% | 0%-2.0% | 0%-4.8% |

Abbreviations: NPV=negative predictive value; PPV=positive predictive value

**Table 12. False Positive, False Alarm, False Negative, and False Reassurance Rates of Testing for Gonococcal Infection in Males**

| Anatomic site | Number of studies | Prevalence | False positive rate range (1-specificity) | False alarm rate range (1-PPV) | False negative rate range (1-sensitivity) | False reassurance rate range (1-NPV) |
|---|---|---|---|---|---|---|
| **Meatal, self-collected** | 1 study[61] | 4.2% | 0.3% | 10.6% | 0% | 0% |
| **Urine** | 2 studies[61,71] | 1.5% and 4.2% | 0.2% and 0.7% | 7.1% and 30.0% | 0% and 7.1% | 0% and 0.2% |

Abbreviations: NPV=negative predictive value; PPV=positive predictive value

**Table 13. Summary of Evidence**

| Key Question | Population | Studies (k) Participants (n) Study Design | Summary of Findings | Consistency and Precision | Limitations | Strength of Evidence | Applicability |
|---|---|---|---|---|---|---|---|
| Key Question 1. Effectiveness of screening vs. no screening | Young women; young adults | Prior review: k=3 n=6,836<br><br>New evidence: k=1 n=63,338<br><br>RCTs | The prior review included 3 studies of screening women at increased risk for chlamydia that favored screening; only 1 study showed statistically significantly reduced rates of PID (RR 0.44; 95% CI 0.20 to 0.90). One new RCT of screening men and women age 16 to 29 for chlamydia found reduced rates of hospital diagnosed PID (RR 0.6; 95% CI, 0.4 to 1.0), though absolute effects were small. There was no difference in rates of PID or epididymitis diagnosed in clinics. No studies of gonorrhea screening were identified. | Consistent; imprecise | Prior trials were underpowered to address health outcomes; limited health outcomes reported in studies. No studies of gonorrhea screening. Limited studies of chlamydia screening in men or pregnant women. | Low | Moderate |
| Key Question 2. Accuracy of risk stratification methods for identifying persons at increased risk | Women, men, MSM, young adults | Prior review: k=0<br><br>New evidence: k=7 n=93,137 | No diagnostic accuracy studies of risk stratification in prior review. Seven studies evaluated accuracy of risk criteria and demonstrated low to moderate accuracy. Two studies of the “Vancouver” risk tool and one study of a 3-item risk score for identifying persons with chlamydial or gonococcal infections reported AUCs that ranged from 0.64 to 0.73. Age criteria alone (≤ 22) performed nearly as well as multiple item criteria for predicting chlamydia infection in women (AUC 0.687, SD 0.014). No studies compared screening intervals or alternative screening strategies such as testing for concurrent infection, including HIV. | Consistent; precise | Studies were retrospective and cross-sectional; models were applied to patients in one geographic location or population; unclear performance in other geographic locations or other populations. | Moderate | Moderate; Most studies conducted in one geographic location or high prevalence setting. |
| Key Question 3. Diagnostic accuracy of anatomic site-specific testing and collection methods | Men, Women, MSM; adolescents | Prior review: k=4 n=9,474<br><br>New evidence: k=5 n=6,730 | Site-specific testing for chlamydia was highly accurate:<br>Endocervical sensitivity range 89 to 100% (7 studies); vaginal sensitivity range 90 to 100% (7 studies); Specificities were 99 to 100% for endocervical testing, 95 to 100% for vaginal testing, and 96 to 100% for urinalysis. Sensitivities were high for meatal (100%), urethral (99%) and rectal (92%), but | Consistent; precise, excluding one outlier study | Some studies included symptomatic participants; prevalence of chlamydial or gonococcal infection ranged up to 27%; limited | Moderate for accuracy of chlamydial and gonococcal testing; low for | High for accuracy of testing; moderate for collection methods |

**Table 13. Summary of Evidence**

| Key Question | Population | Studies (k) Participants (n) Study Design | Summary of Findings | Consistency and Precision | Limitations | Strength of Evidence | Applicability |
|---|---|---|---|---|---|---|---|
| Key Question 3. Cont.'d | | | low for pharyngeal (69%) testing in males based on one study each. Specificities were ≥99 percent at all sites; specificity was not reported for pharyngeal testing.<br>Site-specific testing for gonorrhea was highly accurate:<br>Endocervical sensitivity 96% to 98% (3 studies); vaginal sensitivity range 98% to 100% (3 studies); urinalysis, females: sensitivity 89% and 100% (2 studies); Specificity was high at all sites (95% to 100%).<br>High sensitivity for urinalysis in males: 93% to 100% (1 study); Other sites, males: 89% to 100% (1 study, including rectal and pharyngeal sites).<br>Collection methods for chlamydia were highly accurate:<br>Self-collected, vaginal: sensitivity 90% and 98%, (8 studies, excluding one outlier study that reported 52%); Clinician-collected, vaginal: sensitivity 90% and 100%, (5 studies, excluding one outlier study that reported 56%)<br>Collection methods for gonorrhea in women were highly accurate:<br>Self-collected, vaginal: sensitivity 100% (3 studies); Clinician-collected, vaginal: sensitivity 100% (1 study)<br>No studies compared collection methods in males for chlamydia or gonorrhea testing. | | evidence on collection methods. | collection methods | |

**Table 13. Summary of Evidence**

| Key Question | Population | Studies (k) Participants (n) Study Design | Summary of Findings | Consistency and Precision | Limitations | Strength of Evidence | Applicability |
|---|---|---|---|---|---|---|---|
| Key Question 4. Harms of screening vs. no screening | Men, Women, MSM; adolescents | Prior review:<br>k=4<br>n=9,474<br><br>New evidence:<br>k=4<br>n=5,666 | False negative rates ranged from 0 to 28% and false positive rates were consistently low (range 0 to 2%) across all anatomic sites for female and male samples. For females, false positive rates for self- versus clinician collected methods ranged from 0 to 1.2%; false positive rates ranged from 0 to 12%. No studies reported harms of collection methods in males.<br><br>No studies of psychosocial harms, such as anxiety related to testing, or studies of risk behaviors or risk perception. | Consistent for testing related harms; precise for testing related harms<br><br>N/A for psychosocial or risk behavior related harms | Some studies included symptomatic participants; prevalence of chlamydial or gonococcal infection ranged up to 27% | Moderate for testing related harms. | Moderate for testing related harms. |

Abbreviations: AUC = area under the receiving operator curve; HIV = human immunodeficiency virus; MSM = men who have sex with men; NA = not applicable; PID = pelvic inflammatory disease; SD = standard deviation; RR = relative risk.

**Appendix A1. Search Strategy**

*Ovid MEDLINE® Database Searches for Key Questions 1, 2, and 4*
Search Strategy:

1 exp Chlamydia Infections/ or exp Chlamydia
2 Neisseria gonorrhoeae
3 Gonorrhea
4 chlamydi*.ti,ab,kf.
5 (gonorrhe* or gonorrhoe*).ti,ab,kf.
6 or/1-5
7 *Mass Screening
8 (screen* or test*).ti,ab,kf.
9 7 or 8
10 6 and 9
11 (random* or control* or group* or cohort or placebo or sham or trial).ti,ab,kw
12 exp cohort studies
13 cohort$.tw.
14 controlled clinical trial.pt.
15 epidemiologic methods
16 limit 15 to yr=1966-1989
17 exp case-control studies
18 (case$ and control$).tw.
19 or/12-14,16-18
20 11 or 19
21 10 and 20
22 limit 21 to yr="2014 -Current"
23 limit 22 to english language

*EBM Reviews - Cochrane Central Register of Controlled Trials for Key Questions 1, 2, and 4*
Search Strategy:

1 exp Chlamydia Infections/ or exp Chlamydia
2 Neisseria gonorrhoeae
3 Gonorrhea
4 chlamydi*.ti,ab.
5 (gonorrhe* or gonorrhoe*).ti,ab.
6 or/1-5
7 (screen* or test*).ti,ab.
8 6 and 7
9 limit 8 to yr="2014 -Current"
10 limit 9 to english language

**Appendix A1. Search Strategy**

*Ovid MEDLINE® Database Searches for Key Questions 3*
Search Strategy:

1 exp Chlamydia Infections/ or exp Chlamydia/
2 Neisseria gonorrhoeae/
3 Gonorrhea/
4 chlamydi*.ti,ab,kf.
5 gonorrhe*.ti,ab,kf.
6 or/1-5
7 exp "Sensitivity and Specificity"/
8 (sensitiv* or "predictive value" or accuracy).ti,ab,kf.
9 7 or 8
10 6 and 9
11 limit 10 to yr="2014 - 2019"

*EBM Reviews - Cochrane Central Register of Controlled Trials for Key Questions 3*
Search Strategy:

1 exp Chlamydia Infections/ or exp Chlamydia/
2 Neisseria gonorrhoeae/
3 Gonorrhea/
4 chlamydi*.ti,ab,kf.
5 gonorrhe*.ti,ab,kf.
6 or/1-5
7 exp "Sensitivity and Specificity"/
8 (sensitiv* or "predictive value" or accuracy).ti,ab,kf.
9 7 or 8
10 6 and 9
11 limit 10 to yr="2014 - 2019"

*EBM Reviews - Cochrane Database of Systematic Reviews*
Search Strategy:

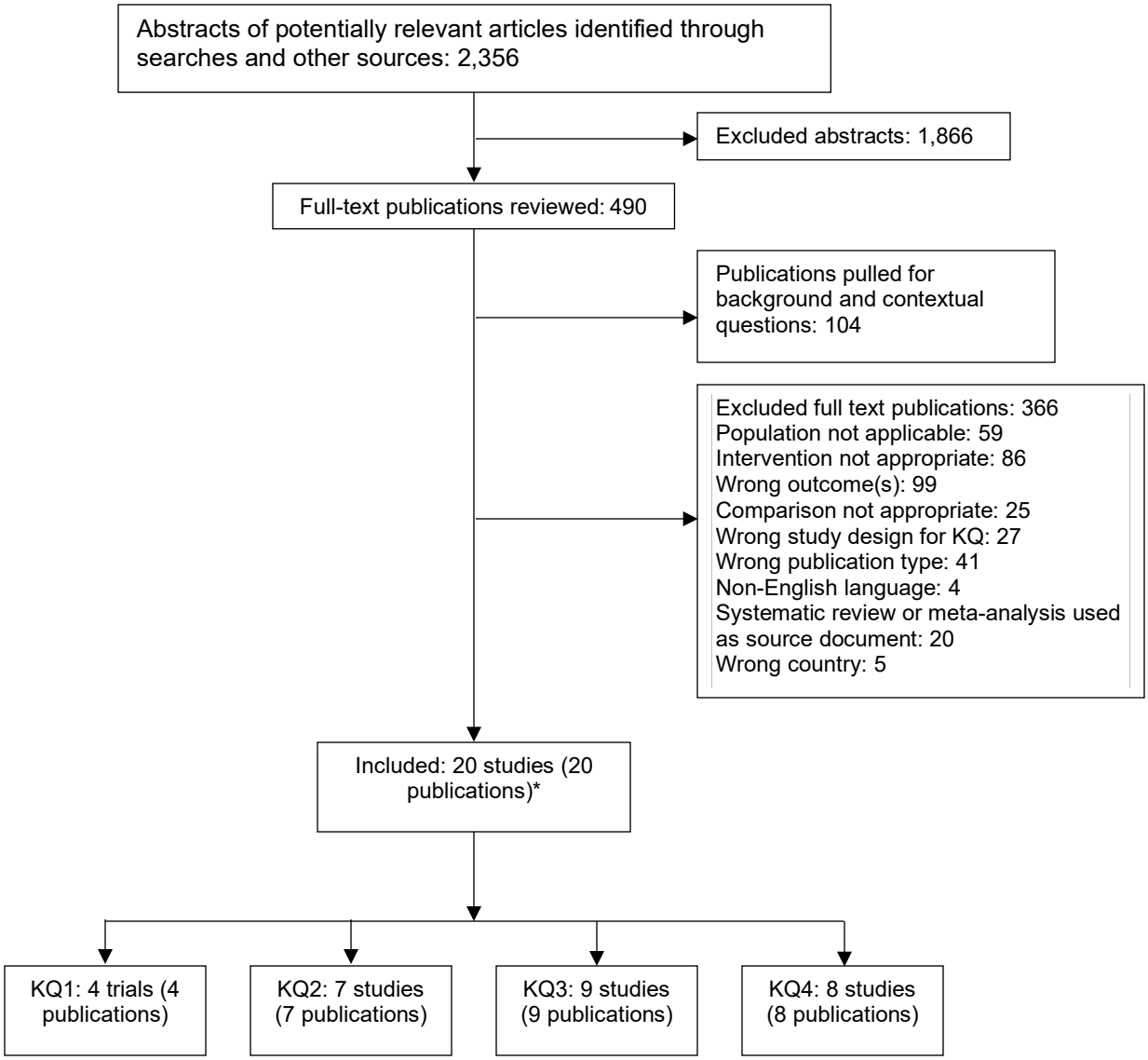
1 chlamydi*.ti,ab,kf.
2 gonorrhoe*.ti,ab.
3 1 or 2
4 limit 3 to full systematic reviews

## Appendix A2. Inclusion and Exclusion Criteria

| | Included | Excluded |
|---|---|---|
| **Populations** | Asymptomatic adults (age ≥18 years) and adolescents (ages 13 to <18 years); pregnant persons | Patients with symptoms of chlamydial or gonococcal infections; patients with current or recent diagnosis of any acute sexually transmitted infection; patients undergoing management for HIV infection; children (age <13 years); studies in which the majority of participants is comprised of persons infected with HIV or persons not infected with HIV and currently using pre-exposure prophylaxis |
| **Interventions** | **KQs 1, 4:** Screening for chlamydial or gonococcal infections<br>**KQ 2:** Screening strategies to detect infection, including selective screening of high-risk groups (such as younger persons, men who have sex with men, persons with high-risk sexual behaviors, or persons with high-risk sexual partners); testing for concurrent sexually transmitted infections, including HIV; using defined screening intervals<br>**KQ 3:** Test methods and approaches (such as self- vs. clinician-collected) to detect chlamydial or gonococcal infections in biological specimens from various anatomical sites (such as urine specimens and samples from the endocervix, urethra, vagina, anus, or pharynx) | No intervention; no screening |
| **Comparisons** | **KQs 1, 2:** Screening vs. no screening or alternate screening strategies or methods<br>**KQ 3:** Gold standard (nucleic acid amplification testing) or other reference standard (if study does not use nucleic acid amplification testing), specific to anatomic site or sites where gold standard sample is collected, when reported | No comparison; testing methods not cleared or approved by the U.S. Food and Drug Administration |
| **Outcomes** | **KQ 1:** Complications of infection (such as pelvic inflammatory disease, ectopic pregnancy, infertility, chronic pelvic pain, or epididymitis); infection transmission or acquisition, including gonorrhea, chlamydia, and HIV; reproductive, pregnancy-related, and perinatal outcomes<br>**KQ 2:** Accuracy of screening strategies<br>**KQ 3:** Diagnostic accuracy of testing at a specific anatomic site; accuracy of self- vs. clinician-collected specimens<br>**KQ 4:** Harms from screening or not screening (such as labeling, false-negative results, false-positive results, or changes in risk perception or risk behaviors) | Intermediate outcomes (outcomes that are not health outcomes, such as eradication of infection or laboratory studies) |
| **Settings** | U.S.-relevant primary care and primary care–referable settings (such as correctional settings, community care, schools, sexually transmitted infection clinics, and family planning settings); emergency departments; military or college intake or entrance settings | Other settings not relevant or referable to primary care in the United States |
| **Study Design** | **All KQs:** Good-quality systematic reviews<br>**Benefits:** Randomized, controlled trials; controlled observational trials<br>**Harms:** Randomized, controlled trials; controlled observational trials; uncontrolled observational trials | Uncontrolled observational trials (except for evidence on screening harms), case reports, small uncontrolled observational trials, and case studies |
| **Study Quality** | Fair- and good-quality studies based on USPSTF criteria | Poor-quality studies |

**Abbreviations:** HIV = human immunodeficiency virus, KQ = key question, USPSTF = U.S. Preventive Services Task Force.

**Appendix A3. Literature Flow Diagram**




*Included publications may be included for multiple key questions.

## Appendix A4. List of Included Studies


1. Berry L, Stanley B. Comparison of self-collected meatal swabs with urine specimens for the diagnosis of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* in men. J Med Microbiol. 2017 Feb;66(2):134-6. doi: 10.1099/jmm.0.000428. PMID: 28068218.
2. Falasinnu T, Gilbert M, Gustafson P, et al. Deriving and validating a risk estimation tool for screening asymptomatic chlamydia and gonorrhea. Sex Transm Dis. 2014 Dec;41(12):706-12. doi: 10.1097/OLQ.0000000000000205. PMID: 25581805.
3. Falasinnu T, Gilbert M, Gustafson P, et al. A validation study of a clinical prediction rule for screening asymptomatic chlamydia and gonorrhoea infections among heterosexuals in British Columbia. Sex Transm Infect. 2016a Feb;92(1):12-8. doi: 10.1136/sextrans-2014-051992. PMID: 25933609.
4. Falasinnu T, Gilbert M, Gustafson P, et al. An assessment of population-based screening guidelines versus clinical prediction rules for chlamydia and gonorrhea case finding. Prev Med. 2016b Aug;89:51-6. doi: 10.1016/j.ypmed.2016.04.001. PMID: 27143496.
5. Fang J, Husman C, DeSilva L, et al. Evaluation of self-collected vaginal swab, first void urine, and endocervical swab specimens for the detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* in adolescent females. J Pediatr Adolesc Gynecol. 2008;21(6):355-60. doi: 10.1016/j.jpag.2008.03.010. PMID: 19064231.
6. Grentzer JM, Peipert JF, Zhao Q, et al. Risk-based screening for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* prior to intrauterine device insertion. Contracept. 2015 Oct;92(4):313-8. doi: 10.1016/j.contraception.2015.06.012. PMID: 26093189.
7. Hocking JS, Temple-Smith M, Guy R, et al. Population effectiveness of opportunistic chlamydia testing in primary care in Australia: a cluster-randomised controlled trial. Lancet. 2018 Oct 20;392(10156):1413-22. doi: 10.1016/S0140-6736(18)31816-6. PMID: 30343857.
8. Javanbakht M, Westmoreland D, Gorbach P. Factors associated with pharyngeal gonorrhea in young people: implications for prevention. Sex Transm Dis. 2018 Sep;45(9):588-93. doi: 10.1097/OLQ.0000000000000822. PMID: 29485543.
9. Lavoue V, Morcel K, Voltzenlogel MC, et al. Scoring system avoids *Chlamydia trachomatis* overscreening in women seeking surgical abortions. Sex Transm Dis. 2014 Aug;41(8):470-4. doi: 10.1097/OLQ.0000000000000153. PMID: 25013973.
10. Miller WC, Hoffman IF, Owen-O'Dowd J, et al. Selective screening for chlamydial infection: which criteria to use? Am J Prev Med. 2000 Feb;18(2):115-22. doi: 10.1016/s0749-3797(99)00146-4. PMID: 10698241.
11. Nye MB, Osiecki J, Lewinski M, et al. Detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* with the cobas CT/NG v2.0 test: performance compared with the BD probetec CT Q and GC Q amplified DNA and aptima AC2 assays. Sex Transm Infect. 2019 03;95(2):87-93. doi: 10.1136/sextrans-2018-053545. PMID: 30126947.
12. Oakeshott P, Kerry S, Aghaizu A, et al. Randomised controlled trial of screening for *Chlamydia trachomatis* to prevent pelvic inflammatory disease: the POPI (prevention of pelvic infection) trial. BMJ (Clinical research ed.). 2010 Apr 8;340:c1642. doi: 10.1136/bmj.c1642. PMID: 20378636.
13. Østergaard L, Andersen B, Moller JK, et al. Home sampling versus conventional swab sampling for screening of *Chlamydia trachomatis* in women: a cluster-randomized 1-year follow-up study. Clin Infect Dis. 2000 Oct;31(4):951-7. doi: 10.1086/318139. PMID: 11049776.
14. Schachter J, McCormack WM, Chernesky MA, et al. Vaginal swabs are appropriate specimens for diagnosis of genital tract infection with *Chlamydia trachomatis*. J Clin Microbiol. 2003 Aug;41(8):3784-9. doi: 10.1128/jcm.41.8.3784-3789.2003. PMID: 12904390.
15. Schoeman SA, Stewart CM, Booth RA, et al. Assessment of best single sample for finding chlamydia in women with and without symptoms: a diagnostic test study. BMJ (Clinical research ed.). 2012 Dec 12;345:e8013. doi: 10.1136/bmj.e8013. PMID: 23236032.

16. Scholes D, Stergachis A, Heidrich FE, et al. Prevention of pelvic inflammatory disease by screening for cervical chlamydial infection. N Engl J Med. 1996 May 23;334(21):1362-6. doi: 10.1056/nejm199605233342103. PMID: 8614421.

17. Shrier LA, Dean D, Klein E, et al. Limitations of screening tests for the detection of *Chlamydia trachomatis* in asymptomatic adolescent and young adult women. Am J Obstet Gynecol. 2004 Mar;190(3):654-62. doi: 10.1016/j.ajog.2003.09.063. PMID: 15041995.

18. Skidmore S, Kaye M, Bayliss D, et al. Validation of COBAS Taqman CT for the detection of *Chlamydia trachomatis* in vulvo-vaginal swabs. Sex Transm Infect. 2008 Aug;84(4):277-8; discussion 8-9. doi: 10.1136/sti.2007.029587. PMID: 18305120.

19. Stewart CM, Schoeman SA, Booth RA, et al. Assessment of self taken swabs versus clinician taken swab cultures for diagnosing gonorrhoea in women: single centre, diagnostic accuracy study. BMJ (Clinical research ed.). 2012 Dec 12;345:e8107. doi: 10.1136/bmj.e8107. PMID: 23236033.

20. Sultan B, White JA, Fish R, et al. The "3 in 1" study: pooling self-taken pharyngeal, urethral, and rectal samples into a single sample for analysis for detection of *Neisseria gonorrhoeae* and *Chlamydia trachomatis* in men who have sex with men. J Clin Microbiol. 2016 Mar;54(3):650-6. doi: 10.1128/JCM.02460-15. PMID: 26719439.

## Appendix A5. List of Excluded Studies With Reasons for Exclusion


1. Abara WE, Llata EL, Schumacher C, et al. Extragenital gonorrhea and chlamydia positivity and the potential for missed extragenital gonorrhea with concurrent urethral chlamydia among men who have sex with men attending sexually transmitted disease clinics-Sexually Transmitted Disease Surveillance Network, 2015-2019. Sexually Transmitted Diseases. 2020;47(6):361-8. doi: 10.1097/OLQ.0000000000001170. PMID: 32413018. **Exclusion: Wrong outcome.**
2. Abbai NS, Moodley P, Reddy T, et al. Clinical evaluation of the OneStep Gonorrhea RapiCard InstaTest for detection of *Neisseria gonorrhoeae* in symptomatic patients from KwaZulu-Natal, South Africa. J Clin Microbiol. 2015;53(4):1348-50. doi: 10.1128/JCM.03603-14. PMID: 25609726. **Exclusion: Wrong population.**
3. Abbai-Shaik NS, Reddy T, Govender S, et al. Poor performance of the chlamydia rapid test device for the detection of asymptomatic infections in South African men: a pilot study. Sex Transm Dis. 2016;2016:8695146. doi: 10.1155/2016/8695146. PMID: 27195171. **Exclusion: Wrong country.**
4. Abou Tayoun AN, Burchard PR, Caliendo AM, et al. A multiplex PCR assay for the simultaneous detection of *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, and *Trichomonas vaginalis*. Exp Mol Pathol. 2015;98(2):214-8. doi: 10.1016/j.yexmp.2015.01.011. PMID: 25595915. **Exclusion: Wrong intervention.**
5. Adachi K, Klausner JD, Bristow CC, et al. Chlamydia and gonorrhea in HIV-infected pregnant women and infant HIV transmission. Sex Transm Dis. 2015;42(10):554-65. doi: 10.1097/OLQ.0000000000000340. PMID: 26372927. **Exclusion: Wrong population.**
6. Adachi K, Klausner JD, Xu J, et al. *Chlamydia trachomatis* and *Neisseria gonorrhoeae* in HIV-infected pregnant women and adverse infant outcomes. Pediatr Infect Dis J. 2016;35(8):894-900. doi: 10.1097/INF.0000000000001199. PMID: 27164464. **Exclusion: Wrong population.**
7. Adachi K, Xu J, Yeganeh N, et al. Combined evaluation of sexually transmitted infections in HIV-infected pregnant women and infant HIV transmission. PLoS One. 2018;13(1):e0189851. doi: 10.1371/journal.pone.0189851. PMID: 29304083. **Exclusion: Wrong population.**
8. Aghaizu A, Reid F, Kerry S, et al. Frequency and risk factors for incident and redetected *Chlamydia trachomatis* infection in sexually active, young, multi-ethnic women: a community based cohort study. Sexually Transmitted Infections. 2014;90(7):524-8. doi: 10.1136/sextrans-2014-051607. PMID: 25100744. **Exclusion: Wrong outcome.**
9. Ahmadi A, Khodabandehloo M, Ramazanzadeh R, et al. The relationship between *Chlamydia trachomatis* genital infection and spontaneous abortion. J Reprod Health Med 2016;17(2):110-6. PMID: 27141466. **Exclusion: Wrong outcome.**
10. Ahmadi MH, Mirsalehian A, Bahador A. Association of *Chlamydia trachomatis* with infertility and clinical manifestations: a systematic review and meta-analysis of case-control studies. Infect Dis. 2016;48(7):517-23. doi: 10.3109/23744235.2016.1160421. PMID: 27064452. **Exclusion: Wrong outcome.**
11. Ako MC, Lewis M, Peterson S, et al. The clinical impact of rapid diagnostics on improving appropriate treatment of STIs in women in the emergency department. Sex Transm Dis. 2016;43(10):S136-. **Exclusion: Wrong publication type.**
12. Akoh CC, Pressman EK, Cooper E, et al. Prevalence and risk factors for infections in a pregnant adolescent population. J Pediatr Adolesc Gynecol. 2017;30(1):71-5. doi: 10.1016/j.jpag.2016.08.001. PMID: 27521899. **Exclusion: Wrong study design for Key Question.**
13. Ampt FH, El Hayek C, Agius PA, et al. Anorectal swabs as a marker of male-to-male sexual exposure in STI surveillance systems. Epidemiol Infect. 2017;145(12):2530-5. doi: 10.1017/S095026881700098X. PMID: 28528588. **Exclusion: Wrong outcome.**
14. Anaene M, Soyemi K, Caskey R. Factors associated with the over-treatment and under-treatment of gonorrhea and chlamydia in adolescents presenting to a public hospital emergency department. Int J Infect Dis. 2016;53:34-8. doi: 10.1016/j.ijid.2016.10.009. PMID: 27771470. **Exclusion: Wrong outcome.**
15. Andreatos N, Grigoras C, Shehadeh F, et al. The impact of HIV infection and socioeconomic factors on the incidence of gonorrhea: a county-level, US-wide analysis. PLoS One. 2017;12(9):e0183938. doi: 10.1371/journal.pone.0183938. PMID: 28863154. **Exclusion: Wrong outcome.**

16. Atkinson LM, Vijeratnam D, Mani R, et al. 'The waiting game': are current chlamydia and gonorrhoea near-patient/point-of-care tests acceptable to service users and will they impact on treatment? Int J STD AIDS. 2016;27(8):650-5. doi: 10.1177/0956462415591414. PMID: 26092579. **Exclusion: Wrong intervention.**

17. August EM, Daley E, Kromrey J, et al. Age-related variation in sexual behaviours among heterosexual men residing in Brazil, Mexico and the USA. J Fam Plann Reprod Health Care. 2014;40(4):261-9. doi: 10.1136/jfprhc-2012-100564. PMID: 24099979. **Exclusion: Wrong comparator.**

18. Badman SG, Willie B, Narokobi R, et al. A diagnostic evaluation of a molecular assay used for testing and treating anorectal chlamydia and gonorrhoea infections at the point-of-care in Papua New Guinea. Clin Microbiol Infect. 2019;25(5):623-7. doi: 10.1016/j.cmi.2018.08.001. PMID: 30107282. **Exclusion: Wrong country.**

19. Badolato GM, Goyal MK. Refining a computerized sexual health screening tool among adolescents presenting to the emergency department. Journal of Adolescent Health. 2019;64(2):S41-. **Exclusion: Wrong publication type.**

20. Baird J, Merchant RC. A randomized controlled trial of the effects of a brief intervention to increase chlamydia and gonorrhea testing uptake among young adult female emergency department patients. Acad Emerg Med. 2014;21(12):1512-20. doi: 10.1111/acem.12539. PMID: 25491714. **Exclusion: Wrong outcome.**

21. Balendra A, Cousins E, Lamplough H, et al. Pilot study for the 'test n treat' trial of on-site rapid chlamydia/gonorrhoea tests and same day treatment. Sex Transm Infect. 2017;93(4):283. doi: 10.1136/sextrans-2016-053084. PMID: 28576786. **Exclusion: Wrong comparator.**

22. Banerjee P, Thorley N, Radcliffe K. A service evaluation comparing home-based testing to clinic-based testing for chlamydia and gonorrhoea in Birmingham and Solihull. International Journal of STD & AIDS. 2018;29(10):974-9. doi: 10.1177/0956462418767180. PMID: 29690825. **Exclusion: Wrong intervention.**

23. Barbee LA, Dombrowski JC, Kerani R, et al. Effect of nucleic acid amplification testing on detection of extragenital gonorrhea and chlamydial infections in men who have sex with men sexually transmitted disease clinic patients. Sex Transm Dis. 2014;41(3):168-72. doi: 10.1097/OLQ.0000000000000093. PMID: 24521722. **Exclusion: Wrong outcome.**

24. Barbee LA, Khosropour CM, Dombrowksi JC, et al. New Human Immunodeficiency Virus Diagnosis Independently Associated With Rectal Gonorrhea and Chlamydia in Men Who Have Sex With Men. Sexually Transmitted Diseases. 2017;44(7):385-9. doi: 10.1097/OLQ.0000000000000614. PMID: 28608786. **Exclusion: Wrong intervention.**

25. Barbee LA, Khosropour CM, Dombrowski JC, et al. An estimate of the proportion of symptomatic gonococcal, chlamydial and non-gonococcal non-chlamydial urethritis attributable to oral sex among men who have sex with men: a case-control study. Sex Transm Infect. 2016;92(2):155-60. doi: 10.1136/sextrans-2015-052214. PMID: 26297719. **Exclusion: Wrong population.**

26. Barnard S, Free C, Bakolis I, et al. Comparing the characteristics of users of an online service for STI self-sampling with clinic service users: a cross-sectional analysis. Sex Transm Infect. 2018;94(5):377-83. doi: 10.1136/sextrans-2017-053302. PMID: 29437985. **Exclusion: Wrong outcome.**

27. Bartelsman M, Straetemans M, Vaughan K, et al. Comparison of two gram stain point-of-care systems for urogenital gonorrhoea among high-risk patients: diagnostic accuracy and cost-effectiveness before and after changing the screening algorithm at an STI clinic in Amsterdam. Sex Transm Infect. 2014;90(5):358-62. doi: 10.1136/sextrans-2013-051500. PMID: 24860102. **Exclusion: Wrong comparator.**

28. Bartelsman M, van Rooijen MS, Alba S, et al. Point-of-care management of urogenital *Chlamydia trachomatis* via gram-stained smear analysis in male high-risk patients. Diagnostic accuracy and cost-effectiveness before and after changing the screening indication at the STI clinic in Amsterdam. Sex Transm Infect. 2015;91(7):479-84. doi: 10.1136/sextrans-2014-051941. PMID: 25855625. **Exclusion: Wrong study design for Key Question.**

29. Batteiger TA, Dixon BE, Wang J, et al. Where do people go for gonorrhea and chlamydia tests: a cross-sectional view of the central Indiana population, 2003-2014. Sex Transm Infect. 2019;46(2):132-6. doi: 10.1097/OLQ.0000000000000928. PMID: 30334869. **Exclusion: Wrong study design for Key Question.**

30. Baud D, Zufferey J, Hohlfeld P, et al. Performance of an automated multiplex immunofluorescence assay for detection of *Chlamydia trachomatis* immunoglobulin G. Diagn Microbiol Infect Dis. 2014;78(3):217-9. doi: 10.1016/j.diagmicrobio.2013.11.022. PMID: 24365033. **Exclusion: Wrong outcome.**

31. Bazan JA, Carr Reese P, Esber A, et al. High prevalence of rectal gonorrhea and chlamydia infection in women attending a sexually transmitted disease clinic. J Womens Health. 2015;24(3):182-9. doi: 10.1089/jwh.2014.4948. PMID: 25692800. **Exclusion: Wrong outcome.**

32. Beanland F, Schoeman S, Davis P, et al. A year of 'sex, steam and stis'. Sex Transm Infect. Conference: BASHH Spring Conference. 2015;91. **Exclusion: Wrong comparator.**

33. Bellaminutti S, Seraceni S, De Seta F, et al. HPV and *Chlamydia trachomatis* co-detection in young asymptomatic women from high incidence area for cervical cancer. J Med Virol. 2014;86(11):1920-5. doi: 10.1002/jmv.24041. PMID: 25132162. **Exclusion: Wrong comparator.**

34. Bercot B, Amarsy R, Goubard A, et al. Assessment of coinfection of sexually transmitted pathogen microbes by use of the anyplex II STI-7 molecular kit. J Clin Microbiol. 2015;53(3):991-3. doi: 10.1128/JCM.03370-14. PMID: 25540390. **Exclusion: Wrong intervention.**

35. Beymer MR, Bolan RK, Flynn RP, et al. Uptake and repeat use of postexposure prophylaxis in a community-based clinic in Los Angeles, California. AIDS Res Hum Retroviruses. 2014;30(9):848-55. doi: 10.1089/AID.2014.0017. PMID: 24970113. **Exclusion: Wrong outcome.**

36. Beymer MR, Llata E, Stirland AM, et al. Evaluation of gonorrhea test of cure at 1 week in a Los Angeles community-based clinic serving men who have sex with men. Sex Transm Dis. 2014;41(10):595-600. doi: 10.1097/OLQ.0000000000000190. PMID: 25211254. **Exclusion: Wrong population.**

37. Bilder CR, Tebbs JM, McMahan CS. Informative group testing for multiplex assays. Biometrics. 2019;75(1):278-88. doi: 10.1111/biom.12988. PMID: 30353548. **Exclusion: Wrong comparator.**

38. Booth AR, Norman P, Goyder E, et al. Pilot study of a brief intervention based on the theory of planned behaviour and self-identity to increase chlamydia testing among young people living in deprived areas. Br J Health Psychol. 2014;19(3):636-51. doi: 10.1111/bjhp.12065. PMID: 24103040. **Exclusion: Wrong outcome.**

39. Borchardt LN, Pickett ML, Tan KT, et al. Expedited partner therapy: pharmacist refusal of legal prescriptions. Sexually Transmitted Diseases. 2018;45(5):350-3. doi: 10.1097/OLQ.0000000000000751. PMID: 29465689. **Exclusion: Wrong outcome.**

40. Bosmans LJ. Conquering chlamydia. Creat Nurs. 2014;20(4):248-53. PMID: 26050420. **Exclusion: Wrong publication type.**

41. Bourgeois-Nicolaos N, Jaureguy F, Pozzi-Gaudin S, et al. Benefits of rapid molecular diagnosis of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* infections in women attending family planning clinics. Sex Transm Dis. 2015;42(11):652-3. doi: 10.1097/OLQ.0000000000000351. PMID: 26462191. **Exclusion: Wrong outcome.**

42. Boyajian AJ, Murray M, Tucker M, et al. Identifying variations in adherence to the CDC sexually transmitted disease treatment guidelines of *Neisseria gonorrhoeae*. Public Health. 2016;136:161-5. doi: 10.1016/j.puhe.2016.04.004. PMID: 27179879. **Exclusion: Wrong study design for Key Question.**

43. Breslin K, Tuchman L, Hayes KL, et al. Sensitivity and specificity of empiric treatment for sexually transmitted infections in a pediatric emergency department. J Pediatr. 2017;189:48-53. doi: 10.1016/j.jpeds.2017.05.050. PMID: 28629687. **Exclusion: Wrong study design for Key Question.**

44. Bristow CC, Mathelier P, Ocheretina O, et al. *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, and *Trichomonas vaginalis* screening and treatment of pregnant women in Port-au-Prince, Haiti. Int J STD AIDS. 2017;28(11):1130-4. doi: 10.1177/0956462416689755. PMID: 28134005. **Exclusion: Wrong outcome.**

45. Brook G. The performance of non-NAAT point-of-care (POC) tests and rapid NAAT tests for chlamydia and gonorrhoea infections. An assessment of currently available assays. Sex Transm Infect. 2015;91(8):539-44. doi: 10.1136/sextrans-2014-051997. PMID: 25935930. **Exclusion: Wrong publication type.**

46. Brown B, Davtyan M, Leon SR, et al. A prospective cohort study characterising the role of anogenital warts in HIV acquisition among men who have sex with men: a study protocol. BMJ Open. 2014;4(9):e005687. doi: 10.1136/bmjopen-2014-005687. PMID: 25227629. **Exclusion: Wrong study design for Key Question.**

47. Brown S, Paterson C, Dougall N, et al. Understanding the attitudes and acceptability of extra-genital chlamydia testing in young women: evaluation of a feasibility study. BMC Public Health. 2019;19(1):992. doi: 10.1186/s12889-019-7313-0. PMID: 31340797. **Exclusion: Wrong intervention.**

48. Browne FA, Wechsberg WM, Kizakevich PN, et al. mHealth versus face-to-face: study protocol for a randomized trial to test a gender-focused intervention for young African American women at risk for HIV in North Carolina. BMC Public Health. 2018;18(1):982. doi: 10.1186/s12889-018-5796-8. PMID: 30081868. **Exclusion: Wrong study design for Key Question.**

49. Burchell AN, Grewal R, Allen VG, et al. Modest rise in chlamydia and gonorrhoea testing did not increase case detection in a clinical HIV cohort in Ontario, Canada. Sex Transm Infect. 2014;90(8):608-14. doi: 10.1136/sextrans-2014-051647. PMID: 25178285. **Exclusion: Wrong population.**

50. Burgess S, Beltrami J, Kearns L, et al. The Louisiana Wellness Centers Program for HIV/STD prevention among gay and bisexual men and transgender persons. J Public Health Manag Pract. 2019;22:22. doi: 10.1097/PHH.0000000000000959. PMID: 30807464. **Exclusion: Wrong outcome.**

51. Butzler MA, Reed JL, McFall SM. A simple and rapid DNA extraction method for *Chlamydia trachomatis* detection from urogenital swabs. Diagn Microbiol Infect Dis. 2017;89(3):182-4. doi: 10.1016/j.diagmicrobio.2017.08.007. PMID: 28918068. **Exclusion: Wrong intervention.**

52. Byrne R, Cooper F, Appleby T, et al. Can express treatment reduce onward transmission? Sexually Transmitted Infections. Conference: BASHH Spring Conference. 2015;91. **Exclusion: Wrong publication type.**

53. Callander D, Cook T, Read P, et al. Sexually transmissible infections among transgender men and women attending Australian sexual health clinics. Medical Journal of Australia. 2019;211(9):406-11. doi: 10.5694/mja2.50322. PMID: 31468530. **Exclusion: Wrong intervention.**

54. Callander D, Guy R, Fairley CK, et al. Gonorrhoea gone wild: rising incidence of gonorrhoea and associated risk factors among gay and bisexual men attending Australian sexual health clinics. Sex Health. 2018;09:09. doi: 10.1071/SH18097. PMID: 30409244. **Exclusion: Wrong outcome.**

55. Camporiondo MP, Farchi F, Ciccozzi M, et al. Detection of HPV and co-infecting pathogens in healthy Italian women by multiplex real-time PCR. Infez Med. 2016;24(1):12-7. PMID: 27031891. **Exclusion: Wrong outcome.**

56. Cassell JA, Dodds J, Estcourt C, et al. The relative clinical effectiveness and cost-effectiveness of three contrasting approaches to partner notification for curable sexually transmitted infections: a cluster randomised trial in primary care. Health Technol Assess. 2015;19(5):1-115, vii-viii. doi: 10.3310/hta19050. PMID: 25619445. **Exclusion: Wrong outcome.**

57. Castell S, Krause G, Schmitt M, et al. Feasibility and acceptance of cervicovaginal self-sampling within the German National Cohort (pretest 2). Bundesgesundheitsblatt, Gesundheitsforschung, Gesundheitsschutz. 2014;57(11):1270-6. doi: 10.1007/s00103-014-2054-9. PMID: 25303829. **Exclusion: Wrong outcome.**

58. Causer LM, Guy RJ, Tabrizi SN, et al. Molecular test for chlamydia and gonorrhoea used at point of care in remote primary healthcare settings: a diagnostic test evaluation. Sex Transm Infects. 2018;94(5):340-5. doi: 10.1136/sextrans-2017-053443. PMID: 29748180. **Exclusion: Wrong intervention.**

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314. Ross CE, Tao G, Patton M, et al. Screening for human immunodeficiency virus and other sexually transmitted diseases among U.S. women with prenatal care. Obstet Gynecol. 2015;125(5):1211-6. doi: 10.1097/AOG.0000000000000756. PMID: 25932850. **Exclusion: Wrong intervention.**

315. Rumyantseva T, Golparian D, Nilsson CS, et al. Evaluation of the new amplisens multiplex real-time PCR assay for simultaneous detection of *Neisseria gonorrhoeae*, *Chlamydia trachomatis*, *Mycoplasma genitalium*, and *Trichomonas vaginalis*. APMIS. 2015;123(10):879-86. doi: 10.1111/apm.12430. PMID: 26299582. **Exclusion: Wrong intervention.**

316. Sachdev D, Patel AL, Sonkar SC, et al. Diagnosis of *Neisseria gonorrhoeae* using molecular beacon. Biomed Res Int. 2015;2015:597432. doi: 10.1155/2015/597432. PMID: 25802857. **Exclusion: Wrong intervention.**

317. Sachdev D, Wasnik K, Patel AL, et al. Multi-centric validation of an in-house-developed beacon-based PCR diagnostic assay kit for chlamydia and neisseria and portable fluorescence detector. J Med Microbiol. 2018;67(9):1287-93. doi: 10.1099/jmm.0.000803. PMID: 30051801. **Exclusion: Wrong intervention.**

318. Sahi SV, Rogozinska E, Sobhy S, et al. Accuracy of tests used to detect infection with *Chlamydia trachomatis* in asymptomatic pregnant women: a systematic review. Curr Opin Obstet Gynecol. 2017;29(6):375-82. doi: 10.1097/GCO.0000000000000411. PMID: 28914654. **Exclusion: Systematic review or meta-analysis used as source document only to identify individual studies.**

319. Sales JM, Smearman EL, Swartzendruber A, et al. Socioeconomic-related risk and sexually transmitted infection among African-American adolescent females. J Adolesc Health. 2014;55(5):698-704. doi: 10.1016/j.jadohealth.2014.05.005. PMID: 24974317. **Exclusion: Wrong intervention.**

320. Salomon SG, Torrone E, Nakatsukasa-Ono W, et al. Missed opportunities for chlamydia screening in title X family planning clinics. Sex Transm Dis. 2017;44(9):519-23. doi: 10.1097/OLQ.0000000000000641. PMID: 28809768. **Exclusion: Wrong intervention.**

321. Schillinger JA. Optimizing the Impact of Expedited Partner Therapy. Sex Transm Dis. 2018;45(5):358-60. doi: 10.1097/olq.0000000000000814. PMID: 29465636. **Exclusion: Wrong publication type.**

322. Schlueter R, Siu A, Shelton J, et al. Routine screening for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* in first trimester abortion. J Infect Public Health. 2018;11(4):584-5. doi: 10.1016/j.jiph.2017.10.012. PMID: 29146429. **Exclusion: Wrong intervention.**

323. Secura GM, Allsworth JE, Madden T, et al. The Contraceptive CHOICE Project: reducing barriers to long-acting reversible contraception. Am J Obstet Gynecol. 2010;203(2):115.e1-7. doi: 10.1016/j.ajog.2010.04.017. PMID: 20541171. **Exclusion: Wrong publication type.**

324. Sexton ME, Baker JJ, Nakagawa K, et al. How reliable is self-testing for gonorrhea and chlamydia among men who have sex with men? J Fam Pract. 2013;62(2):70-8. PMID: 23405376. **Exclusion: Wrong population.**

325. Shannon CL, Keizur EM, Fehrenbacher A, et al. Sexually transmitted infection positivity among adolescents with or at high-risk for Human Immunodeficiency Virus infection in Los Angeles and New Orleans. Sexually Transmitted Diseases. 2019b;46(11):737-42. doi: 10.1097/OLQ.0000000000001056. PMID: 31453926. **Exclusion: Wrong intervention.**

326. Sirivongrangson P, Girdthep N, Sukwicha W, et al. The first year of the global enhanced gonococcal antimicrobial surveillance programme (EGASP) in Bangkok, Thailand, 2015-2016. PLoS One. 2018;13(11):e0206419. doi: 10.1371/journal.pone.0206419. PMID: 30412586. **Exclusion: Wrong population.**

327. Skulska E, Mlynarczyk-Bonikowska B, Walter de Walthoffen S, et al. [The comparison of real-time PCR and direct immunofluorescence in laboratory diagnostics of chlamydiosis in patients of department of dermatology and venereology medical university of Warsaw]. Med Dosw Mikrobiol. 2015;67(3-4):173-80. PMID: 27019911. **Exclusion: Not English language but possibly relevant.**

328. Slutsker JS, Tsang LB, Schillinger JA. Do prescriptions for expedited partner therapy for chlamydia get filled? Findings from a multi-jurisdictional evaluation, United States, 2017-2019. Sex Transm Dis. 2020;47(6):376-82. doi: 10.1097/olq.0000000000001163. PMID: 32149956. **Exclusion: Wrong intervention.**

329. Soetens LC, van Benthem BH, Op de Coul EL. Chlamydia test results were associated with sexual risk behavior change among participants of the chlamydia screening implementation in the Netherlands. Sex Transm Dis. 2015;42(3):109-14. doi: 10.1097/OLQ.0000000000000234. PMID: 25668640. **Exclusion: Wrong comparator.**

330. Speers DJ, Chua IJ, Manuel J, et al. Detection of *Neisseria gonorrhoeae* and *Chlamydia trachomatis* from pooled rectal, pharyngeal and urine specimens in men who have sex with men. Sex Transm Infect. 2018;94(4):293-7. doi: 10.1136/sextrans-2017-053303. PMID: 29066627. **Exclusion: Wrong outcome.**

331. Sugunendran H, Birley HD, Mallinson H, et al. Comparison of urine, first and second endourethral swabs for PCR based detection of genital *Chlamydia trachomatis* infection in male patients. Sex Transm Infect. 2001;77(6):423-6. doi: 10.1136/sti.77.6.423. PMID: 11714940. **Exclusion: Wrong population.**

332. Swartzendruber A, Sales JM, Brown JL, et al. Correlates of incident *Trichomonas vaginalis* infections among African American female adolescents. Sex Transm Dis. 2014;41(4):240-5. doi: 10.1097/OLQ.0000000000000094. PMID: 24622635. **Exclusion: Wrong intervention.**

333. Sweet RL. Pelvic inflammatory disease: current concepts of diagnosis and management. Curr Infect Dis Rep. 2012;14:194-203. doi: 10.1007/s11908-012-0243-y. PMID: 22298157. **Exclusion: Wrong publication type.**

334. Tamarelle J, Thiebaut ACM, Sabin B, et al. Early screening for *Chlamydia trachomatis* in young women for primary prevention of pelvic inflammatory disease (i-Predict): study protocol for a randomised controlled trial. Trials 2017;18(1):534. doi: 10.1186/s13063-017-2211-1. PMID: 29132441. **Exclusion: Wrong publication type.**

335. Taylor MM, Frasure-Williams J, Burnett P, et al. Interventions to improve sexually transmitted disease screening in clinic-based settings. Sex Transm Dis. 2016;43(2 Suppl 1):S28-41. doi: 10.1097/OLQ.0000000000000294. PMID: 26779685. **Exclusion: Wrong outcome.**

336. Taylor SN, Liesenfeld O, Lillis RA, et al. Evaluation of the roche cobas(R) CT/NG test for detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* in male urine. Sex Transm Dis. 2012;39(7):543-9. doi: 10.1097/OLQ.0b013e31824e26ff. PMID: 22706217. **Exclusion: Wrong intervention.**

337. Taylor SN, Van Der Pol B, Lillis R, et al. Clinical evaluation of the BD probetec *Chlamydia trachomatis* qx amplified DNA assay on the BD viper system with XTR technology. Sex Transm Dis. 2011;38(7):603-9. doi: 10.1097/OLQ.0b013e31820a94d2. PMID: 21301389. **Exclusion: Wrong intervention.**

338. Ten Hoor G, Hoebe CJ, van Bergen JE, et al. The influence of two different invitation letters on chlamydia testing participation: randomized controlled trial. J Med Internet Res. 2014;16(1):e24. doi: 10.2196/jmir.2907. PMID: 24480721. **Exclusion: Wrong outcome.**

339. Thielemans E, Wyndham-Thomas C, Henrard S, et al. Screening for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* infections in men who have sex with men: diagnostic accuracy of nucleic acid amplification test on pooled urine, anorectal, and pharyngeal specimens. Sex Transm Dis. 2018;45(3):195-8. doi: 10.1097/OLQ.0000000000000722. PMID: 29419710. **Exclusion: Wrong population.**

340. Trebach JD, Chaulk CP, Page KR, et al. Neisseria gonorrhoeae and Chlamydia trachomatis among women reporting extragenital exposures. Sexually Transmitted Diseases. 2015;42(5):233-9. doi: 10.1097/OLQ.0000000000000248. PMID: 25868133. **Exclusion: Wrong outcome.**

341. Tsoumanis A, Hens N, Kenyon CR. Is screening for chlamydia and gonorrhea in men who have sex with men associated with reduction of the prevalence of these infections? A systematic review of observational studies. Sex Transm Dis. 2018;45(9):615-22. doi: 10.1097/OLQ.0000000000000824. PMID: 29485537. **Exclusion: Systematic review or meta-analysis used as source document only to identify individual studies.**

342. Valejo Coelho MM, Matos-Pires E, Serrao V, et al. Extragenital gonorrhoea in men who have sex with men: a retrospective study in a STI clinic in Lisbon, Portugal. Acta Medica Portuguesa. 2018;31(5):247-53. doi: 10.20344/amp.10146. PMID: 29916355. **Exclusion: Wrong outcome.**

343. van der Helm JJ, Hoebe CJ, van Rooijen MS, et al. High performance and acceptability of self-collected rectal swabs for diagnosis of Chlamydia trachomatis and Neisseria gonorrhoeae in men who have sex with men and women. Sex Transm Dis. 2009;36(8):493-7. doi: 10.1097/OLQ.0b013e3181a44b8c. PMID: 19617869. **Exclusion: Wrong population.**

344. Van Der Pol B, Daniel G, Williams J, et al. Performance of the BD MAXTM CT/GC/TV assay for detection of chlamydia, gonorrhoea and trichomonas. Sex Transm Infect. Conference: BASHH Spring Conference. 2015;91. **Exclusion: Wrong publication type.**

345. Van Der Pol B, Fife K, Taylor SN, et al. Evaluation of the performance of the cobas CT/NG test for use on the cobas 6800/8800 systems for detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* in male and female urogenital samples. J Clin Microbiol. 2019;57(4) doi: 10.1128/JCM.01996-18. PMID: 30651389. **Exclusion: Wrong intervention.**

346. Van Der Pol B, Liesenfeld O, Williams JA, et al. Performance of the cobas CT/NG test compared to the aptima AC2 and viper CTQ/GCQ assays for detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae*. J Clin Microbiol. 2012;50(7):2244-9. doi: 10.1128/jcm.06481-11. PMID: 22518864. **Exclusion: Wrong intervention.**

347. Van Der Pol B, Taylor SN, Lebar W, et al. Clinical evaluation of the BD probetec *Neisseria gonorrhoeae* qx amplified DNA assay on the BD viper system with XTR technology. Sex Transm Dis. 2012;39(2):147-53. doi: 10.1097/OLQ.0b013e3182372fd8. PMID: 22249304. **Exclusion: Wrong intervention.**

348. Van Der Pol B, Taylor SN, Mena L, et al. Evaluation of the performance of a point-of-care test for chlamydia and gonorrhea. JAMA Network Open. 2020;3(5):e204819. doi: 10.1001/jamanetworkopen.2020.4819. PMID: 32407506. **Exclusion: Wrong comparator.**

349. Van Der Pol B, Williams JA, Fuller D, et al. Combined testing for chlamydia, gonorrhea, and trichomonas by use of the BD max CT/GC/TV assay with genitourinary specimen types. J Clin Microbiol. 2017;55(1):155-64. doi: 10.1128/JCM.01766-16. PMID: 27795343. **Exclusion: Wrong intervention.**

350. van Dommelen L, van Tiel FH, Ouburg S, et al. Alarmingly poor performance in *Chlamydia trachomatis* point-of-care testing. Sex Transm Infect. 2010;86(5):355-9. doi: 10.1136/sti.2010.042598. PMID: 20876754. **Exclusion: Wrong intervention.**

351. Verougstraete N, Verbeke V, De Canniere AS, et al. To pool or not to pool? Screening of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* in female sex workers: pooled versus single-site testing. Sexually Transmitted Infections. 2020;0:1-5. doi: 10.1136/sextrans-2019-054357. PMID: 32404400. **Exclusion: Wrong intervention.**

352. Wijers J, van Liere G, Hoebe C, et al. Test of cure, retesting and extragenital testing practices for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* among general practitioners in different socioeconomic status areas: a retrospective cohort study, 2011-2016. PLoS One. 2018;13(3):e0194351. doi: 10.1371/journal.pone.0194351. PMID: 29538469. **Exclusion: Wrong study design for Key Question.**

353. Willis SJ, Elder H, Cocoros N, et al. More screening or more disease? Gonorrhea testing and positivity patterns among men in three large clinical practices in Massachusetts, 2010-2017. Clinical Infectious Diseases. 2020 doi: 10.1093/cid/ciaa066. PMID: 31967644. **Exclusion: Wrong intervention.**

354. Wilson E, Free C, Morris TP, et al. Can internet-based sexual health services increase diagnoses of sexually transmitted infections (STI)? Protocol for a randomized evaluation of an internet-based STI testing and results service. JMIR Res Protoc. 2016;5(1):e9. doi: 10.2196/resprot.4094. PMID: 26772143. **Exclusion: Wrong publication type.**

355. Wilson E, Free C, Morris TP, et al. Internet-accessed sexually transmitted infection (e-STI) testing and results service: a randomised, single-blind, controlled trial. PLoS Med. 2017;14(12):e1002479. doi: 10.1371/journal.pmed.1002479. PMID: 29281628. **Exclusion: Wrong outcome.**

356. Wilson E, Free C, Morris TP, et al. Effect of an internet-based sexually transmitted infection testing and results service on diagnoses and testing uptake: a single-blind, randomised controlled trial. Lancet. 2017;390(SPEC.ISS 1):S95-. **Exclusion: Wrong publication type.**

357. Wilson E, Free C, T PM, et al. E-sti testing and results service: a single blind randomised controlled trial. Sex Transm Infect. 2017;Conference:. 2017 STI and HIV world congress. Brazil 93(Supplement 2):A190. **Exclusion: Wrong publication type.**

358. Wilson J, Wallace H, Loftus-Keeling M, et al. Extra-genital samples for gonorrhoea and chlamydia in women and MSM: self-taken samples analysed separately compared with self-taken pooled samples. Sex Transm Infect. 2016;92. **Exclusion: Wrong publication type.**

359. Wilson J, Wallace H, Loftus-Keeling M, et al. Self-taken extra-genital samples compared with clinician-taken extra-genital samples for the diagnosis of gonorrhoea and chlamydia in women and MSM. Sex Transm Infect. 2016;92:A2-A3. **Exclusion: Wrong publication type.**

360. Wilson J, Wallace H, Loftus-Keeling M, et al. Clinician-taken extra-genital samples for gonorrhoea and chlamydia in women and msm compared with self-taken samples analysed separately and self-taken pooled

samples. Sex Transm Infect. 2017;Conference:. 2017 STI and HIV world congress. Brazil 93(Supplement 2):A26. **Exclusion: Wrong publication type.**

361. Wisniewski CA, White JA, Michel C-EC, et al. Optimal method of collection of first-void urine for diagnosis of *Chlamydia trachomatis* infection in men. J Clin Microbiol. 2008;46(4):1466-9. doi: 10.1128/JCM.02241-07. PMID: 18234860. **Exclusion: Wrong intervention.**

362. Wood M, Ellks R, Grobicki M. Outreach sexual infection screening and postal tests in men who have sex with men: are they comparable to clinic screening? Int J STD AIDS. 2015;26(6):428-31. doi: 10.1177/0956462414539668. PMID: 24912535. **Exclusion: Wrong outcome.**

363. Wood SM, McGeary A, Wilson M, et al. Effectiveness of a quality improvement intervention to improve rates of routine *Chlamydia trachomatis* screening in female adolescents seeking primary preventive care. J Pediatr Adolesc Gynecol. 2019;32(1):32-8. doi: 10.1016/j.jpag.2018.10.004. PMID: 30394335. **Exclusion: Wrong outcome.**

364. Yang TZT, Chen MY, Read TRH, et al. Sampling technique and detection rates of oropharyngeal and anorectal gonorrhoea using nucleic acid amplification tests in men who have sex with men. Sex Transm Infect. 2018;94(4):287-92. doi: 10.1136/sextrans-2017-053339. PMID: 29133523. **Exclusion: Wrong outcome.**

365. Yussman SM, Urbach K. Introduction of universal chlamydia and gonorrhea screening in an urban school-based health center. Journal of Adolescent Health. 2018;62(2):S80-S1. **Exclusion: Wrong publication type.**

366. Zou H, Meng X, Grulich A, et al. A randomised controlled trial to evaluate the impact of sexual health clinic based automated text message reminders on testing of HIV and other sexually transmitted infections in men who have sex with men in China: protocol for the T2T study. BMJ Open. 2017;7(7):e015787. doi: 10.1136/bmjopen-2016-015787. PMID: 28698334. **Exclusion: Wrong publication type.**

## Randomized Controlled Trials (RCTs) and Cohort Studies

Criteria:
Initial assembly of comparable groups:
For RCTs: Adequate randomization, including first concealment and whether potential confounders were distributed equally among groups
For cohort studies: Consideration of potential confounders, with either restriction or measurement for adjustment in the analysis; consideration of inception cohorts
Maintenance of comparable groups (includes attrition, cross-overs, adherence, contamination)
Important differential loss to followup or overall high loss to followup
Measurements: equal, reliable, and valid (includes masking of outcome assessment)
Clear definition of interventions
All important outcomes considered
Analysis: adjustment for potential confounders for cohort studies or intention-to treat analysis for RCTs

Definition of ratings based on above criteria:
**Good:** Meets all criteria: Comparable groups are assembled initially and maintained throughout the study (followup ≥80%); reliable and valid measurement instruments are used and applied equally to all groups; interventions are spelled out clearly; all important outcomes are considered; and appropriate attention to confounders in analysis. In addition, intention-to-treat analysis is used for RCTs.
**Fair:** Studies are graded "fair" if any or all of the following problems occur, without the fatal flaws noted in the "poor" category below: Generally comparable groups are assembled initially, but some question remains whether some (although not major) differences occurred with followup; measurement instruments are acceptable (although not the best) and generally applied equally; some but not all important outcomes are considered; and some but not all potential confounders are accounted for. Intention-to-treat analysis is used for RCTs.
**Poor:** Studies are graded "poor" if any of the following fatal flaws exists: Groups assembled initially are not close to being comparable or maintained throughout the study; unreliable or invalid measurement instruments are used or not applied equally among groups (including not masking outcome assessment); and key confounders are given little or no attention. Intention-to-treat analysis is lacking for RCTs

**Source:** U.S. Preventive Services Task Force. Procedure Manual. https://www.uspreventiveservicestaskforce.org/Page/Name/appendix-vi-criteria-for-assessing-internal-validity-of-individual-studies Accessed on 4/12/19.

### Appendix A7. Expert Reviewers of the Draft Report

- Erin Abramsohn, MPH, DrPH, Centers for Disease Control and Prevention
- Andria Apostolou, PhD, MPH, Indian Health Service
- Jennifer Fuld, PhD, Centers for Disease Control and Prevention
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- Dr. Elena Gorodetsky, MD, PhD, National Institutes of Health Office of Research on Women's Health
- Katherine K. Hsu, MD, MPH, Boston University School of Medicine
- Sonia Lee, PhD, National Institutes of Health Eunice Kennedy Shriver National Institute of Child Health and Human Development
- Susan Tuddenham, MD, MPH, Johns Hopkins University
- Sung Sug (Sarah) Yoon, PhD, RN, National Institutes of Health National Institute of Nursing Research

Note: Reviewers provided comments on a prior version of the draft report and may or may not agree with the report findings.

**Appendix B Table 1. Evidence Table: Effectiveness of Screening to Reduce Complications and Transmission—Study Characteristics**

| Author, Year, Study name | Eligibility criteria | Number approached, eligible, enrolled, analyzed | Population characteristics (age, sex, race) | Country & setting | Duration of followup | Interventions |
|---|---|---|---|---|---|---|
| Hocking *et al*., 2018[67] ACCEPt Trial | Age: 16-29 years<br>Sex: female and male<br>Sexual risk practices: sexually active | *Cluster RCT, not reported by population*<br>Approached: 165 clinics<br>Eligible: 149 clinics<br>Enrolled: 130 clinics<br>Analyzed: 126 clinics | Mean age NR; 35% age 16-19, 32% age 20-24, 33% age 25-29<br>49% female, 51% male<br>Race not reported | Australia<br>Primary care | Mean 3.1 years | Multifaceted screening program (includes clinician education, EMR alert, patient reminder system, quarterly testing report for clinic, clinician payment incentive, partner notification; n=30,527)<br>Usual care (n=32,811) |
| Oakeshott *et al*., 2010*[74]<br>POPI Trial†<br><br>**Includes personal communication data* | Age: ≤27 years<br>Sex: female<br>Sexual risk practices: sexually active | Approached: 3,528<br>Eligible: 2,563<br>Enrolled: 2,529<br>Analyzed: 2,377 (including 1,648 asymptomatic women) | Mean age 21 years<br>100% female<br>61% white; 27% black; 4% Asian; 8% other race | United Kingdom<br>Community | 1 year | Immediate screening (n=1,259)<br>Deferred (1 year) screening (n=1,270) |
| Ostergaard *et al*., 2000†[75] | Age: high school students (age range not reported)<br>Sex: female<br>Sexual risk practices: sexually experienced | Approached: 5,487<br>Eligible: 1,761<br>Enrolled: 1,700<br>Analyzed: 930 | *Population characteristics reported for followup population only (n=930)*<br>Mean age not reported; 9% age 15 years, 27% age 16 years, 33% age 17 years, 22% age 18 years, 9% age ≥19 years<br>100% female<br>>95% white; other races not reported | Denmark<br>High school | 1 year | Home screening (n=867)<br>Usual care (opportunistic screening in a clinic; n=833) |

**Appendix B Table 1. Evidence Table: Effectiveness of Screening to Reduce Complications and Transmission—Study Characteristics**

| Author, Year, Study name | Eligibility criteria | Number approached, eligible, enrolled, analyzed | Population characteristics (age, sex, race) | Country & setting | Duration of followup | Interventions |
|---|---|---|---|---|---|---|
| Scholes *et al.*, 1996†[78] | Age: 18-34 years<br>Sex: female<br>Sexual risk practices: increased risk of infection based on scoring algorithm that included age ≤24 years, Black race, nulliparity, douching in the preceding 12 months; ≥2 sexual partners in the preceding 12 months | Approached: 36,547<br>Eligible: 3,111<br>Enrolled: 2,607<br>Analyzed: 2,607 | Mean age 22 years<br>100% female<br>71% white; 21% black; 2% Asian; 4% other race; 2% Hispanic/Latino | United States<br>HMO | 1 year | Immediate, clinic-based screening (n=1,009)<br>Usual care (as-needed clinic visit) (n=1,598) |

Abbreviations: ACCEPt = the Australian Chlamydia Control Effectiveness Pilot; EMR = electronic medical record; HMO = health maintenance organization; NR = not reported; POPI = prevention of pelvic infection; RCT = randomized controlled trial

† Included in prior USPSTF review

**Appendix B Table 2. Evidence Table: Effectiveness of Screening to Reduce Complications and Transmission—Study Outcomes**

| Author, Year, Study Name | Attrition | Outcomes | Subgroups | Adverse events/harms | Sponsor | Quality rating |
|---|---|---|---|---|---|---|
| Hocking *et al*., 2018[67]<br>ACCEPt Trial | A vs B<br>Not reported | A vs B<br>Repeat chlamydia infection: OR 3.1; 95% CI, 0.7 to 13.8<br>Incidence of PID* in clinics: 0.45% (293/65,519) vs 0.39% (237/60,384); RR 1.1 (95% CI 0.7 to 1.8)<br>Incidence of PID in hospitals: 0.24% (57/23,527) vs 0.37% (88/23,219); RR 0.6; 95% CI, 0.4 to 1.0<br>Incidence of epididymitis in clinics**: 0.26% (106/41,168) vs 0.27% (106/38,717); RR 0.9 (95% CI 0.6 to 1.4)<br><br>*denominator=number of women aged 16–33 years with at least one consultation during the intervention period<br>**denominator=women age 15-34<br>**denominator=number of men aged 16–29 years with at least one consultation during the intervention period.<br><br><u>CT prevalence</u><br>76/2,237 (3.4%) vs. 59/1,716 (3.4%)<br>OR 0.9 (95% CI 0.5 to 1.5)<br>aOR 0.9 (95% CI 0.5 to 1.6) | Not reported | None reported in any clinic | Australian Government Department of Health, National Health and Medical Research Council, Victorian Department of Health and Human Services, and New South Wales Ministry of Health. | Good |
| Oakeshott *et al.,* 2010*[74]<br>POPI Trial†<br><br>**Includes personal communication data* | A vs B<br>5% vs 7% | A vs B<br>Incidence of PID: 1.3% (15/1191) vs 1.9% (23/1186); RR 0.65 (95% CI 0.34 to 1.22) | A vs B<br>Incidence of PID, asymptomatic at baseline: 0.6% (5/787) vs 1.6% (14/861); RR 0.39 (95% CI 0.14 to 1.08) | Not reported | BUPA Foundation | Good |

**Appendix B Table 2. Evidence Table: Effectiveness of Screening to Reduce Complications and Transmission—Study Outcomes**

| Author, Year, Study Name | Attrition | Outcomes | Subgroups | Adverse events/harms | Sponsor | Quality rating |
|---|---|---|---|---|---|---|
| Ostergaard *et al.*, 2000†[75] | A vs B<br>49% vs 42% | A vs B<br>Incidence of PID: 2.1% (9/443) vs 4.2% (20/487); RR 0.50 (95% CI, 0.23 to 1.08)<br>Incidence of new chlamydia infection: 2.9% (13/443) vs 6.6% (32/487); RR 0.45 (95% CI, 0.24 to 0.84) | Not reported | Not reported | Danish National Board of Health; Løvens Kemiske Fabriks Research Foundation; Nycomed DAK; Jacob Madsen's & Hustru Olga Madsen's Foundation; Helga and Peter Kornings Foundation; Aarhus County Medical District Association | Fair |
| Scholes *et al.*, 1996†[78] | 24% (not reported by intervention group) | A vs B<br>Incidence of PID: 0.9% (9/1,009) vs 2.1% (33/1,598); RR 0.44 (95% CI, 0.20 to 0.90) | Not reported | Not reported | National Institute of Allergy and Infectious Diseases; Bristol-Myers Squibb. | Fair |

Abbreviations: ACCEPt = the Australian Chlamydia Control Effectiveness Pilot; CI = confidence interval; CT = Chlamydia trachomatis; PID = pelvic inflammatory disease; POPI = prevention of pelvic infection; RR = relative risk.
† Included in prior USPSTF review

**Appendix B Table 3. Quality Assessment of Studies of Effectiveness of Screening to Reduce Complications and Transmission**

| Author, year Study name | Randomization adequate? | Allocation concealment adequate? | Groups similar at baseline? | Eligibility criteria specified? | Outcome assessors masked? | Care provider masked? | Patient masked? | Attrition and withdrawals reported? | Loss to followup: differential (>10%)/ high (>20%)? | Analyze people in the groups in which they were randomized? | Quality |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Hocking *et al.*, 2018[67] ACCEPt Trial | Yes | Yes | Yes | Yes | Yes | No | Yes | Yes | Differential: no High overall: no | Yes | Good |
| Oakeshott *et al.*, 2010*[74] POPI Trial† | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Differential: no High overall: no | Yes | Good |
| Ostergaard *et al.*, 2000*[75] | Yes | Unclear | Yes | Yes | Yes | Unclear | Unclear | Yes | Differential: no High overall: yes | Yes | Fair |
| Scholes *et al.,* 1996*[78] | Unclear | Unclear | Yes | Yes | Yes | Unclear | Unclear | Yes | Differential: unclear High overall: yes | Yes | Fair |

* Included in prior USPSTF review

**Appendix B Table 4. Evidence Table: Accuracy of Risk Stratification Methods or Screening Strategies—Study Characteristics**

| Author, year<br>Study name | Study design | Country & setting | Comparison | Study duration<br>Mean followup | Eligibility criteria | Number enrolled<br>Number analyzed<br>Withdrawals | Baseline demographics |
|---|---|---|---|---|---|---|---|
| Falasinnu *et al*., 2014[62] | Cross-sectional | Canada<br>Specialty clinic (STI) | Derivation population for clinical risk prediction tool (n=10,437)<br>Validation population for clinical risk prediction tool (n=14,956) | NA (cross sectional population) | Age criteria not reported;<br>Female or heterosexual male;<br>Asymptomatic;<br>attending clinic for STI testing | Enrolled: 25,393<br>Analyzed: 25,393<br>Withdrawals: NA<br>Loss to followup: NA | Age<br>Mean age NR<br>14-19 years: 2%<br>20-24 years: 16%<br>25-29 years: 28%<br>30-39 years: 32%<br>≥ 40 years: 22%<br>Sex<br>Female: 35%<br>Male: 65%<br>Race/Ethnicity<br>White: 71%<br>Nonwhite: 29%<br>Sexual partners in previous 6 months<br>0 partners: 5%<br>1-2 partners: 63%<br>≥ 3 partners: 31%<br>Condom use<br>Never: 22%<br>Sometimes: 51%<br>Always: 27%<br>CT or NG positive: 2% |
| Falasinnu *et al*., 2016[63] (Sexually Transmitted Infections)<br><br>Related publications: Falasinnu *et al*., 2014 | Cross-sectional | Canada<br>Specialty clinic (STI) | Derivation population for clinical risk prediction tool* (n=10,437)<br>Validation population for clinical risk prediction tool (n=10,425)<br><br>**Same derivation population as Falasinnu 2014* | NA (cross sectional population) | Age criteria not reported;<br>Female or heterosexual male;<br>Asymptomatic, attending clinic for STI testing | Enrolled: 20,862<br>Analyzed: 20,862<br>Withdrawals: NA<br>Loss to followup: NA | NR |

**Appendix B Table 4. Evidence Table: Accuracy of Risk Stratification Methods or Screening Strategies—Study Characteristics**

| Author, year<br>Study name | Study design | Country & setting | Comparison | Study duration<br>Mean followup | Eligibility criteria | Number enrolled<br>Number analyzed<br>Withdrawals | Baseline demographics |
|---|---|---|---|---|---|---|---|
| Falasinnu *et al.*, 2016[64]<br><br>(Preventive Medicine) | Cross-sectional | Canada<br>Specialty clinic (STI) | Population-based screening (according to published guidelines)<br>Clinical prediction-based screening (according to risk score)<br><br>Total n=35,818 | NA (cross sectional population) | Age criteria not reported;<br>Female or heterosexual male;<br>Asymptomatic, attending clinic for STI testing | Enrolled: 35,818<br>Analyzed: 35,818<br>Withdrawals: NA<br>Loss to followup: NA | Age<br>Mean age: NR 14-19 years: 6%<br>20-24 years: 20%<br>25-29 years: 25%<br>30-39 years: 28%<br>≥40 years: 21%<br>Sex<br>Female: 37%<br>Male: 63%<br>Race/ethnicity<br>White: 72%<br>Nonwhite: 28%<br>Sexual partners in previous 6 months<br>0 partners: 6%<br>1-2 partners: 64%<br>≥3 partners: 30%<br>Condom use<br>Never or sometimes: 71%<br>Always: 29%<br>CT or NG positive: 3% |
| Grentzer *et al.*, 2015[66] | Cross-sectional | USA<br>Specialty clinic (IUD placement) | Age-based screening (≤25 years)<br>Age + partner-based screening (≤25 years + multiple partners)<br>Risk-based screening (≤25 years, multiple partners, history of STI, inconsistent condom use) | NA (cross sectional population) | Age 14-45 years;<br>Female;<br>At risk for unwanted pregnancy; attending clinic for IUD insertion | Enrolled: 5,087<br>Analyzed: 5,087<br>Withdrawals: NA<br>Loss to followup: NA | Age<br>Mean age: NR<br>14-19 years: 10%<br>20-25 years: 43%<br>26-45 years: 47%<br>100% female<br>Race/ethnicity<br>White: 46%<br>Black: 46%<br>Other: 8% |

**Appendix B Table 4. Evidence Table: Accuracy of Risk Stratification Methods or Screening Strategies—Study Characteristics**

| Author, year<br>Study name | Study design | Country & setting | Comparison | Study duration<br>Mean followup | Eligibility criteria | Number enrolled<br>Number analyzed<br>Withdrawals | Baseline demographics |
|---|---|---|---|---|---|---|---|
| Javanbakht *et al.*, 2018[68] | Case-control (positive NG=cases; negative NG=control) | USA<br>Specialty clinic (STI) | *Single group*<br>Association between self-reported risk factor and positive NG test<br><br>Total n=245 | 2 years | Age 15 to 29 years; Female or male; Reported giving oral sex to a partner of the opposite sex in the past 90 days | Enrolled: 245<br>Analyzed: 245<br>Withdrawals: NA<br>Loss to followup: NA | Age<br>Mean age: NR<br>15-19 years: 21%<br>20-24 years: 48%<br>25-29 years: 31%<br>Sex<br>Female: 56%<br>Male: 44%<br>Race/ethnicity<br>Black: 50%<br>White: 9%<br>Hispanic/Latino: 35%<br>Other: 6%<br>Pharyngeal NG infection<br>7% |
| Lavoue *et al.*, 2014[69] | Cross-sectional | France; population based setting | A: Derivation data set, n=652<br>B: Validation data set, n=326 | 9 months; between January and September 2010 | Women who had a surgical abortion with an interpretable CT test result | Eligible: 1277<br>Enrolled: 1000<br>Analyzed: 978<br>Withdrawals: NA | CT Result<br>Positive: 48/652 (7.3%), 18/326 (5.6%)<br>Sex<br>Female: 100%<br>Age<br><20: 162<br>20-24: 298<br>25-29: 207<br>30-34: 164<br>>34:164<br>Race<br>NR |

**Appendix B Table 4. Evidence Table: Accuracy of Risk Stratification Methods or Screening Strategies—Study Characteristics**

| Author, year<br>Study name | Study design | Country & setting | Comparison | Study duration<br>Mean followup | Eligibility criteria | Number enrolled<br>Number analyzed<br>Withdrawals | Baseline demographics |
|---|---|---|---|---|---|---|---|
| Miller *et al.*, 2000[70] | Cross-sectional | North Carolina, US; population based setting | Compare 8 sets of screening criteria (Table 1) for CT infections plus age alone | 4 to 9 months in each county, depending on clinic volume; NR | Women undergoing pelvic examination in the study sites | Enrolled: 7150 (4754 women in family planning clinics and 2396 women in STD clinics)<br>Analyzed: 6672<br>Withdrawals: NA<br><br>Ineligible<br>Resent testing or hysterectomy: 156<br>Missing questionnaires: 286<br>Women with unsatisfactory specimens: 36 | CT Results<br>Positive: 7.8% (95% CI 7.0-8.6%)<br>vs. 11% (95% CI 9.7-12.4%)<br>Sex<br>Female: 100%<br>Age<br>≤ 20: 183/1394 (13.1%) vs. 120/586 (20.5%)<br>21-24: 1345/4471 (30.1%) vs. 697/2201 (31.7%)<br>≥25: 1732/4471 (38.7%) vs. 918/2201 (41.7%)<br>Race/Ethnicity<br>White: 1999/4471 (44.7%) vs. 874/2201 (39.7%)<br>Black: 2007/4471 (44.9% vs. 1120/2201 (50.9%)<br>Native American: 235/4471 (5.3%) vs. 96/2201 (4.4%)<br>Latina: 146/4471 (3.3%) vs. 56/2201 (2.5%)<br>Other: 84/4471 (1.9%) vs. 55/2201 (2.5%)<br>Genitourinary symptoms<br>No: 3064/4471 (68.5%) vs. 456/2201 (20.7)<br>Yes: 1407/4471 (31.5%) vs. 1745/2201 (79.3%) |

Abbreviations: CT = Chlamydia trachomatis; IUD = intrauterine device; NA = not applicable; NG = Neisseria gnorrhoeae; NR = not reported; STD = sexually transmitted disease; STI = sexually transmitted infection.

**Appendix B Table 5. Evidence Table: Accuracy of Risk Stratification Methods—Study Outcomes**

| Author, year Study name | Adjusted variables for statistical analysis | Intermediate/Clinical health outcome results | Adverse events/ harms | Sponsor | Quality rating |
|---|---|---|---|---|---|
| Falasinnu *et al*., 2014[62] | Unadjusted | A vs. B<br>Risk estimation model AUC (model includes age, nonwhite race/ethnicity, number of sexual partners, previous chlamydia diagnosis, and previous gonorrhea diagnosis) 0.74 (95% CI 0.70 to 0.77) vs. 0.64 (95% CI 0.61 to 0.67)<br>Prevalence based on risk score category<br>≤0: 0/267 (0%) vs. 0/287 (0.1%)<br>1-5: 16/3,098 (0.5%) vs. 55/4,493 (1.2%)<br>6-10: 53/4,377 (1.2%) vs. 135/6,494 (2.1%)<br>Prevalence according to risk score - sensitivity; specificity; PPV (see also Sheet 2)<br>≥-2: 100%; 0%; 1.8% vs. 100%; 0%; 2.2%<br>≥-1: 100%; 1.2%; 1.8% vs. 100%; 0.9%; 2.2%<br>≥0: 100%; 1.3%; 1.8% vs. 100%; 0.9%; 2.2%<br>≥1: 100%; 2.6%; 1.8% vs. 99.9%; 2.0%; 2.3%<br>≥2: 99.5%; 3.7%; 1.8% vs. 99.9%; 2.7%; 2.3%<br>≥3: 99.5%; 3.7%; 1.8% vs. 99.9%; 2.7%; 2.3%<br>≥4: 96.7%; 16.7%; 2.0% vs. 91.0%; 15.7%; 2.4%<br>≥5: 95.8%; 22.2%; 2.2% vs. 87.2%; 22.6%; 2.5%<br>≥6: 91.2%; 32.7%; 2.4% vs. 83.3%; 32.3%; 2.7% | NR | Canadian Institutes of Health Research | Fair |

**Appendix B Table 5. Evidence Table: Accuracy of Risk Stratification Methods—Study Outcomes**

| Author, year Study name | Adjusted variables for statistical analysis | Intermediate/Clinical health outcome results | Adverse events/ harms | Sponsor | Quality rating |
|---|---|---|---|---|---|
| Falasinnu *et al*., 2016[63] (Sexually Transmitted Infections)<br><br>Related publications: Falasinnu, 2014 | Unadjusted | A vs. B<br>Risk estimation model AUC (model includes age, nonwhite race/ethnicity, number of sexual partners, previous chlamydia diagnosis, and previous gonorrhea diagnosis) 0.74 (95% CI 0.70 to 0.77) vs. 0.69 (95% CI 0.67 to 0.71)<br>Prevalence according to risk score category<br>≤0: 0/267 (0%) vs. 0/169 (0.1%)<br>1-5: 16/3,098 (0.5%) vs. 30/2,084 (1.5%)<br>6-10: 53/4,377 (1.2%) vs. (181/4,173 (4.3%)<br>Prevalence according to risk score - sensitivity; specificity; PPV (see also Sheet 2)<br>≥-2: 100%; 0%; 1.8% vs. 100%; 0%; 5.3%<br>≥-1: 100%; 1.2%; 1.8% vs. 100%; 0.7%; 5.4%<br>≥0: 100%; 1.3%; 1.8% vs. 100%; 0.7%; 5.4%<br>≥1: 100%; 2.6%; 1.8% vs. 99.9%; 1.7%; 5.4%<br>≥2: 99.5%; 3.7%; 1.8% vs. 99.9%; 2.5%; 5.5%<br>≥3: 99.5%; 3.7%; 1.8% vs. 99.9%; 2.5%; 5.5%<br>≥4: 96.7%; 16.7%; 2.0% vs. 97.1%; 10.8%; 5.8%<br>≥5: 95.8%; 22.2%; 2.2% vs. 96.2%; 13.7%; 5.9%<br>≥6: 91.2%; 32.7%; 2.4% vs. 94.5%; 22.5%; 6.4%<br>≥7: 84.9%; 47.7%; 2.8% vs. 90.1%; 34.1%; 7.2%<br>≥8: 82.2%; 53.0%; 3.0% vs. 86.0%; 37.9%; 7.2% | NR | Canadian Institutes of Health Research | Fair |
| Falasinnu *et al*., 2016[64] (Preventive Medicine) | Unadjusted | A vs. B AUC:<br>population (guideline)-based screening including no risk factors, 0.55 (95% CI: 0.54 to 0.56);<br>population (guideline)-based screening including risk factors, 0.64 (95% CI 0.63 to 0.66) vs. risk-based screening 0.73 (95% CI 0.71 to 0.74)<br>Prevalence according to risk score - sensitivity; specificity; PPV (see also Sheet 2):<br>≥0: 100%; 0%; 3.0% vs. 100%; 0.1%; 3.0%<br>≥1: 94.5%; 15.4%; 3.3% vs. 99.9%; 0.2%; 3.0%<br>≥2: 68.0%; 54.9%; 4.4% vs. 99.9%; 0.6%; 3.0%<br>≥3: 23.9%; 89.8%; 6.7% vs. 99.8%; 2.0%; 3.0%<br>≥4: 2.8%; 98.4%; 5.2% vs. 99.8%; 2.0%; 3.0%<br>≥5: 0.2%; 99.8%; 3.2% vs. 99.7%; 3.4%; 3.1%<br>≥6: 0.0%; 100%; 0% vs. 98.2%; 5.8%; 3.1% | NR | Canadian Institutes of Health Research | Fair |

**Appendix B Table 5. Evidence Table: Accuracy of Risk Stratification Methods—Study Outcomes**

| Author, year Study name | Adjusted variables for statistical analysis | Intermediate/Clinical health outcome results | Adverse events/ harms | Sponsor | Quality rating |
|---|---|---|---|---|---|
| Grentzer *et al.*, 2015[66] | Unadjusted | A vs. B vs. C (see also Sheet 2) Sensitivity; specificity; NPV; PPV<br>80.7%; 48.1%; 98.8%; 4.5% vs. 84.7% vs. 44.8% vs. 99.0% vs. 4.5% vs. 99.3%; 7.6%; 99.7%; 3.2 | NR | Susan Thompson Buffett Foundation, Eunice Kennedy Shriver National Institute of Child Health & Human Development, National Center for Advancing Translational Sciences | Fair |

**Appendix B Table 5. Evidence Table: Accuracy of Risk Stratification Methods—Study Outcomes**

| Author, year Study name | Adjusted variables for statistical analysis | Intermediate/Clinical health outcome results | Adverse events/ harms | Sponsor | Quality rating |
|---|---|---|---|---|---|
| Javanbakht *et al*., 2018[68] | Adjusted ORs included demographic characteristics, substance use, and other risk behaviors | Association between specific risk factors and pharyngeal NG infection<br>Age (vs age 25-29 years)<br>15-19 years: OR 2.2 (95% CI 0.8 to 6.2); aOR 2.1 (95% CI 0.7 to 6.9)<br>20-24 years: OR 1.7 (95% CI 0.7 to 4.3); aOR 1.6 (95% CI 0.6 to 4.4)<br>Female: OR 1.6 (95% CI 0.8 to 3.4); aOR1.2 (95% CI 0.6 to 2.8)<br>Race/Ethnicity (vs. white race)<br>Black: OR 1.8 (95% CI 0.4 to 8.5)<br>Hispanic/Latino: OR 1.7 (95% CI 0.4 to 8.4)<br>Other: OR 0.7 (95% CI 0.1 to 8.2)<br>Homeless: OR 2.1 (95% CI 0.6 to 6.8) Sex of sex partners (vs. MSW) MSMW: OR 9.9 (95% CI 1.7 to 56.4)<br>Sex of sex partners (vs. WSM)<br>WSMW: OR 1.8 (95% CI 0.6 to 5.5)<br>No. sex partners, past 3 months (vs. 1 partner)<br>2 to 4: OR 1.9 (95% CI 0.8 to 4.1)<br>≥5: OR 2.0 (95% CI 0.6 to 6.2)<br>No. oral sex partners, past 3 months (vs. 1 partner)<br>2 to 4: OR 2.5 (95% CI 1.2 to 5.5); aOR 3.3 (95% CI 1.4 to 7.8)<br>≥5: OR 4.1 (95% CI 1.1 to 15.1); aOR 5.7 (95% CI 1.3 to 24.6)<br>Partner ejaculates in mouth, all of the time, past 3 months<br>OR 3.6 (95% CI 1.2 to 10.5); aOR 3.1 (95% CI 1.3 to 7.5)<br>Swallows ejaculate/vaginal fluids, all of the time, past 3 months<br>OR 2.3 (95% CI 1.0 to 5.3); aOR 2.5 (95% CI 1.1 to 6.3) | NR | National Institutes of Health/National Institutes of Allergy and Infectious Diseases | Fair |

**Appendix B Table 5. Evidence Table: Accuracy of Risk Stratification Methods—Study Outcomes**

| Author, year Study name | Adjusted variables for statistical analysis | Intermediate/Clinical health outcome results | Adverse events/ harms | Sponsor | Quality rating |
|---|---|---|---|---|---|
| Lavoue *et al.*, 2014[69] | Unadjusted | Predictive factors associated with CT in the multiple logistic regression model (Table 3)<br>Parity, aOR, 95% CI<br>0-1: 3.46, 1.34-9.93<br>>1: 1<br>Contraception<br>No: 2.70, 1.41-5.16<br>Yes: 1<br>Gestational age at induced abortion, aOR, 95% CI<br>≤ 10 weeks:1<br>> 10 weeks: 1.96, 1.06-3.64 | NR | University Hospital of Rennes, France | Fair |
| Miller *et al.*, 2000[70] | Unadjusted | Table 3<br>Family Planning Clinics: ROC area (SD), Sensitivity, Specificity<br>CDC<br>N/A, 0.85, 0.38<br>Seattle-1<br>0.599 (0.017), 0.56, 0.54<br>Wisconsin<br>0.604 (0.023), 0.50, 0.66<br>Ontario<br>0.630 (0.017), 0.76, 0.41<br>California-1<br>0.633 (0.016), 0.94, 0.20<br>California-2<br>0.701 (0.015), 0.97, 0.09<br>Seattle-2<br>0.726 (0.014), 0.84, 0.51<br>Seattle-3<br>0.723 (0.015), 0.92, 0.31<br>Age ≤ 22<br>0.687 (0.014), 0.77, 0.51 | NR | Centers for Disease Control and Prevention, UNC STD Clinical Research Center, Robert Wood Johnson Clinical Scholars Program, Clinical Associate Physician Program of the General Clinical Research Center | Fair |

Abbreviations: aOR = adjusted odds ratio ; AUC = area under the receiver operating characteristic curve; CDC = Centers for disease control and prevention; CI = confidence interval; CT = Chlamydia trachomatis; NPV = negative predictive value; NG = Neisseria gonorrhoeae; NR = not reported; MSW = men who have sex with women; MSMW = men who have sex with men and women; OR = odds ratio; PPV = positive predictive value; ROC; receiver operating characteristic; SD = standard deviation; WSM = women who have sex with men; WSMW = women who have sex with men and women.

**Appendix B Table 6. Quality Assessment of Studies of Risk Stratification Methods or Screening Strategies—Cohort Studies**

| Author, Year | Study Design | Did the study attempt to enroll all (or a random sample of) patients meeting inclusion criteria, or a random sample (inception cohort)? | Did the study use accurate methods for ascertaining exposures and potential confounders? | Were outcome assessors and/or data analysts blinded to the exposure being studied? | Did the article report attrition? | Is there high attrition? | Were outcomes pre- specified and defined, and ascertained using accurate methods? | Quality rating |
|---|---|---|---|---|---|---|---|---|
| Falasinnu *et al.*, 2014[62] | Cross-sectional | Yes | Yes | No | N/A | N/A | Yes | Fair |
| Falasinnu *et al.*, 2016[63] (Sexually Transmitted Infections)<br><br>Related publications: Falasinnu *et al.,* 2014 | Cross-sectional | Yes | Yes | No | N/A | N/A | Yes | Fair |
| Falasinnu *et al.*, 2016[64] (Preventive Medicine) | Cross-sectional | Yes | Yes | No | N/A | N/A | Yes | Fair |
| Grentzer *et al.*, 2015[66] | Cross-sectional | Yes | Yes | No | N/A | N/A | Yes | Fair |
| Javanbakht *et al.*, 2018[68] | Case-control | Yes | Yes | Yes | No | N/A | Yes | Fair |
| Lavoue *et al.*, 2014[69] | Cross-sectional | Yes | Yes | No | N/A | N/A | Yes | Fair |
| Miller *et al.*, 2000[70] | Cross-sectional | Yes | Yes | No | N/A | N/A | Yes | Fair |

Abbreviations: NA = not applicable.
Note: Standard cohort quality assessment criteria was modified in this table for cross-sectional studies

**Appendix B Table 7. Evidence Table: Diagnostic Accuracy of Anatomic Site-Specific Testing—Study Characteristics**

| Study, year | Condition | Screening test(s) | Sex | Definition of a positive screening exam | Reference standard(s) | Country Setting Prevalence | Population Characteristics | Eligibility Criteria | Sample size Proportion with condition | Proportion unexaminable by screening test |
|---|---|---|---|---|---|---|---|---|---|---|
| Fang *et al*., 2008[65] | Chlamydia trachomatis | BDProbeTec ET NAAT Site: vaginal swab (self-collected) | Female | Positive result from at least two of the collection sites (urine, self-collected vaginal swab, clinician-collected endocervical swab) | Sites: endocervical (clinician-collected) and urine sample | USA Adolescent clinic Prevalence: 26.6% | Age, median: 16 years Sex: 100% female Race: Black: 96% Symptomatic: not reported | Age 12-18 Sexually active | 133 26.6% | Not reported |
| Fang *et al*., 2008[65] | Chlamydia trachomatis | BDProbeTec ET NAAT Site: urine sample | Female | Positive result from at least two of the collection sites (urine, self-collected vaginal swab, clinician-collected endocervical swab) | Site: Endocervical (clinician-collected) and vaginal swab (self-collected) | USA Adolescent clinic Prevalence: 26.6% | Age, median: 16 years Sex: 100% female Race: Black: 96% Symptomatic: not reported | Age 12-18 Sexually active | 133 26.6% | Not reported |
| Fang *et al*., 2008[65] | Chlamydia trachomatis | BDProbeTec ET NAAT Site: endocervical swab (clinician-collected) | Female | Positive result from at least two of the collection sites (urine, self-collected vaginal swab, clinician-collected endocervical | Sites: vaginal swab (self-collected) and urine sample | USA Adolescent clinic Prevalence: 26.6% | Age, median: 16 years Sex: 100% female Race: Black: 96% Symptomatic: not reported | Age 12-18 Sexually active | 133 26.6% | Not reported |
| Fang *et al*., 2008[65] | Chlamydia trachomatis | BDProbeTec ET NAAT Site: urine sample | Female | Positive result from at least two of the collection sites (urine, self-collected vaginal swab, clinician-collected endocervical | Site: endocervical (clinician-collected) and vaginal swab (self-collected) | USA Adolescent clinic Prevalence: 11.7% | Age, median: 16 years Sex: 100% female Race: Black: 96% Symptomatic: not reported | Age 12-18 Sexually active | 133 11.7% | Not reported |

**Appendix B Table 7. Evidence Table: Diagnostic Accuracy of Anatomic Site-Specific Testing—Study Characteristics**

| Study, year | Condition | Screening test(s) | Sex | Definition of a positive screening exam | Reference standard(s) | Country Setting Prevalence | Population Characteristics | Eligibility Criteria | Sample size Proportion with condition | Proportion unexaminable by screening test |
|---|---|---|---|---|---|---|---|---|---|---|
| Nye *et al*., 2019[71] | Chlamydia trachomatis | Cobas CT/NG 2.0 Site: endocervical swab | Female | Two confirmatory NAATs from endocervical and/or urine specimens | Aptima Combo 2 Assay BD ProbeTec CTQ/GCQ Site: Urine and/or endocervical | USA Settings: 39% family planning clinics, 22% obstetrics/ gynecology, 38% STI clinics (includes symptomatic patients) | Age, mean: 29 Female: 88% Race: Black: 45% White: 46.4% (includes symptomatic patients) | VENUS and VENUS II enrollment: ≥14 years old Eligible for screening per clinical site's standard practice Excluded use of Replens vaginal lubricant within 3 days Excluded antimicrobial use in past 21 days for GC or CT<br><br>VENUS II only: Asymptomatic women only | 3174 Prevalence: 5.9% | 31/6045 (0.04%), not reported for asymptomatic population |

**Appendix B Table 7. Evidence Table: Diagnostic Accuracy of Anatomic Site-Specific Testing—Study Characteristics**

| Study, year | Condition | Screening test(s) | Sex | Definition of a positive screening exam | Reference standard(s) | Country Setting Prevalence | Population Characteristics | Eligibility Criteria | Sample size Proportion with condition | Proportion unexaminable by screening test |
|---|---|---|---|---|---|---|---|---|---|---|
| Nye *et al*., 2019[71] | Chlamydia trachomatis | Cobas CT/NG 2.0 Site: Female urine | Female | Two confirmatory NAATs from endocervical and/or urine specimens | Aptima Combo 2 Assay BD ProbeTec CTQ/GCQ Site: Urine and/or endocervical | USA Settings: 39% family planning clinics, 22% obstetrics/ gynecology, 38% STI clinics (includes symptomatic patients) | Age, mean: 29 Female: 88% Race: Black: 45% White: 46.4% (includes symptomatic patients) | VENUS and VENUS II enrollment: ≥14 years old Eligible for screening per clinical site's standard practice Excluded use of Replens vaginal lubricant within 3 days Excluded antimicrobial use in past 21 days for GC or CT<br><br>VENUS II only: Asymptomatic women only | 3190 Prevalence: 6.3% | 31/6045 (0.04%), not reported for asymptomatic population |

**Appendix B Table 7. Evidence Table: Diagnostic Accuracy of Anatomic Site-Specific Testing—Study Characteristics**

| Study, year | Condition | Screening test(s) | Sex | Definition of a positive screening exam | Reference standard(s) | Country Setting Prevalence | Population Characteristics | Eligibility Criteria | Sample size Proportion with condition | Proportion unexaminable by screening test |
|---|---|---|---|---|---|---|---|---|---|---|
| Nye *et al*., 2019[71] | Chlamydia trachomatis | Cobas CT/NG 2.0<br>Site: clinician-collected vaginal swab | Female | Two confirmatory NAATs from endocervical and/or urine specimens | Aptima Combo 2 Assay<br>BD ProbeTec CTQ/GCQ<br>Site: Urine and/or endocervical | USA<br>Settings: 39% family planning clinics, 22% obstetrics/ gynecology, 38% STI clinics (includes symptomatic patients) | Age, mean: 29<br>Female: 88%<br>Race: Black: 45%<br>White: 46.4%<br>(includes symptomatic patients) | VENUS and VENUS II enrollment:<br>≥14 years old<br>Eligible for screening per clinical site's standard practice<br>Excluded use of Replens vaginal lubricant within 3 days<br>Excluded antimicrobial use in past 21 days for GC or CT<br><br>VENUS II only:<br>Asymptomatic women only | 2241<br>Prevalence: 6.4% | 31/6045 (0.04%), not reported for asymptomatic population |

**Appendix B Table 7. Evidence Table: Diagnostic Accuracy of Anatomic Site-Specific Testing—Study Characteristics**

| Study, year | Condition | Screening test(s) | Sex | Definition of a positive screening exam | Reference standard(s) | Country Setting Prevalence | Population Characteristics | Eligibility Criteria | Sample size Proportion with condition | Proportion unexaminable by screening test |
|---|---|---|---|---|---|---|---|---|---|---|
| Nye *et al*., 2019[71] | Chlamydia trachomatis | Cobas CT/NG 2.0<br>Site: self-collected vaginal swab | Female | Two confirmatory NAATs from endocervical and/or urine specimens | Aptima Combo 2 Assay<br>BD ProbeTec CTQ/GCQ<br>Site: Urine and/or endocervical | USA<br>Settings: 39% family planning clinics, 22% obstetrics/ gynecology, 38% STI clinics (includes symptomatic patients) | Age, mean: 29<br>Female: 88%<br>Race: Black: 45%<br>White: 46.4%<br>(includes symptomatic patients) | VENUS and VENUS II enrollment: ≥14 years old<br>Eligible for screening per clinical site's standard practice<br>Excluded use of Replens vaginal lubricant within 3 days<br>Excluded antimicrobial use in past 21 days for GC or CT<br><br>VENUS II only: Asymptomatic | 996<br>Prevalence: 5.0% | 31/6045 (0.04%), not reported for asymptomatic population |
| Schachter *et al*., 2003[76]* | Chlamydia trachomatis | Amplified CT Assay<br>Site: FCU | Female | Agreement between positive results with vaginal swab and cervical swab or FCU | Culture | U.S. and Canada<br>Family planning, obstetrics/ gynecology, and STI clinics<br>CT prevalence across sites: 5.4 to 10.2% by culture | Age (range): 16 to 25 years<br>100% female<br>Race: NR | Females Age 16 to 25<br>Excluded antibiotics within 30 days<br>Excluded symptoms or partner with symptoms | 1388<br>Proportion with CT by culture of 1 specimen: 8.6% | Not reported |

**Appendix B Table 7. Evidence Table: Diagnostic Accuracy of Anatomic Site-Specific Testing—Study Characteristics**

| Study, year | Condition | Screening test(s) | Sex | Definition of a positive screening exam | Reference standard(s) | Country Setting Prevalence | Population Characteristics | Eligibility Criteria | Sample size Proportion with condition | Proportion unexaminable by screening test |
|---|---|---|---|---|---|---|---|---|---|---|
| Schachter *et al*., 2003[76]* | Chlamydia trachomatis | Amplified CT Assay<br>Site: cervix | Female | Agreement between positive results with vaginal swab and cervical swab or FCU | Culture | U.S. and Canada<br>Family planning, obstetrics/ gynecology, and STI clinics<br>CT prevalence across sites: 5.4 to 10.2% by culture | Age (range): 16 to 25 years<br>100% female<br>Race: NR | Females Age 16 to 25<br>Excluded antibiotics within 30 days<br>Excluded symptoms or partner with symptoms | 1408<br>Proportion with CT by culture of 1 specimen: 8.5% | Not reported |
| Schachter *et al*., 2003[76]* | Chlamydia trachomatis | Amplified CT Assay<br>Site: clinician-collected vaginal | Female | Agreement between positive results with vaginal swab and cervical swab or FCU | Culture | U.S. and Canada<br>Family planning, obstetrics/ gynecology, and STI clinics<br>CT prevalence across sites: 5.4 to 10.2% by culture | Age (range): 16 to 25 years<br>100% female<br>Race: NR | Females Age 16 to 25<br>Excluded antibiotics within 30 days<br>Excluded symptoms or partner with symptoms | 1408<br>Proportion with CT by culture of 1 specimen: 8.5% | Not reported |

**Appendix B Table 7. Evidence Table: Diagnostic Accuracy of Anatomic Site-Specific Testing—Study Characteristics**

| Study, year | Condition | Screening test(s) | Sex | Definition of a positive screening exam | Reference standard(s) | Country Setting Prevalence | Population Characteristics | Eligibility Criteria | Sample size Proportion with condition | Proportion unexaminable by screening test |
|---|---|---|---|---|---|---|---|---|---|---|
| Schachter *et al*., 2003[76]* | Chlamydia trachomatis | Amplified CT Assay<br>Site: self-collected vaginal | Female | Agreement between positive results with vaginal swab and cervical swab or FCU | Culture | U.S. and Canada<br>Family planning, obstetrics/ gynecology, and STI clinics<br>CT prevalence across sites: 5.4 to 10.2% by culture | Age (range): 16 to 25 years<br>100% female<br>Race: NR | Females Age 16 to 25<br>Excluded antibiotics within 30 days<br>Excluded symptoms or partner with symptoms | 1408<br>Proportion with CT by culture of 1 specimen: 8.5% | Not reported |
| Schachter *et al*., 2003[76]* | Chlamydia trachomatis | Amplified CT Assay<br>Site: urethral swab | Female | Agreement between positive results with vaginal swab and cervical swab or FCU | Culture | U.S. and Canada<br>Family planning, obstetrics/ gynecology, and STI clinics<br>CT prevalence across sites: 5.4 to 10.2% by culture | Age (range): 16 to 25 years<br>100% female<br>Race: NR | Females Age 16 to 25<br>Excluded antibiotics within 30 days<br>Excluded symptoms or partner with symptoms | 1407<br>Proportion with CT by culture of 1 specimen: 8.5% | Not reported |

**Appendix B Table 7. Evidence Table: Diagnostic Accuracy of Anatomic Site-Specific Testing—Study Characteristics**

| Study, year | Condition | Screening test(s) | Sex | Definition of a positive screening exam | Reference standard(s) | Country Setting Prevalence | Population Characteristics | Eligibility Criteria | Sample size Proportion with condition | Proportion unexaminable by screening test |
|---|---|---|---|---|---|---|---|---|---|---|
| Schachter *et al*., 2003[76]* | Chlamydia trachomatis | Amplicor Site: FCU | Female | Agreement between positive results with vaginal swab and cervical swab or FCU | Culture | U.S. and Canada Family planning, obstetrics/ gynecology, and STI clinics CT prevalence across sites: 5.4 to 10.2% by culture | Age (range): 16 to 25 years 100% female Race: NR | Females Age 16 to 25 Excluded antibiotics within 30 days Excluded symptoms or partner with symptoms | 577 Proportion with CT by culture of 1 specimen: 13.0% | Not reported |
| Schachter *et al*., 2003[76]* | Chlamydia trachomatis | Amplicor Site: cervix | Female | Agreement between positive results with vaginal swab and cervical swab or FCU | Culture | U.S. and Canada Family planning, obstetrics/ gynecology, and STI clinics CT prevalence across sites: 5.4 to 10.2% by culture | Age (range): 16 to 25 years 100% female Race: NR | Females Age 16 to 25 Excluded antibiotics within 30 days Excluded symptoms or partner with symptoms | 600 Proportion with CT by culture of 1 specimen: 12.5% | Not reported |

**Appendix B Table 7. Evidence Table: Diagnostic Accuracy of Anatomic Site-Specific Testing—Study Characteristics**

| Study, year | Condition | Screening test(s) | Sex | Definition of a positive screening exam | Reference standard(s) | Country Setting Prevalence | Population Characteristics | Eligibility Criteria | Sample size Proportion with condition | Proportion unexaminable by screening test |
|---|---|---|---|---|---|---|---|---|---|---|
| Schachter *et al*., 2003[76]* | Chlamydia trachomatis | Amplicor Site: clinician-collected vaginal | Female | Agreement between positive results with vaginal swab and cervical swab or FCU | Culture | U.S. and Canada Family planning, obstetrics/ gynecology, and STI clinics CT prevalence across sites: 5.4 to 10.2% by culture | Age (range): 16 to 25 years 100% female Race: NR | Females Age 16 to 25 Excluded antibiotics within 30 days Excluded symptoms or partner with symptoms | 579 Proportion with CT by culture of 1 specimen: 13.0% | Not reported |
| Schachter *et al*., 2003[76]* | Chlamydia trachomatis | Amplicor Site: self- collected vaginal | Female | Agreement between positive results with vaginal swab and cervical swab or FCU | Culture | U.S. and Canada Family planning, obstetrics/ gynecology, and STI clinics CT prevalence across sites: 5.4 to 10.2% by culture | Age (range): 16 to 25 years 100% female Race: NR | Females Age 16 to 25 Excluded antibiotics within 30 days Excluded symptoms or partner with symptoms | 568 Proportion with CT by culture of 1 specimen: 13.2% | Not reported |

**Appendix B Table 7. Evidence Table: Diagnostic Accuracy of Anatomic Site-Specific Testing—Study Characteristics**

| Study, year | Condition | Screening test(s) | Sex | Definition of a positive screening exam | Reference standard(s) | Country Setting Prevalence | Population Characteristics | Eligibility Criteria | Sample size Proportion with condition | Proportion unexaminable by screening test |
|---|---|---|---|---|---|---|---|---|---|---|
| Schachter *et al*., 2003[76]* | Chlamydia trachomatis | Amplicor Site: urethral swab | Female | Agreement between positive results with vaginal swab and cervical swab or FCU | Culture | U.S. and Canada Family planning, obstetrics/ gynecology, and STI clinics CT prevalence across sites: 5.4 to 10.2% by culture | Age (range): 16 to 25 years 100% female Race: NR | Females Age 16 to 25 Excluded antibiotics within 30 days Excluded symptoms or partner with symptoms | 602 Proportion with CT by culture of 1 specimen: 12.5% | Not reported |
| Schachter *et al*., 2003[76]* | Chlamydia trachomatis | LCx Probe Site: FCU | Female | Agreement between positive results with vaginal swab and cervical swab or FCU | Culture | U.S. and Canada Family planning, obstetrics/ gynecology, and STI clinics CT prevalence across sites: 5.4 to 10.2% by culture | Age (range): 16 to 25 years 100% female Race: NR | Females Age 16 to 25 Excluded antibiotics within 30 days Excluded symptoms or partner with symptoms | 499 Proportion with CT by culture of 1 specimen: 9.6% | Not reported |

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| Study, year | Condition | Screening test(s) | Sex | Definition of a positive screening exam | Reference standard(s) | Country Setting Prevalence | Population Characteristics | Eligibility Criteria | Sample size Proportion with condition | Proportion unexaminable by screening test |
|---|---|---|---|---|---|---|---|---|---|---|
| Schachter *et al*., 2003[76]* | Chlamydia trachomatis | LCx Probe Site: cervix | Female | Agreement between positive results with vaginal swab and cervical swab or FCU | Culture | U.S. and Canada Family planning, obstetrics/ gynecology, and STI clinics CT prevalence across sites: 5.4 to 10.2% by culture | Age (range): 16 to 25 years 100% female Race: NR | Females Age 16 to 25 Excluded antibiotics within 30 days Excluded symptoms or partner with symptoms | 498 Proportion with CT by culture of 1 specimen: 9.6% | Not reported |
| Schachter *et al*., 2003[76]* | Chlamydia trachomatis | LCx Probe Site: clinician-collected vaginal | Female | Agreement between positive results with vaginal swab and cervical swab or FCU | Culture | U.S. and Canada Family planning, obstetrics/ gynecology, and STI clinics CT prevalence across sites: 5.4 to 10.2% by culture | Age (range): 16 to 25 years 100% female Race: NR | Females Age 16 to 25 Excluded antibiotics within 30 days Excluded symptoms or partner with symptoms | 497 Proportion with CT by culture of 1 specimen: 9.7% | Not reported |

**Appendix B Table 7. Evidence Table: Diagnostic Accuracy of Anatomic Site-Specific Testing—Study Characteristics**

| Study, year | Condition | Screening test(s) | Sex | Definition of a positive screening exam | Reference standard(s) | Country Setting Prevalence | Population Characteristics | Eligibility Criteria | Sample size Proportion with condition | Proportion unexaminable by screening test |
|---|---|---|---|---|---|---|---|---|---|---|
| Schachter *et al*., 2003[76]* | Chlamydia trachomatis | LCx Probe Site: self-collected vaginal | Female | Agreement between positive results with vaginal swab and cervical swab or FCU | Culture | U.S. and Canada Family planning, obstetrics/ gynecology, and STI clinics CT prevalence across sites: 5.4 to 10.2% by culture | Age (range): 16 to 25 years 100% female Race: NR | Females Age 16 to 25 Excluded antibiotics within 30 days Excluded symptoms or partner with symptoms | 500 Proportion with CT by culture of 1 specimen: 9.6% | Not reported |
| Schachter *et al*., 2003[76]* | Chlamydia trachomatis | LCx Probe Site: urethral swab | Female | Agreement between positive results with vaginal swab and cervical swab or FCU | Culture | U.S. and Canada Family planning, obstetrics/ gynecology, and STI clinics CT prevalence across sites: 5.4 to 10.2% by culture | Age (range): 16 to 25 years 100% female Race: NR | Females Age 16 to 25 Excluded antibiotics within 30 days Excluded symptoms or partner with symptoms | 500 Proportion with CT by culture of 1 specimen: 9.6% | Not reported |
| Schoeman *et al*., 2012[77]* | Chlamydia trachomatis | AC2 Site: endocervix | Female | Positive result from one NAAT confirmed by second NAAT | Aptima CT | United Kingdom Sexual health clinic Prevalence: NR | Age (mean): 25 years 100% female Ethnicity: 80% white, 9% black, 7% mixed, 4% other | Females ≥16 years Excluded if used antibiotics in the preceding 28 days | 3974 enrolled 1347 asymptomatic 10.3% of enrolled with CT | 0.7% |

**Appendix B Table 7. Evidence Table: Diagnostic Accuracy of Anatomic Site-Specific Testing—Study Characteristics**

| Study, year | Condition | Screening test(s) | Sex | Definition of a positive screening exam | Reference standard(s) | Country Setting Prevalence | Population Characteristics | Eligibility Criteria | Sample size Proportion with condition | Proportion unexaminable by screening test |
|---|---|---|---|---|---|---|---|---|---|---|
| Schoeman *et al*., 2012[77]* | Chlamydia trachomatis | AC2 Site: self-collected vaginal | Female | Positive result from one NAAT confirmed by second NAAT | Aptima CT | United Kingdom Sexual health clinic Prevalence: NR | Age (mean): 25 years 100% female Ethnicity: 80% white, 9% black, 7% mixed, 4% other | Females ≥16 years Excluded if used antibiotics in the preceding 28 days | 3974 enrolled 10.3% with CT | 0.7% |
| Shrier *et al*., 2004[79]* | Chlamydia trachomatis | Amplicor Site: endocervix | Female | 1 positive culture or 2 positive nonculture tests or 1 positive nonculture test confirmed by nested PCR | Culture Amplicor Abbot LCx assay | United States; University medical center and children's hospital; 21.6% positive for CT at any site | Age (mean): 19 years 100% female 22% history of CT Median time since previous CT infection: 539 days (range: 43 to 2738) 8% with history of other STI | Females aged 16 to 25 years Excluded if symptoms Excluded if treated for CT in previous 6 weeks Excluded if sexual contact with a partner diagnosed with an STI | 139 eligible 126 analyzed 21.6% CT 2% NG or trichomoniasis (1 participant had CT and NG) | 1 participant excluded because no samples were collected by physician |
| Shrier *et al*., 2004[79]* | Chlamydia trachomatis | Amplicor Site: FCU | Female | 1 positive culture or 2 positive nonculture tests or 1 positive nonculture test confirmed by nested PCR | Culture Amplicor Abbot LCx assay | United States; University medical center and children's hospital; 21.6% positive for CT at any site | Age (mean): 19 years 100% female 22% history of CT Median time since previous CT infection: 539 days (range: 43 to 2738) 8% with history of other STI | Females aged 16 to 25 years Excluded if symptoms Excluded if treated for CT in previous 6 weeks Excluded if sexual contact with a partner diagnosed with an STI | 139 eligible 126 analyzed 21.6% CT 2% NG or trichomoniasis (1 participant had CT and NG) | 1 participant excluded because no samples were collected by physician |

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| Study, year | Condition | Screening test(s) | Sex | Definition of a positive screening exam | Reference standard(s) | Country Setting Prevalence | Population Characteristics | Eligibility Criteria | Sample size Proportion with condition | Proportion unexaminable by screening test |
|---|---|---|---|---|---|---|---|---|---|---|
| Shrier *et al*., 2004[79]* | Chlamydia trachomatis | Amplicor Site: clinician-collected vaginal | Female | 1 positive culture or 2 positive nonculture tests or 1 positive nonculture test confirmed by nested PCR | Culture Amplicor Abbot LCx assay | United States; University medical center and children's hospital; 21.6% positive for CT at any site | Age (mean): 19 years 100% female 22% history of CT Median time since previous CT infection: 539 days (range: 43 to 2738) 8% with history of other STI | Females aged 16 to 25 years Excluded if symptoms Excluded if treated for CT in previous 6 weeks Excluded if sexual contact with a partner diagnosed | 139 eligible 126 analyzed 21.6% CT 2% NG or trichomoniasis (1 participant had CT and NG) | 1 participant excluded because no samples were collected by physician |
| Shrier *et al*., 2004[79]* | Chlamydia trachomatis | Amplicor Site: self- collected vaginal | Female | 1 positive culture or 2 positive nonculture tests or 1 positive nonculture test confirmed by nested PCR | Culture Amplicor Abbot LCx assay | United States; University medical center and children's hospital; 21.6% positive for CT at any site | Age (mean): 19 years 100% female 22% history of CT Median time since previous CT infection: 539 days (range: 43 to 2738) 8% with history of other STI | Females aged 16 to 25 years Excluded if symptoms Excluded if treated for CT in previous 6 weeks Excluded if sexual contact with a partner diagnosed | 139 eligible 126 analyzed 21.6% CT 2% NG or trichomoniasis (1 participant had CT and NG) | 1 participant excluded because no samples were collected by physician |
| Skidmore et al., 2008[72] | Chlamydia trachomatis | Cobas Taqman 48 CT Site: ulvo-vaginal swab (self-collected) | Female | Not reported. | Cobas Taqman 48 CT Site: endocervical swab | United Kingdom Genitourinary medicine clinic Prevalence: 93% | Age: 18-24m mean not reported 100% female Race: not reported | Females age 18-24 years Additional criteria not reported | 267 enrolled 9.3% with CT | Not reported |

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| Study, year | Condition | Screening test(s) | Sex | Definition of a positive screening exam | Reference standard(s) | Country Setting Prevalence | Population Characteristics | Eligibility Criteria | Sample size Proportion with condition | Proportion unexaminable by screening test |
|---|---|---|---|---|---|---|---|---|---|---|
| Berry *et al*., 2017[61] | Chlamydia trachomatis | BD Viper XTR Site: Meatal swab (self-collected) | Male | Agreement between both collection methods, or samples confirmed by Real-time CT/NG assay or positive GC culture | BC Viper XTR Site: Urine sample | United Kingdom Sexual health clinic Prevalence: 10.5% | Age: NR Sex: 100% male Race: NR | Men attending sexual health clinic for sexual health screening. Additional criteria NR. | 1728 screened, 1517 analyzed 10.5% | 12.20% |
| Berry *et al*., 2017[61] | Chlamydia trachomatis | BD Viper XTR Site: Urine sample | Male | Agreement between both collection methods, or samples confirmed by Real-time CT/NG assay or positive GC culture | BC Viper XTR Site: Meatal swab | United Kingdom Sexual health clinic Prevalence: 10.5% | Age: NR Sex: 100% male Race: NR | Men attending sexual health clinic for sexual health screening. Additional criteria NR. | 1728 screened, 1517 analyzed 10.5% | 12.20% |

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| Study, year | Condition | Screening test(s) | Sex | Definition of a positive screening exam | Reference standard(s) | Country Setting Prevalence | Population Characteristics | Eligibility Criteria | Sample size Proportion with condition | Proportion unexaminable by screening test |
|---|---|---|---|---|---|---|---|---|---|---|
| Nye *et al*., 2019[71] | Chlamydia trachomatis | Cobas CT/NG 2.0<br>Site: Male urine | Male | Two confirmatory NAATs from urethral and/or urine specimens | Aptima Combo 2 Assay<br>BD ProbeTec CTQ/GCQ<br>Site: Urine and/or urethral swab | USA<br>Settings: 39% family planning clinics, 22% obstetrics/ gyneacology, 38% STI clinics (includes symptomatic patients) | Age, mean: 29<br>Female: 88%<br>Race: Black: 45%<br>White: 46.4%<br>(includes symptomatic patients) | VENUS and VENUS II enrollment:<br>≥14 years old<br>Eligible for screening per clinical site's standard practice<br>Excluded use of Replens vaginal lubricant within 3 days<br>Excluded antimicrobial use in past 21 days for GC or CT<br><br>VENUS II only:<br>Asymptomatic women only | 460<br>Prevalence: 11.3% | 31/6045 (0.04%), not reported for asymptomatic population |
| Sultan et al., 2016[73] | Chlamydia trachomatis | AC2<br>Site: pooled sample of pharyngeal, urine/urethral, and rectal specimens | Male | Positive test, confirmed with Aptima single-analyte assay | Standard of care testing at each anatomical site | United Kingdom<br>Sexual health clinic<br>Prevalence: 16%<br>(includes symptomatic patients) | Age: <35: 43%<br>35-45 years: 37%<br>>45 years: 20%<br>100% male<br>Sexual risk practices: men who have sex with men | Males ≥18 years<br>Men who have sex with men<br>Excluded if received antibiotics in previous 4 weeks | 1064 enrolled 771 asymptomatic<br>16% of full sample with CT | Not reported |

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| Study, year | Condition | Screening test(s) | Sex | Definition of a positive screening exam | Reference standard(s) | Country Setting Prevalence | Population Characteristics | Eligibility Criteria | Sample size Proportion with condition | Proportion unexaminable by screening test |
|---|---|---|---|---|---|---|---|---|---|---|
| Fang *et al*., 2008[65] | Neisseria gonorrhoeae | BDProbeTec ET NAAT Site: vaginal swab (self-collected) | Female | Positive result from at least two of the collection sites (urine, self-collected vaginal swab, clinician-collected endocervical swab) | Sites: endocervical (clinician-collected) and urine sample | USA Adolescent clinic Prevalence: 11.7% | Age, median: 16 years Sex: 100% female Race: Black: 96% Symptomatic: not reported | Age 12-18 Sexually active | 133 11.7% | Not reported |
| Fang *et al*., 2008[65] | Neisseria gonorrhoeae | BDProbeTec ET NAAT Site: endocervical swab (clinician-collected) | Female | Positive result from at least two of the collection sites (urine, self-collected vaginal swab, clinician-collected endocervical swab) | Sites: vaginal swab (self-collected) and urine sample | USA Adolescent clinic Prevalence: 11.7% | Age, median: 16 years Sex: 100% female Race: Black: 96% Symptomatic: not reported | Age 12-18 Sexually active | 133 11.7% | Not reported |

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| Study, year | Condition | Screening test(s) | Sex | Definition of a positive screening exam | Reference standard(s) | Country Setting Prevalence | Population Characteristics | Eligibility Criteria | Sample size Proportion with condition | Proportion unexaminable by screening test |
|---|---|---|---|---|---|---|---|---|---|---|
| Nye *et al*., 2019[71] | Neisseria gonorrhoeae | Cobas CT/NG 2.0 Site: endocervical swab | Female | Two confirmatory NAATs from endocervical and/or urine specimens | Aptima Combo 2 Assay BD ProbeTec CTQ/GCQ Site: Urine and/or endocervical | USA Settings: 39% family planning clinics, 22% obstetrics/ gyneacology, 38% STI clinics (includes symptomatic patients) | Age, mean: 29 Female: 88% Race: Black: 45% White: 46.4% (includes symptomatic patients) | VENUS and VENUS II enrollment: ≥14 years old Eligible for screening per clinical site's standard practice Excluded use of Replens vaginal lubricant within 3 days Excluded antimicrobial use in past 21 days for GC or CT<br><br>VENUS II only: Asymptomatic women only | 3174 Prevalence: 1.5% | 31/6045 (0.04%), not reported for asymptomatic population |

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| Study, year | Condition | Screening test(s) | Sex | Definition of a positive screening exam | Reference standard(s) | Country Setting Prevalence | Population Characteristics | Eligibility Criteria | Sample size Proportion with condition | Proportion unexaminable by screening test |
|---|---|---|---|---|---|---|---|---|---|---|
| Nye *et al*., 2019[71] | Neisseria gonorrhoeae | Cobas CT/NG 2.0<br>Site: Female urine | Female | Two confirmatory NAATs from endocervical and/or urine specimens | Aptima Combo 2 Assay<br>BD ProbeTec CTQ/GCQ<br>Site: Urine and/or endocervical | USA<br>Settings: 39% family planning clinics, 22% obstetrics/ gyneacology, 38% STI clinics (includes symptomatic patients) | Age, mean: 29<br>Female: 88%<br>Race: Black: 45%<br>White: 46.4%<br>(includes symptomatic patients) | VENUS and VENUS II enrollment:<br>≥14 years old<br>Eligible for screening per clinical site's standard practice<br>Excluded use of Replens vaginal lubricant within 3 days<br>Excluded antimicrobial use in past 21 days for GC or CT<br><br>VENUS II only:<br>Asymptomatic women only | 3190<br>Prevalence: 1.5% | 31/6045 (0.04%), not reported for asymptomatic population |

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| Study, year | Condition | Screening test(s) | Sex | Definition of a positive screening exam | Reference standard(s) | Country Setting Prevalence | Population Characteristics | Eligibility Criteria | Sample size Proportion with condition | Proportion unexaminable by screening test |
|---|---|---|---|---|---|---|---|---|---|---|
| Nye *et al*., 2019[71] | Neisseria gonorrhoeae | Cobas CT/NG 2.0<br>Site: clinician-collected vaginal swab | Female | Two confirmatory NAATs from endocervical and/or urine specimens | Aptima Combo 2 Assay<br>BD ProbeTec CTQ/GCQ<br>Site: Urine and/or endocervical | USA<br>Settings: 39% family planning clinics, 22% obstetrics/ gyneacology, 38% STI clinics (includes symptomatic patients) | Age, mean: 29<br>Female: 88%<br>Race: Black: 45%<br>White: 46.4%<br>(includes symptomatic patients) | VENUS and VENUS II enrollment:<br>≥14 years old<br>Eligible for screening per clinical site's standard practice<br>Excluded use of Replens vaginal lubricant within 3 days<br>Excluded antimicrobial use in past 21 days for GC or CT<br><br>VENUS II only:<br>Asymptomatic women only | 2240<br>Prevalence: 1.7% | 31/6045 (0.04%), not reported for asymptomatic population |

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| Study, year | Condition | Screening test(s) | Sex | Definition of a positive screening exam | Reference standard(s) | Country Setting Prevalence | Population Characteristics | Eligibility Criteria | Sample size Proportion with condition | Proportion unexaminable by screening test |
|---|---|---|---|---|---|---|---|---|---|---|
| Nye *et al*., 2019[71] | Neisseria gonorrhoeae | Cobas CT/NG 2.0<br>Site: self-collected vaginal swab | Female | Two confirmatory NAATs from endocervical and/or urine specimens | Aptima Combo 2 Assay<br>BD ProbeTec CTQ/GCQ<br>Site: Urine and/or endocervical | USA<br>Settings: 39% family planning clinics, 22% obstetrics/ gyneacology, 38% STI clinics (includes symptomatic patients) | Age, mean: 29<br>Female: 88%<br>Race: Black: 45%<br>White: 46.4%<br>(includes symptomatic patients) | VENUS and VENUS II enrollment: ≥14 years old<br>Eligible for screening per clinical site's standard practice<br>Excluded use of Replens vaginal lubricant within 3 days<br>Excluded antimicrobial use in past 21 days for GC or CT<br><br>VENUS II only: Asymptomatic women only | 996<br>Prevalence: 0.9% | 31/6045 (0.04%), not reported for asymptomatic population |
| Stewart *et al*., 2012[80*] | Neisseria gonorrhoeae | AC2<br>Site: self-collected vaginal | Female | Positive culture with biochemical confirmation or positive result from one NAAT confirmed by second NAAT | Culture<br>Aptima GC | United Kingdom<br>Sexual health clinic<br>Prevalence: NR | Age (mean): 25 years<br>100% female<br>Ethnicity: 80% white, 9% black, 7% mixed, 4% other | Women ≥16 years<br>Excluded if used antibiotics in the preceding 28 days | 3973 enrolled 2.5% with NG | 0.8% |

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| Study, year | Condition | Screening test(s) | Sex | Definition of a positive screening exam | Reference standard(s) | Country Setting Prevalence | Population Characteristics | Eligibility Criteria | Sample size Proportion with condition | Proportion unexaminable by screening test |
|---|---|---|---|---|---|---|---|---|---|---|
| Stewart *et al*., 2012[80]* | Neisseria gonorrhoeae | AC2 Site: endocervical | Female | Positive culture with biochemical confirmation or positive result from one NAAT confirmed by second NAAT | Culture Aptima GC | United Kingdom Sexual health clinic Prevalence: NR | Age (mean): 25 years 100% female Ethnicity: 80% white, 9% black, 7% mixed, 4% other | Women ≥16 years Excluded if used antibiotics in the preceding 28 days | 3973 enrolled 2.5% with NG | 0.8% |
| Berry *et al.,* 2017[61] | Neisseria gonorrhoeae | BD Viper XTR Site: Meatal swab (self-collected) | Male | Agreement between both collection methods, or samples confirmed by Real-time CT/NG assay or positive GC culture | BC Viper XTR Site: Urine sample | United Kingdom Sexual health clinic Prevalence: 4.2% | Age: NR Sex: 100% male Race: NR | Men attending sexual health clinic for sexual health screening. Additional criteria NR. | 1728 screened, 1517 analyzed 4.2% | 12.20% |
| Berry *et al*., 2017[61] | Neisseria gonorrhoeae | BD Viper XTR Site: Urine sample | Male | Agreement between both collection methods, or samples confirmed by Real-time CT/NG assay or positive GC culture | BC Viper XTR Site: Meatal swab | United Kingdom Sexual health clinic Prevalence: 4.2% | Age: NR Sex: 100% male Race: NR | Men attending sexual health clinic for sexual health screening. Additional criteria NR. | 1728 screened, 1517 analyzed 4.2% | 12.20% |

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| Study, year | Condition | Screening test(s) | Sex | Definition of a positive screening exam | Reference standard(s) | Country Setting Prevalence | Population Characteristics | Eligibility Criteria | Sample size Proportion with condition | Proportion unexaminable by screening test |
|---|---|---|---|---|---|---|---|---|---|---|
| Nye *et al.,* 2019[71] | Neisseria gonorrhoeae | Cobas CT/NG 2.0<br>Site: Male urine | Male | Two confirmatory NAATs from endocervical and/or urine specimens | Aptima Combo 2 Assay<br>BD ProbeTec CTQ/GCQ<br>Site: Urine and/or urethral swab | USA<br>Settings: 39% family planning clinics, 22% obstetrics/ gyneacology, 38% STI clinics (includes symptomatic patients) | Age, mean: 29<br>Female: 88%<br>Race: Black: 45%<br>White: 46.4%<br>(includes symptomatic patients) | VENUS and VENUS II enrollment: ≥14 years old<br>Eligible for screening per clinical site's standard practice<br>Excluded use of Replens vaginal lubricant within 3 days<br>Excluded antimicrobial use in past 21 days for GC or CT<br><br>VENUS II only: Asymptomatic women only | 460<br>Prevalence: 1.5% | 31/6045 (0.04%), not reported for asymptomatic population |
| Sultan *et al*., 2016[73] | Neisseria gonorrhoeae | AC2<br>Site: pooled sample of pharyngeal, urine/urethral, and rectal specimens | Male | Positive test, confirmed with Aptima single-analyte assay | Standard of care testing at each anatomical site | United Kingdom<br>Sexual health clinic<br>Prevalence: 27% (includes symptomatic patients) | Age: <35: 43%<br>35-45 years: 37%<br>>45 years: 20%<br>100% male<br>Sexual risk practices: men who have sex with men | Males ≥18 years<br>Men who have sex with men<br>Excluded if received antibiotics in previous 4 weeks | 1064 enrolled 771 asymptomatic<br>27% of full sample with NG | Not reported |

Abbreviations: AC2 = Aptima Combo 2; CT = Chlamydia trachomatis; FCU = first-catch urines; GC = Neisseria gonorrhoeae; LCx = ligase chain reaction; NAATs = nucleic acid amplification tests; NG = Neisseria gonorrhoeae; NR = not reported; STI = sexually transmitted infection.
*Study included in prior USPSTF review.

**Appendix B Table 8. Evidence Table: Diagnostic Accuracy of Anatomic Site-Specific Testing—Study Outcomes Part 1**

| Study, year | Condition | Screening test(s) | Sex | Number of indeterminate results | Proportion who underwent reference standard and included in analysis | True positives | False positives | False negatives | True negatives | Sensitivity (95% CI) | Specificity (95% CI) |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Fang *et al*., 2008[65] | Chlamydia trachomatis | BDProbeTec ET NAAT Site: vaginal swab (self-collected) | Female | 5.5% (indeterminate results were included in calculations of sensitivity) | 100% | 108 | 5 | 2 | 919 | 98.2 (93.59-99.78) | 99.46 (98.74-99.82) |
| Fang et al., 2008[65] | Chlamydia trachomatis | BDProbeTec ET NAAT Site: urine sample | Female | 3.90% | 100% | 99 | 5 | 12 | 926 | 89.2 (81.88-94.29) | 99.46 (98.75-99.82) |
| Fang et al., 2008[65] | Chlamydia trachomatis | BDProbeTec ET NAAT Site: endocervical swab (clinician-collected) | Female | 0.40% | 100% | 100 | 4 | 11 | 961 | 90.1 (82.92-94.95) | 99.6 (98.94-99.89) |
| Fang et al., 2008[65] | Chlamydia trachomatis | BDProbeTec ET NAAT Site: urine sample | Female | 6.00% | 100% | 39 | 1 | 4 | 996 | 90.70 (77.86-97.1) | 99.9 (99.44-100) |
| Nye *et al*., 2019[71] | Chlamydia trachomatis | Cobas CT/NG 2.0 Site: endocervical swab | Female | Unclear | Unclear | 174* | 6* | 13* | 2981* | 93.0 (88.5 to 95.5) | 99.8 (99.6 to 99.9) |
| Nye *et al*., 2019[71] | Chlamydia trachomatis | Cobas CT/NG 2.0 Site: Female urine | Female | Unclear | Unclear | 186 | 9 | 14 | 2981 | 93.1 (88.7 to 95.8) | 99.7 (99.4 to 99.8) |
| Nye *et al*., 2019[71] | Chlamydia trachomatis | Cobas CT/NG 2.0 Site: clinician- | Female | Unclear | Unclear | 140 | 6 | 3 | 2092 | 97.9 (94 to 99.3) | 99.7 (99.4 to 99.9) |

**Appendix B Table 8. Evidence Table: Diagnostic Accuracy of Anatomic Site-Specific Testing—Study Outcomes Part 1**

| Study, year | Condition | Screening test(s) | Sex | Number of indeterminate results | Proportion who underwent reference standard and included in analysis | True positives | False positives | False negatives | True negatives | Sensitivity (95% CI) | Specificity (95% CI) |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | collected vaginal swab | | | | | | | | | |
| Nye *et al*., 2019[71] | Chlamydia trachomatis | Cobas CT/NG 2.0<br>Site: self-collected vaginal swab | Female | Unclear | Unclear | 47 | 6 | 2 | 941 | 96.0 (86.5 to 98.9) | 99.4 (98.6 to 99.7) |
| Schachter *et al*., 2003[76] | Chlamydia trachomatis | Amplified CT Assay<br>Site: FCU | Female | Not reported | Unclear | 86* | 6* | 33* | 1262* | 72.27 (63.32-80.08) | 99.53 (98.97-99.83) |
| Schachter *et al*., 2003[76] | Chlamydia trachomatis | Amplified CT Assay<br>Site: cervix | Female | Not reported | Unclear | 106 | 9 | 13 | 1280 | 89.1% (82.04-94.05) | 99.3% (98.68-99.68) |
| Schachter *et al*., 2003[76] | Chlamydia trachomatis | Amplified CT Assay<br>Site: clinician-collected vaginal | Female | Not reported | Unclear | 107 | 8 | 12 | 1281 | 89.9 (83.05-94.68) | 99.4 (98.78-99.73) |
| Schachter *et al*., 2003[76] | Chlamydia trachomatis | Amplified CT Assay<br>Site: self-collected vaginal | Female | Not reported | Unclear | 111 | 5 | 8 | 1284 | 93.3 (87.18-97.05) | 99.6 (99.10-99.87) |
| Schachter *et al*., 2003[76] | Chlamydia trachomatis | Amplified CT Assay<br>Site: urethral swab | Female | Not reported | Unclear | 105 | 9 | 14 | 1279 | 88.1 (81.05-93.42) | 99.3 (98.68-99.68) |
| Schachter *et al*., 2003[76] | Chlamydia trachomatis | Amplicor<br>Site: FCU | Female | Not reported | Unclear | 63 | 5 | 12 | 497 | 84.0 (73.72-91.45) | 99.0 (97.69-99.68) |
| Schachter *et al*., 2003[76] | Chlamydia trachomatis | Amplicor<br>Site: cervix | Female | Not reported | Unclear | 68 | 3 | 7 | 522 | 90.7 (81.71- | 99.4 (98.34- |

**Appendix B Table 8. Evidence Table: Diagnostic Accuracy of Anatomic Site-Specific Testing—Study Outcomes Part 1**

| Study, year | Condition | Screening test(s) | Sex | Number of indeterminate results | Proportion who underwent reference standard and included in analysis | True positives | False positives | False negatives | True negatives | Sensitivity (95% CI) | Specificity (95% CI) |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | 96.16) | 99.88) |
| Schachter *et al*., 2003[76] | Chlamydia trachomatis | Amplicor Site: clinician-collected vaginal | Female | Not reported | Unclear | 70 | 6 | 5 | 498 | 93.3 (85.12-97.80) | 98.8 (98.38-99.73) |
| Schachter *et al*., 2003[76] | Chlamydia trachomatis | Amplicor Site: self-collected vaginal | Female | Not reported | Unclear | 68 | 5 | 7 | 488 | 90.7 (81.71-96.16) | 98.99 (97.65-99.67) |
| Schachter *et al*., 2003[76] | Chlamydia trachomatis | Amplicor Site: urethral swab | Female | Not reported | Unclear | 73 | 9 | 2 | 518 | 97.3 (90.70-99.68) | 98.2 (96.78-99.22) |
| Schachter *et al*., 2003[76] | Chlamydia trachomatis | LCx Probe Site: FCU | Female | Not reported | Unclear | 47 | 9 | 1 | 442 | 97.92 (88.93-99.95) | 98 (96.25-99.08) |
| Schachter *et al*., 2003[76] | Chlamydia trachomatis | LCx Probe Site: cervix | Female | Not reported | Unclear | 46 | 1 | 2 | 449 | 95.8 (85.75-99.49) | 99.8 (98.77-99.99) |
| Schachter *et al* ., 2003[76] | Chlamydia trachomatis | LCx Probe Site: clinician-collected vaginal | Female | Not reported | Unclear | 48 | 1 | 0 | 448 | 100 (92.6 100) | 99.8 (98.77-99.99) |
| Schachter *et al*., 2003[76] | Chlamydia trachomatis | LCx Probe Site: self-collected vaginal | Female | Not reported | Unclear | 47 | 2 | 1 | 450 | 97.92 (88.93-99.95) | 99.5 (98.41-99.95) |
| Schachter *et al*., 2003[76] | Chlamydia trachomatis | LCx Probe Site: urethral swab | Female | Not reported | Unclear | 44 | 1 | 4 | 451 | 91.67 (80.02-97.68) | 99.8 (98.77-99.99) |
| Schoeman *et al*., 2012[77] | Chlamydia trachomatis | AC2 Site: endocervix | Female | 4 | 97.3% | 163 | 0 | 20 | 2050 | 89.0% (84.0 to 93.0) | 100% (99.8 to 100.0) |

**Appendix B Table 8. Evidence Table: Diagnostic Accuracy of Anatomic Site-Specific Testing—Study Outcomes Part 1**

| Study, year | Condition | Screening test(s) | Sex | Number of indeterminate results | Proportion who underwent reference standard and included in analysis | True positives | False positives | False negatives | True negatives | Sensitivity (95% CI) | Specificity (95% CI) |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Schoeman *et al*., 2012[77] | Chlamydia trachomatis | AC2 Site: self-collected vaginal | Female | 4 | See above | 178 | 1 | 5 | 2049 | 97.0% (94.0 to 99.0%) | 99.9% (99.7 to 100.0%) |
| Shrier *et al*., 2004[79] | Chlamydia trachomatis | Amplicor Site: endocervix | Female | None reported; 8 participants had a single-positive result that needed confirmation by nested PCR | 90.6% (analysis only included eligible participants with results on all tests) | 14 | 0 | 13 | 99 | 51.9% (32.0 to 71.3%) | 100% (96.5 to 100%) |
| Shrier *et al*., 2004[79] | Chlamydia trachomatis | Amplicor Site: FCU | Female | None reported; 8 participants had a single-positive result that needed confirmation by nested PCR | 90.6% (analysis only included eligible participants with results on all tests) | 12 | 0 | 15 | 99 | 44.4% (26.9 to 63.6%) | 100% (96.5 to 100%) |
| Shrier *et al*., 2004[79] | Chlamydia trachomatis | Amplicor Site: clinician-collected vaginal | Female | None reported; 8 participants had a single-positive result that needed confirmation by nested PCR | 90.6% (analysis only included eligible participants with results on all tests) | 15 | 0 | 12 | 99 | 55.6% (36.4 to 73.1%) | 100% (96.5 to 100%) |
| Shrier *et al*., 2004[79] | Chlamydia trachomatis | Amplicor Site: self- | Female | None reported; 8 participants had | 90.6% (analysis | 14 | 1 | 13 | 98 | 51.9% (32.0 to | 99.0% (95.0 to |

**Appendix B Table 8. Evidence Table: Diagnostic Accuracy of Anatomic Site-Specific Testing—Study Outcomes Part 1**

| Study, year | Condition | Screening test(s) | Sex | Number of indeterminate results | Proportion who underwent reference standard and included in analysis | True positives | False positives | False negatives | True negatives | Sensitivity (95% CI) | Specificity (95% CI) |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | collected vaginal | | a single-positive result that needed confirmation by nested PCR | only included eligible participants with results on all tests) | | | | | 71.3%) | 100%) |
| Skidmore et al., 2008[72] | Chlamydia trachomatis | Cobas Taqman 48 CT<br>Site: ulvo-vaginal swab (self-collected) | Female | 4.5% (12/267) | 95.5% (255/267) | 23 | 0 | 0 | 232 | 100% (85.18 to 100) | 100% (98.42 to 100) |
| Berry *et al*., 2017[61] | Chlamydia trachomatis | BD Viper XTR<br>Site: Meatal swab (self-collected) | Male | 0 | 87.80% | 126 | 5 | 11 | 1375 | 91.97 (86.09-95.92) | 99.64 (99.16-99.88) |
| Berry *et al*., 2017[61] | Chlamydia trachomatis | BD Viper XTR<br>Site: Urine sample | Male | 0 | 87.80% | 137 | 4 | 0 | 1376 | 100 (97.34-100) | 99.7 (99.26-99.92) |
| Nye *et al*., 2019[71] | Chlamydia trachomatis | Cobas CT/NG 2.0<br>Site: Male urine | Male | Unclear | Unclear | 51 | 3 | 1 | 405 | 98.1 (89.9 to 99.7) | 99.3 (97.9 to 99.7) |
| Sultan *et al*., 2016[73] | Chlamydia trachomatis | AC2<br>Site: pooled sample of pharyngeal, urine/urethral, and rectal specimens | Male | Not reported | Not reported | 26 | Unable to calculate | Unable to calculate | Unable to calculate | 88.5% (69.8 to 97.6) | Unable to calculate |

**Appendix B Table 8. Evidence Table: Diagnostic Accuracy of Anatomic Site-Specific Testing—Study Outcomes Part 1**

| Study, year | Condition | Screening test(s) | Sex | Number of indeterminate results | Proportion who underwent reference standard and included in analysis | True positives | False positives | False negatives | True negatives | Sensitivity (95% CI) | Specificity (95% CI) |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Fang *et al*., 2008[65] | Neisseria gonorrhoeae | BDProbeTec ET NAAT Site: vaginal swab (self-collected) | Female | 4.70% | 100% | 44 | 6 | 0 | 980 | 100 (91.96-100) | 99.4 (98.68-99.78) |
| Fang *et al*., 2008[65] | Neisseria gonorrhoeae | BDProbeTec ET NAAT Site: endocervical swab (clinician-collected) | Female | 0.30% | 100% | 42 | 0 | 2 | 1032 | 94.5 (84.53-99.44) | 100 (99.64-100) |
| Nye *et al*., 2019[71] | Neisseria gonorrhoeae | Cobas CT/NG 2.0 Site: endocervical swab | Female | Unclear | Unclear | 47 | 3 | 1 | 3123 | 97.9 (88.9 to 99.6) | 99.9 (99.7 to 100) |
| Nye *et al*., 2019[71] | Neisseria gonorrhoeae | Cobas CT/NG 2.0 Site: Female urine | Female | Unclear | Unclear | 48 | 13 | 0 | 3129 | 100 (92.6 to 100) | 99.6 (99.3 to 99.8) |
| Nye *et al*., 2019[71] | Neisseria gonorrhoeae | Cobas CT/NG 2.0 Site: clinician-collected vaginal swab | Female | Unclear | Unclear | 38 | 7 | 0 | 2195 | 100 (90.6 to 100) | 99.7 (99.4 to 99.9) |
| Nye *et al*., 2019[71] | Neisseria gonorrhoeae | Cobas CT/NG 2.0 Site: self-collected vaginal swab | Female | Unclear | Unclear | 9 | 0 | 0 | 987 | 100 (70.1 to 100) | 100 (99.6 to 100) |

**Appendix B Table 8. Evidence Table: Diagnostic Accuracy of Anatomic Site-Specific Testing—Study Outcomes Part 1**

| Study, year | Condition | Screening test(s) | Sex | Number of indeterminate results | Proportion who underwent reference standard and included in analysis | True positives | False positives | False negatives | True negatives | Sensitivity (95% CI) | Specificity (95% CI) |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Stewart *et al*., 2012[80] | Neisseria gonorrhoeae | AC2<br>Site: self-collected vaginal | Female | None | 97% | 39 | 0 | 1 | 2194 | 98.0% (87.0 to 100.0%) | 100.0% (99.8 to 100.0%)* |
| Stewart *et al*., 2012[80] | Neisseria gonorrhoeae | AC2<br>Site: endocervical | Female | None | 97% | 36 | 0 | 4 | 2194 | 90.0% (77.0 to 96.0) | 100.00% (99.8 to 100.0)* |
| Berry *et al.*, 2017[61] | Neisseria gonorrhoeae | BD Viper XTR<br>Site: Meatal swab (self-collected) | Male | 0 | 87.80% | 42 | 5 | 0 | 1470 | 100 (91.59-100) | 99.7 (99.21-99.89) |
| Berry *et al*., 2017[61] | Neisseria gonorrhoeae | BD Viper XTR<br>Site: Urine sample | Male | 0 | 87.80% | 39 | 3 | 3 | 1472 | 92.9 (80.52-98.50) | 99.8 (99.41-99.96) |
| Nye *et al.*, 2019[71] | Neisseria gonorrhoeae | Cobas CT/NG 2.0<br>Site: Male urine | Male | Unclear | Unclear | 7 | 3 | 0 | 450 | 100 (64.6 to 100) | 99.3 (98.1 to 99.8) |
| Sultan *et al*., 2016[73] | Neisseria gonorrhoeae | AC2<br>Site: pooled sample of pharyngeal, urine/urethral, and rectal specimens | Male | Not reported | Not reported | 49 | Unable to calculate | Unable to calculate | Unable to calculate | 81.6% (68.0 to 91.2) | Unable to calculate |

**Abbreviations**: AC2 = Aptima Combo 2; CT = Chlamydia trachomatis; FCU = first- catch urines; GC = Neisseria gonorrhoeae; LCx = ligase chain reaction; NAATs = nucleic acid amplification tests; NG = Neisseria gonorrhoeae; NR = not reported; STI = sexually transmitted infection.

**Appendix B Table 9. Evidence Table: Diagnostic Accuracy Studies of Anatomic Site-Specific Testing—Study Outcomes, Part 2**

| Study, year | Condition | Screening test(s) | Sex | Positive likelihood ratio (95% CI) | Negative likelihood ratio (95% CI) | Positive predictive value (95% CI) | Negative predictive value (95% CI) | False positive rate | False alarm rate | False negative rate | False reassurance rate | Sponsor | Quality rating |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Fang *et al*., 2008[65] | Chlamydia trachomatis | BDProbeTec ET NAAT Site: vaginal swab (self-collected) | Female | 181.44 (75.67-435) | 0.02 (0.00-0.07) | 94.7 | 95.1 | 0.54 | 12 | 1.8 | 4.8 | National Institute of Child Health and Human Development | Fair |
| Fang *et al*., 2008[65] | Chlamydia trachomatis | BDProbeTec ET NAAT Site: urine sample | Female | 166.07 (69.12-399) | 0.11 (0.06-0.19) | 95% | 94.9 | 0.54 | 5 | 10.8 | 5.1 | National Institute of Child Health and Human Development | Fair |
| Fang *et al*., 2008[65] | Chlamydia trachomatis | BDProbeTec ET NAAT Site: endocervical swab (clinician-collected) | Female | 217.34 (81.58-579.05) | 0.10 (81.58-579.05) | 96% | 98.5 | 0.4 | 4 | 8.9 | 1.5 | National Institute of Child Health and Human Development | Fair |
| Fang *et al*., 2008[65] | Chlamydia trachomatis | BDProbeTec ET NAAT Site: urine sample | Female | 904.26 (127.20-6428) | 0.09 (0.04-0.24) | 95.1 | 96 | 0.1 | 4.9 | 9.3 | 4 | National Institute of Child Health and Human Development | Fair |
| Nye *et al*., 2019[71] | Chlamydia trachomatis | Cobas CT/NG 2.0 Site: endocervical swab | Female | 463.22 (208.07 to 1031.26)* | 0.07 (0.04 to 0.12)* | 96.70% | 99.60% | 0.20% | 3.30% | 7.00% | 0.40% | Roche Molecular Systems | Fair |
| Nye *et al*., 2019[71] | Chlamydia trachomatis | Cobas CT/NG 2.0 Site: Female urine | Female | 308.97 (160.74 to 593.89) | 0.07 (0.04 to 0.12) | 94.9 | 99.5 | 0.3 | 5.1 | 6.9 | 0.5 | Roche Molecular Systems | Fair |
| Nye *et al*., 2019[71] | Chlamydia trachomatis | Cobas CT/NG 2.0 Site: clinician-collected vaginal swab | Female | 342.33 (153.91 to 761.40) | 0.02 (0.01 to 0.06) | 95.9 | 99.9 | 0.3 | 4.1 | 2.1 | 0.1 | Roche Molecular Systems | Fair |

**Appendix B Table 9. Evidence Table: Diagnostic Accuracy Studies of Anatomic Site-Specific Testing—Study Outcomes, Part 2**

| Study, year | Condition | Screening test(s) | Sex | Positive likelihood ratio (95% CI) | Negative likelihood ratio (95% CI) | Positive predictive value (95% CI) | Negative predictive value (95% CI) | False positive rate | False alarm rate | False negative rate | False reassurance rate | Sponsor | Quality rating |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Nye *et al*., 2019[71] | Chlamydia trachomatis | Cobas CT/NG 2.0 Site: self-collected vaginal swab | Female | 151.39 (68.04 to 336.83) | 0.04 (0.01 to 0.16) | 88.9 | 99.8 | 0.6 | 10.1 | 4 | 0.2 | Roche Molecular Systems | Fair |
| Schachter *et al*., 2003[76] | Chlamydia trachomatis | Amplified CT Assay Site: FCU | Female | 131.3 (62.2 to 277.2)* | 0.28 (0.21 to 0.37)* | 92.5% (85.1 to 96.9%)* | 97.5% (96.5 to 98.2%)* | 0.5 | 7.5 | 27.7 | 2.5 | Roche Molecular Systems; Abbott Laboratories; Gen-Probe, Inc.; Centers for Disease Control | Fair |
| Schachter *et al*., 2003[76] | Chlamydia trachomatis | Amplified CT Assay Site: cervix | Female | 113.3 (60.9 to 210.7)* | 0.11 (0.07 to 0.18)* | 91.4% (84.7 to 95.8%)* | 99.0% (98.3 to 99.5%)* | 0.7 | 8.6 | 11.9 | 1 | Roche Molecular Systems; Abbott Laboratories; Gen-Probe, Inc.; Centers for Disease Control | Fair |
| Schachter *et al*., 2003[76] | Chlamydia trachomatis | Amplified CT Assay Site: clinician-collected vaginal | Female | 127.1 (66.1 to 244.4)* | 0.10 (0.06 to 0.17)* | 92.2% (85.8 to 96.4%)* | 99.1% (98.4 to 99.5%)* | 0.6 | 7.8 | 11.9 | 0.9 | Roche Molecular Systems; Abbott Laboratories; Gen-Probe, Inc.; Centers for Disease Control | Fair |

**Appendix B Table 9. Evidence Table: Diagnostic Accuracy Studies of Anatomic Site-Specific Testing—Study Outcomes, Part 2**

| Study, year | Condition | Screening test(s) | Sex | Positive likelihood ratio (95% CI) | Negative likelihood ratio (95% CI) | Positive predictive value (95% CI) | Negative predictive value (95% CI) | False positive rate | False alarm rate | False negative rate | False reassurance rate | Sponsor | Quality rating |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Schachter *et al*., 2003[76] | Chlamydia trachomatis | Amplified CT Assay Site: self-collected vaginal | Female | 197.8 (88.9 to 440.0)* | 0.07 (0.03 to 0.13)* | 94.9% (89.2 to 98.1%) | 99.4% (98.8 to 99.7%) | 0.4 | 5.1 | 6.7 | 0.6 | Roche Molecular Systems; Abbott Laboratories; Gen-Probe, Inc.; Centers for Disease Control | Fair |
| Schachter *et al*., 2003[76] | Chlamydia trachomatis | Amplified CT Assay Site: urethral swab | Female | 126.27 (65.64 to 242.94) | 0.12 (0.07 to 0.19) | 92.11% (85.84 to 95.73) | 98.92% (98.24 to 99.34) | 0.7 | 7.9 | 11.9 | 1.1 | Roche Molecular Systems; Abbott Laboratories; Gen-Probe, Inc.; Centers for Disease Control | Fair |
| Schachter *et al*., 2003[76] | Chlamydia trachomatis | Amplicor Site: FCU | Female | 85.0 (35.3 to 204.5) | 0.16 (0.10 to 0.27)* | 92.7% (83.7 to 97.5%)* | 97.7% (96.0 to 98.8%)* | 0.1 | 7.3 | 6 | 2.3 | Roche Molecular Systems; Abbott Laboratories; Gen-Probe, Inc.; Centers for Disease Control | Fair |
| Schachter *et al*., 2003[76] | Chlamydia trachomatis | Amplicor Site: cervix | Female | 152.9 (49.4 to 473.7)* | 0.09 (0.05 to 0.19)* | 95.8% (88.1 to 99.1%)* | 98.6% (97.2 to 99.4%)* | 0.6 | 4.2 | 9.3 | 1.4 | Roche Molecular Systems; Abbott Laboratories; Gen-Probe, Inc.; | Fair |

**Appendix B Table 9. Evidence Table: Diagnostic Accuracy Studies of Anatomic Site-Specific Testing—Study Outcomes, Part 2**

| Study, year | Condition | Screening test(s) | Sex | Positive likelihood ratio (95% CI) | Negative likelihood ratio (95% CI) | Positive predictive value (95% CI) | Negative predictive value (95% CI) | False positive rate | False alarm rate | False negative rate | False reassurance rate | Sponsor | Quality rating |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | | Centers for Disease Control | |
| Schachter *et al*., 2003[76] | Chlamydia trachomatis | Amplicor Site: clinician-collected vaginal | Female | 78.7 (35.5 to 174.7)* | 0.07 (0.03 to 0.16)* | 92.1% (83.6 to 97.0%)* | 99.0% (97.7 to 99.7%)* | 1.2 | 7.9 | 6.7 | 1 | Roche Molecular Systems; Abbott Laboratories; Gen-Probe, Inc.; Centers for Disease Control | Fair |
| Schachter *et al*., 2003[76] | Chlamydia trachomatis | Amplicor Site: self- collected vaginal | Female | 91.8 (38.2 to 220.2)* | 0.09 (0.05 to 0.19)* | 93.2% (84.7 to 97.7%)* | 98.6% (97.2 to 99.4%)* | 1 | 6.8 | 9.3 | 1.4 | Roche Molecular Systems; Abbott Laboratories; Gen-Probe, Inc.; Centers for Disease Control | Fair |
| Schachter *et al*., 2003[76] | Chlamydia trachomatis | Amplicor Site: urethral swab | Female | 56.99 (29.79 to 109.04) | 0.03 (0.01 to 0.11) | 89.02% (80.91 to 93.95) | 99.62% (98.51 to 99.90) | 1.8 | 11 | 2.7 | 0.4 | Roche Molecular Systems; Abbott Laboratories; Gen-Probe, Inc.; Centers for Disease Control | Fair |

**Appendix B Table 9. Evidence Table: Diagnostic Accuracy Studies of Anatomic Site-Specific Testing—Study Outcomes, Part 2**

| Study, year | Condition | Screening test(s) | Sex | Positive likelihood ratio (95% CI) | Negative likelihood ratio (95% CI) | Positive predictive value (95% CI) | Negative predictive value (95% CI) | False positive rate | False alarm rate | False negative rate | False reassurance rate | Sponsor | Quality rating |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Schachter *et al*., 2003[76] | Chlamydia trachomatis | LCx Probe Site: FCU | Female | 49.07 (25.66-93.81) | 0.02 (0.00 to 0.15) | 83.93% (73.20 to 90.90) | 99.77% (98.45 to 99.97) | 2 | 16.1 | 2.1 | 0.2 | Roche Molecular Systems; Abbott Laboratories; Gen-Probe, Inc.; Centers for Disease Control | Fair |
| Schachter *et al*., 2003[76] | Chlamydia trachomatis | LCx Probe Site: cervix | Female | 431.25 (60.82 to 3057.64) | 0.04 (0.01 0.16) | 97.87% (86.65 to 99.69) | 99.56% (98.30 to 99.89) | 0.2 | 2.1 | 4.2 | 0.44 | Roche Molecular Systems; Abbott Laboratories; Gen-Probe, Inc.; Centers for Disease Control | Fair |
| Schachter *et al*., 2003[76] | Chlamydia trachomatis | LCx Probe Site: clinician-collected vaginal | Female | 449.00 (63.38 to 3180.64) | 0 | 97.96% (87.14 to 99.71) | 100 | 0.2 | 2 | 0 | 0 | Roche Molecular Systems; Abbott Laboratories; Gen-Probe, Inc.; Centers for Disease Control | Fair |
| Schachter *et al*., 2003[76] | Chlamydia trachomatis | LCx Probe Site: self-collected vaginal | Female | 221.29 (55.48 to 882.67) | 0.02 (0.00 to 0.15) | 95.92% (85.49 to 98.94) | 99.78% (98.48 to 99.97) | 0.5 | 4.1 | 2.1 | 0.2 | Roche Molecular Systems; Abbott Laboratories; Gen-Probe, Inc.; | Fair |

**Appendix B Table 9. Evidence Table: Diagnostic Accuracy Studies of Anatomic Site-Specific Testing—Study Outcomes, Part 2**

| Study, year | Condition | Screening test(s) | Sex | Positive likelihood ratio (95% CI) | Negative likelihood ratio (95% CI) | Positive predictive value (95% CI) | Negative predictive value (95% CI) | False positive rate | False alarm rate | False negative rate | False reassurance rate | Sponsor | Quality rating |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | | Centers for Disease Control | |
| Schachter *et al*., 2003[76] | Chlamydia trachomatis | LCx Probe Site: urethral swab | Female | 414.33 (58.38 to 2940.57) | 0.08 (0.03 to 0.21) | 97.78% (86.11 to 99.68) | 99.12% (97.78 to 99.65) | 0.2 | 2.2 | 8.3 | 0.9 | Roche Molecular Systems; Abbott Laboratories; Gen-Probe, Inc.; Centers for Disease Control | Fair |
| Schoeman *et al*., 2012[77] | Chlamydia trachomatis | AC2 Site: endocervix | Female | Unable to calculate | 0.11 (0.07 to 0.17)* | 100.0% (97.7 to 100.0)* | 99.0% (98.5 to 99.4)* | 0 | 0 | 11 | 1 | None reported (Gen- Probe provided supplies) | Fair |
| Schoeman *et al*., 2012[77] | Chlamydia trachomatis | AC2 Site: self-collected vaginal | Female | 1994.0 (281.0 to 14151.3)* | 0.03 (0.01 to 0.06)* | 99.4% (96.9 to 99.9%)* | 99.8% (99.4 to 99.9%)* | 0.1 | 0.6 | 3 | 0.2 | None reported (Gen- Probe provided supplies) | Fair |
| Shrier *et al*., 2004[79] | Chlamydia trachomatis | Amplicor Site: endocervix | Female | Unable to calculate | 0.48 (0.33 to 0.71)* | 100% (77.0 to 100%) | 88.4% (81.1 to 93.6%) | 0 | 0 | 48.1 | 11.6 | Roche Molecular Systems, Inc.; Centers for Disease Control and Prevention; National Institute of Mental Health, National Institutes of Health | Fair |

**Appendix B Table 9. Evidence Table: Diagnostic Accuracy Studies of Anatomic Site-Specific Testing—Study Outcomes, Part 2**

| Study, year | Condition | Screening test(s) | Sex | Positive likelihood ratio (95% CI) | Negative likelihood ratio (95% CI) | Positive predictive value (95% CI) | Negative predictive value (95% CI) | False positive rate | False alarm rate | False negative rate | False reassurance rate | Sponsor | Quality rating |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Shrier *et al.*, 2004[79] | Chlamydia trachomatis | Amplicor Site: FCU | Female | 0.56 (0.40 to 0.78) | Unable to calculate | 100% (76.4 to 100%) | 86.8% (79.6 to 92.3%) | 0 | 0 | 55.6 | 13.2 | Roche Molecular Systems, Inc.; Centers for Disease Control and Prevention ; National Institute of Mental Health, National Institutes of Health | Fair |
| Shrier *et al.*, 2004[79] | Chlamydia trachomatis | Amplicor Site: clinician-collected vaginal | Female | Unable to calculate | 0.44 (0.29 to 0.68)* | 100% (78.7 to 100%) | 89.2% (82.4 to 94.0%) | 0 | 0 | 44.4 | 10.8 | Roche Molecular Systems, Inc.; Centers for Disease Control and Prevention ; National Institute of Mental Health, National Institutes of Health | Fair |
| Shrier *et al.*, 2004[79] | Chlamydia trachomatis | Amplicor Site: self- collected vaginal | Female | 51.3 (7.1 to 373.2)* | 0.49 (0.33 to 0.72)* | 93.3% (69.8 to 99.7%) | 88.3% (81.0 to 93.5%) | 1.0 | 6.7 | 48.1 | 11.7 | Roche Molecular Systems, Inc.; Centers for Disease Control and Prevention ; National Institute of | Fair |

**Appendix B Table 9. Evidence Table: Diagnostic Accuracy Studies of Anatomic Site-Specific Testing—Study Outcomes, Part 2**

| Study, year | Condition | Screening test(s) | Sex | Positive likelihood ratio (95% CI) | Negative likelihood ratio (95% CI) | Positive predictive value (95% CI) | Negative predictive value (95% CI) | False positive rate | False alarm rate | False negative rate | False reassurance rate | Sponsor | Quality rating |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | | Mental Health, National Institutes of Health | |
| Skidmore *et al*., 2008[72] | Chlamydia trachomatis | Cobas Taqman 48 CT Site: ulvo-vaginal swab (self-collected) | Female | Unable to calculate | 0 | 100 | 100 | 0 | 0 | 0 | 0 | Test kits provided by Roche Diagnostic s | |
| Berry *et al*., 2017[61] | Chlamydia trachomatis | BD Viper XTR Site: Meatal swab (self-collected) | Male | 253.84 (105.67 to 609.75) | 0.08 (0.05 to 0.14) | 96.18 (91.3 to 98.37) | 99.21 (98.61 to 99.55) | 0.36 | 3.8 | 8.03 | 0.8 | Becton Dickinson and Coventry and Warwicksh ire Partnershi p Trust | Fair |
| Berry *et al*., 2017[61] | Chlamydia trachomatis | BD Viper XTR Site: Urine sample | Male | 345.00 (129.67 to 917.93) | 0 | 97.2 | 100 | 0.3 | 2.8 | 0 | 0 | Becton Dickinson and Coventry and Warwicksh ire Partnershi p Trust | Fair |
| Nye *et al*., 2019[71] | Chlamydia trachomatis | Cobas CT/NG 2.0 Site: Male urine | Male | 133.38 (43.17 to 412.12) | 0.02 (0.00 to 0.13) | 94.4 | 99.8 | 0.7 | 5.6 | 1.9 | 0.2 | Roche Molecular Systems | Fair |
| Sultan *et al*., 2016[73] | Chlamydia trachomatis | AC2 Site: pooled sample of pharyngeal, urine/urethral, and rectal specimens | Male | Unable to calculate | Unable to calculate | Unable to calculate | Unable to calculate | Unable to calculate | Unable to calculate | 11.5 | Unable to calculate | NHS bodies, Camden Provider Services, NHS Foundatio n | |

**Appendix B Table 9. Evidence Table: Diagnostic Accuracy Studies of Anatomic Site-Specific Testing—Study Outcomes, Part 2**

| Study, year | Condition | Screening test(s) | Sex | Positive likelihood ratio (95% CI) | Negative likelihood ratio (95% CI) | Positive predictive value (95% CI) | Negative predictive value (95% CI) | False positive rate | False alarm rate | False negative rate | False reassurance rate | Sponsor | Quality rating |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | | Trust | |
| Fang *et al*., 2008[65] | Neisseria gonorrhoeae | BDProbeTec ET NAAT Site: vaginal swab (self-collected) | Female | 164.22 (74.01-364.90) | 0 | 88% | 95.2 | 0.6 | 12 | 0 | 4.8 | National Institute of Child Health and Human Developm ent | Fair |
| Fang *et al*., 2008[65] | Neisseria gonorrhoeae | BDProbeTec ET NAAT Site: endocervical swab (clinician-collected) | Female | | | 100 | 99.5 | 0 | 0 | 5.5 | 0.5 | National Institute of Child Health and Human Developm ent | Fair |
| Nye *et al*., 2019[71] | Neisseria gonorrhoeae | Cobas CT/NG 2.0 Site: endocervical swab | Female | 1020.29 (328.99 to 3164.21) | 0.02 (0.00 to 0.15) | 93.9 | 100 | 0.1 | 6.1 | 2.1 | 0 | Roche Molecular Systems | Fair |
| Nye *et al*., 2019[71] | Neisseria gonorrhoeae | Cobas CT/NG 2.0 Site: Female urine | Female | 241.69 (140.50 to 415.78) | 0 | 80 | 100 | 0.4 | 20 | 0 | 0 | Roche Molecular Systems | Fair |
| Nye *et al*., 2019[71] | Neisseria gonorrhoeae | Cobas CT/NG 2.0 Site: self-collected vaginal swab | Female | Not calculated | 0 | 100 | 100 | 0 | 0 | 0 | 0 | Roche Molecular Systems | Fair |
| Stewart *et al*., 2012[80] | Neisseria gonorrhoeae | AC2 Site: self-collected vaginal | Female | Unable to calculate | 0.03 (0.00 to 0.17)* | 100.0% (90.9 to 100.0%)* | 100.0 (99.8 to 100.0%)* | 0 | 0 | 2 | 0 | See above | See above |
| Stewart *et al*., 2012[80] | Neisseria gonorrhoeae | AC2 Site: endocervical | Female | Unable to calculate | 0.10 (0.04 to 0.25)* | 100.0% (90.2 to 100.0)* | 99.8% (99.5 to 100.0)* | 0 | 0 | 10 | 0.2 | None reported (Gen- Probe provided supplies) | Good |

**Appendix B Table 9. Evidence Table: Diagnostic Accuracy Studies of Anatomic Site-Specific Testing—Study Outcomes, Part 2**

| Study, year | Condition | Screening test(s) | Sex | Positive likelihood ratio (95% CI) | Negative likelihood ratio (95% CI) | Positive predictive value (95% CI) | Negative predictive value (95% CI) | False positive rate | False alarm rate | False negative rate | False reassurance rate | Sponsor | Quality rating |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Berry *et al.*, 2017[61] | Neisseria gonorrhoeae | BD Viper XTR Site: Meatal swab (self-collected) | Male | 295.00 (122.97 to 707.70) | 0 | 89.4 (77.78 to 95.27) | 100 | 0.3 | 10.6 | 0 | 0 | Becton Dickinson and Coventry and Warwickshire Partnership Trust | Fair |
| Berry *et al.*, 2017[61] | Neisseria gonorrhoeae | BD Viper XTR Site: Urine sample | Male | 465.55 (146.96 to 1418.36) | 0.07 (0.02 to 0.21) | 92.9 | 99.8 | 0.2 | 7.1 | 7.1 | 0.2 | Becton Dickinson and Coventry and Warwickshire Partnership Trust | Fair |
| Nye *et al.*, 2019[71] | Neisseria gonorrhoeae | Cobas CT/NG 2.0 Site: Male urine | Male | 151.00 (48.88 to 466.44) | 0 | 70 | 100 | 0.7 | 30 | 0 | 0 | Roche Molecular Systems | Fair |
| Sultan *et al.*, 2016[73] | Neisseria gonorrhoeae | AC2 Site: pooled sample of pharyngeal, urine/urethral, and rectal specimens | Male | Unable to calculate | Unable to calculate | Unable to calculate | Unable to calculate | Unable to calculate | Unable to calculate | 18.4 | Unable to calculate | NHS bodies, Camden Provider Services, NHS Foundation Trust | |

Abbreviations: AC2 = Aptima Combo 2; CT = Chlamydia trachomatis; FCU = first- catch urines; GC = Neisseria gonorrhoeae; LCx = ligase chain reaction; NAATs = nucleic acid amplification tests; NG = Neisseria gonorrhoeae; NR = not reported; STI = sexually transmitted infection.

**Appendix B Table 10. Quality Assessment of Diagnostic Accuracy Studies of Anatomic Site-Specific Testing**

| Author, year | Was a consecutive or random sample of patients enrolled? | Was a case-control design avoided? | Did the study avoid inappropriate exclusions? | Were the index test results interpreted without knowledge of the results of the reference standard? | If a threshold was used, was it pre-specified? | Is the reference standard likely to correctly classify the target condition? | Were the reference standard results interpreted without knowledge of the results of the index text? | Was there an appropriate interval between index test(s) and reference standard? | Did all patients receive a reference standard? | Did patients receive the same reference standard? | Were all patients included in the analysis? | Quality rating |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Berry et al., 2017[61] | Unclear | Yes | Unclear | Unclear | NA | Yes | Unclear | Yes | Yes | Yes | Yes, excluding those with only one sample (n=211) | Fair |
| Fang et al., 2008[65] | Unclear | Yes | Yes | Unclear | NA | Yes | Unclear | Yes | Yes | Yes | Unclear | Fair |
| Nye et al., 2019[71] | Unclear | Yes | Yes | Unclear | NA | Yes | Unclear | Yes | Yes | Yes | Yes | Fair |
| Schachter et al., 2003[76] | Unclear | Yes | Yes | Unclear | NA | Yes | Unclear | Yes | Yes | Yes, at least one culture | Yes | Fair |
| Shoeman et al., 2012[77] | Unclear | Yes | Yes | Unclear | NA | Yes | Unclear | Yes | Yes | Yes | Yes | Fair |
| Shrier et al., 2004[79] | Unclear | Yes | Yes | Unclear | NA | Yes | Unclear | Yes | Yes | Yes | No, approximately 9% excluded | Fair |
| Skidmore et al., 2008[72] | Unclear | Yes | Unclear | Unclear | NA | Yes | Unclear | Yes | Yes | Yes | Yes | Fair |
| Stewart et al., 2012[80] | Unclear | Yes | Yes | Unclear | NA | Yes | Unclear | Yes | Yes | Yes | No, 97% | Fair |

**Appendix B Table 10. Quality Assessment of Diagnostic Accuracy Studies of Anatomic Site-Specific Testing**

| Author, year | Was a consecutive or random sample of patients enrolled? | Was a case-control design avoided? | Did the study avoid inappropriate exclusions? | Were the index test results interpreted without knowledge of the results of the reference standard? | If a threshold was used, was it pre-specified? | Is the reference standard likely to correctly classify the target condition? | Were the reference standard results interpreted without knowledge of the results of the index text? | Was there an appropriate interval between index test(s) and reference standard? | Did all patients receive a reference standard? | Did patients receive the same reference standard? | Were all patients included in the analysis? | Quality rating |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Sultan et al., 2016[73] | Unclear | Yes | Yes | Unclear | NA | Yes | Unclear | Yes | Yes | No, but similar. All were standard of care for each clinic | Unclear | Fair |

Abbreviations: NA = not applicable.

## Appendix C. Selective Screening Criteria for Chlamydial Infection as Described in Miller, 2000

Source: *Miller WC, Hoffman IF, Owen-O'Dowd J, et al. Selective screening for chlamydial infection: which criteria to use? Am J Prev Med. 2000 Feb;18(2):115-22. PMID: 10698241.*

CDC Recommendations
Indications for screening:
Mucopurulent discharge
Age < 20 years
Age 20–24 years with 1 risk marker
Age > 24 years with 2 risk markers
Risk markers:
No or inconsistent condom use
New sex partner or ≥ 2 sex partners in past 3 months

Seattle–1
Any 2 risk markers:
Age ≤ 24 years
No condom use
New sex partner in past 3 months
Cervical friability
Mucopurulent discharge

Wisconsin
Any 1 risk marker:
New sex partner in past 3 months
≥2 sex partners in past 3 months
Partner with STD
Cervical friability
Mucopurulent discharge
PID
Gonorrheal infection

Ontario
Any 1 risk marker:
New sex partner in past year
Urinary frequency
Bleeding
Cervical friability
Mucopurulent discharge
Genital warts

California–1
Any 2 risk markers:
Age ≤ 24 years
Unmarried
No condom use
New sex partner in past 3 months
Cervical friability

California–2
Any 1 risk marker:
Age ≤ 24 years
Unmarried
Cervicitis (mucopurulent discharge, cervical friability, PID)

Seattle–2
Sum≥4 points:
1 point – Age ≤ 24 years
2 points – Unmarried
1 point – African-American
1 point – Nulliparous
1 point – ≥ 2 sex partners in past year
1 point – Vaginal douche in past year
2 point – Cervical ectopy

Seattle–3
Sum ≥ 3 points:
1 point – Age ≤ 24 years
2 points – African-American
1 point – Nulliparous
1 point – ≥ 2 sex partners in past year
1 point – Vaginal douche in past year